efsa
European Food Safety Authority
Supporting Publications

MRL Applications Manual

European Food Safety Authority (EFSA)

Table of Contents

Introduction

REGULATORY BACKGROUND FOR MRL APPLICATIONS

The **procedures** for MRLs applications are set by the Regulation (EC) No 396/2005[1] on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Articles 6 to 11 and Article 14(1)).

Article 8(1)(g) of Regulation (EC) No 1107/2009[2] on the placing of plant protection products on the market refers to, where relevant, the inclusion of a copy of the MRL application, in accordance with Article 7 of Regulation (EC) No 396/2005, in the dossier for the approval of an active substance.

The **purpose of an MRL application** can be one (or more than one) of the following:

- amend existing residue definition
- delete maximum residue level(s)
- evaluation of confirmatory data following review according to Article 12
- include active substance/product combinations into Annex VII
- include an active substance in Annex IV
- set import tolerance(s) (changing current EU MRL listed in Annex II or III)
- set import tolerance(s) (new active substance not mentioned in Annex II/III/IV)
- set specific maximum residue level(s) (changing current EU MRL listed in Annex II or III)

DATA REQUIREMENTS FOR MRL APPLICATIONS

The **data requirements** for an MRL application dossier are indicated in the **Regulation (EU) No 283/2013**[3] ("new" data requirements) setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and in the Commission **Regulation (EU) No 544/2011**[4] ("old" data requirements) implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances.

Following the entry into force of the **Transparency Regulation** (Regulation (EU) 2019/1381[5]), the General Food Law has been amended by introducing **new requirements**

[1] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[3] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

[4] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances

[5] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

regarding transparency of submitted data, including the **submission of the dossiers for MRL applications using IUCLID format**[6].

These new requirements, as implemented by the **Practical Arrangements**[7] laid down by EFSA, are reflected in the **EFSA "Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure**[8]" and apply to all **MRL applications submitted as of 27 March 2021**.

The **IUCLID dossier for an MRL application** shall contain**:**

1. a **MIXTURE DATASET:** with data on the representative mixture (including the GAP, as a mandatory document);
2. an **ACTIVE SUBSTANCE DATASET:** with data on the TARGET active substance;
3. (if appropriate) **one additional OTHER SUBSTANCE DATASET(s) for each relevant METABOLITE:** with data on the relevant metabolite(s);
4. (if appropriate) **OTHER SUBSTANCEs** relevant FOR ASSESSMENT **dataset:** with data on any substance of concern (e.g. relevant impurities)

Applicants are required to create a new "Mixture" dataset and select the Working context 'EU_PPP MRL application'.

Following the Table of Content, applicants are required to:

1) report data in the **relevant IUCLID entities** (Endpoint summaries, Endpoint study records, Flexible records, Flexible summaries, etc);

2) in line with the provisions of the Transparency Regulation, provide **full study reports** (including publications and QSAR, QMRF or QPRF reporting forms) and other **supporting materials** (e.g. excel templates).

For each document provided, applicants must submit:

- a confidential version (not for public disclosure) with all information visible and no blackening applied. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked;
- a non-confidential version (public version) with all elements claimed to be confidential blackened (public version).

For details on Intellectual Property Rights (IPR) rules please see section "Data source (Literature Reference) – common block" section of this manual.

In the working context of "EU PPP MRL application", a GAP document is mandatory. In addition, the **mandatory sections** are Section 4, Section 6.1, Section 6.2.1, Section 6.2.2, Section 6.3, Section 6.4, Section 6.5.1, Section 6.5.3, Section 6.9 and Section 6.10.1. For sections 4, 6.1, 6.2.1, 6.2.2, 6.3, 6.4, 6.5.1, 6.5.3 and 6.10.1, applicants are requested to complete at least one endpoint study record and one endpoint summary. For Section 6.9, only an endpoint summary is required. Although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for those other Sections.

[6] Ref: Commission working document under revision
[7] https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
[8] https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance

When no data is submitted, a **justification for waiving** is needed as the validation tool of IUCLID will check for completeness of the mandatory sections according to the validation rules indicated in this manual.

Direct instructions on the **compilation of the fields** of each of the IUCLID entities are given in this manual in the relevant IUCLID dossier section.

Instructions provided for the Active substance dataset are applicable also to the Metabolite dataset and to Other substances for assessment dataset.

Direct instructions on **where to include individual supporting documents** are provided in the applicable chapter of this manual and in the section hereafter on the "overview of the main cases".

Any additional documents not specifically required in the respective sections of this manual can be attached, either to the "Dossier header" section (for administrative documents only) or to Section 11.2 "Other reports".

The dossier header should only be used to upload administrative documents. The motivation and the nature of the attachments should be specified in the remark fields of the attachment.

Section 11.2 should be used to upload any additional reports that further facilitate the assessment of the dossier. The nature of the report should be specified in the field "type or report". See also specific instructions in the dedicated Chapters on "dossier header" and on Section 11.2 of the present manual.

MRL DOSSIERS SUBMITTED AS PART OF AN ACTIVE SUBSTANCE APPROVAL OR RENEWAL PROCESS

As explained in the Administrative guidance[9], when the applicant submits an MRL dossier as part of an approval or renewal process, a separate dossier (EU PPP MRL application) should be created in IUCLID. The dossier supporting the approval or renewal process and the one supporting the MRL application should be provided at the same time but submitted separately in the EFSA central submission system.[10]

As for any stand-alone MRL application, the purpose of the MRL application submitted as part of the peer-review should be indicated in the dossier header of the MRL dossier following the instructions in IUCLID. The link between the active substance dossier and the MRL dossier should be indicated in both dossier headers (i.e. active substance and MRL). In the dossier headers, the applicant should tick the check box under the section "Other submission related information" and specify the submission number of the other dossier (please also refer to the dedicated Chapter on MRL Dossier header).

[9] Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure

[10] For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

Further specific instructions are given in the section hereafter on the "overview of the main cases" (see Case 3).

OVERVIEW OF THE MAIN CASES AND HOW THEY SHOULD BE HANDLED IN IUCLID:

If the MRL dossier is submitted AFTER the active substance approval/renewal, go to **CASE 1**.

If the MRL dossier is submitted for a NOT APPROVED active substance, go to **CASE 2**.

If the MRL dossier is submitted AS PART OF the active substance approval/renewal, go to **CASE 3**.

For the specific purpose of application: "delete maximum residue level(s)", go to **CASE 4**.

CASE 1- MRL dossiers submitted AFTER an active substance approval/renewal:

These instructions are valid for all the following purposes of application: setting specific maximum residue level(s), evaluation of confirmatory data following review according to Article 12, include an active substance in Annex IV, amending residue definition, setting import tolerances (for EU approved substance).

If the MRL dossier is submitted AFTER the active substance approval/renewal, it should be a 'stand-alone' MRL dossier. Such a dossier follows the standard rules defined above. Therefore, at least one GAP document should be submitted and all mandatory endpoints (study records and summaries) of Section 4 and Section 6 should be addressed by the applicant. Although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for those other Sections (e.g. Section 5: Toxicological and metabolism studies on the active substance).

The new studies submitted in the context of the MRL dossier shall be reported and fully summarised in the study records (including full and sanitized version of any reports used to support the dossier). However, when MRL requests are done after an active substance approval/renewal, it is acknowledged that several studies were already reported and assessed in the context of the approval/renewal of the active substance. Reference can be made to the previous evaluation frameworks (case 1.1) or to studies already in IUCLID that can be reused in the context of the MRL dossier (case 1.2).

In all cases, the background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

For import tolerances (IT) requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

1.1 – If the active substance approval/renewal dossier was not submitted in IUCLID

In the first year of IUCLID being used for EU PPP MRL applications, it is likely that MRL dossiers will be submitted for active substances for which approval/renewal will have been assessed before IUCLID.

For those endpoints that are addressed by studies already assessed in a previous active substance approval/renewal (and not available in IUCLID), it is not requested to provide full summaries and study report(s). Nevertheless, applicant should indicate whether and how each mandatory endpoint is addressed. When those studies are used to address a data requirement, the following approach is proposed:

- **In the endpoint study records,** applicant should use the "data waiving" field with the option "other justification". In the field "justification for data waiving", select "other" and specify "supporting studies assessed previously in another context". In the "remark" field, specify in which context the studies were assessed. Finally, in the chapter "Applicant's summary and conclusion", please discuss and conclude whether the endpoint is addressed in the context of the MRL dossier.
- **In the endpoint summaries**: applicant should highlight whether the Section is addressed in the context to the present application and summarise the new endpoint derived in the context to the present application (e.g. new MRLs proposals, new consumer exposure)

1.2 - If the active substance approval/renewal dossier was previously submitted in IUCLID

This scenario is unlikely to happen in 2021. But should it happen, the active substance IUCLID dataset created in the context on the approval/renewal of the substance can be reused and updated for the context of the new MRL dossier, adding eventually new studies.

It is however required to go through all the endpoints (study records and summaries) and update them if necessary.

CASE 2- Setting import tolerances (IT) for an active substance NOT approved in the EU:

The principles of a stand-alone MRL dossier described in case 1 also apply. In addition to the mandatory endpoints of Section 4 and Section 6, it is sensible that other sections (e.g. Section 5: Toxicological and metabolism studies on the active substance) also need to be addressed by the applicant by means of new studies. Therefore, although not mandatory, the other sections of the table of content should be carefully checked and applicant should evaluate if data or information is needed for all the other Sections.

For all those studies never assessed in the context of EU approval/renewal of the active substance, the endpoint study records should be fully completed, including full and sanitized version of any reports used to support the application.

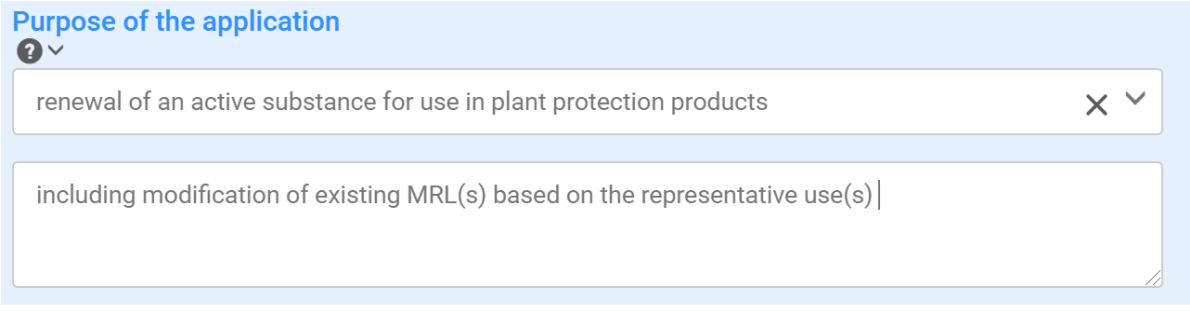
For import tolerances (IT) requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

CASE 3- MRL dossiers submitted AS PART OF approval/renewal of the active substance:

3.1 - Setting specific maximum residue level(s) or changing current EU MRLs (under the approval/renewal dossier):

3.1-a: If the **GAP(s) relevant for the MRL dossier is/are identical to the representative use(s)** of the approval/renewal dossier, it is **not required to create a separate MRL dossier**. In such case, the MRL proposal(s) can be directly derived in the approval/renewal dossier, highlighting the rationale of the proposed new MRLs in the endpoint summary 6.7.2.

The fact that MRL changes are proposed in the dossier (based on the representative uses assessed in the dossier) may be simply highlighted in the dossier header, as a remark under the purpose of the application:



All background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.1-b: If the **GAP(s) relevant for the MRL dossier is/are different compared to the representative use(s)** of the approval/renewal dossier, **a separate MRL dossier is required.** Respective GAP documents must be created in the approval/renewal dossier and in the MRL dossier.

In the MRL dossier submitted as part of the approval/renewal, it is not required to submit all the studies already submitted in the approval/renewal dossier. However, the dataset created for the approval/renewal dossier can be reused. The core studies (e.g. storage stability studies, metabolism studies, toxicological studies) related to the approval/renewal of the active substance should be included in the approval/renewal dossier. This can be repeated in the MRL dossier. However, the study records that are specifically linked to the MRL dossier (e.g. studies on magnitude of residues in plant commodities related to GAPs for which MRLs are proposed), should only be included in the MRL dossier.

All endpoint summaries should be addressed separately in each dossier. Typically, the core endpoints of Section 6.1 (storage stability) and Section 6.2 (metabolism in plants, rotational crops and livestock) should be exhaustively summarised in the approval/renewal dossier, considering all the available studies. In the MRL dossier, a copy/paste of these endpoint summaries can be made for these sections (6.1 and 6.2) but a statement as to whether those sections were sufficiently elucidated in the context of the MRL dossier has to be made in the respective endpoint summaries of the MRL dossier. Furthermore, the endpoint summaries of Sections 6.3 (magnitude of residues in plants), 6.4 (magnitude of residues in livestock

commodities), 6.5 (effect of processing), 6.7 (proposed residue definitions and MRLs), 6.9 (dietary exposure), 6.10.1 (effect on residue level in pollen and bee products) should be compiled for the specific scenario of the MRL dossier.

3.2 - Evaluation of **confirmatory data following review according to Article 12** (under the renewal dossier):

The submission of confirmatory data for art.12 **should be done in a separate MRL dossier,** using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPs to be assessed for the MRL assessment and to report specific studies (e.g. residue trials) outside the core active substance dossier. The GAPs can be the same as the ones assessed in the reasoned opinion on the MRL review or adjusted GAPs, as defined in the "COMMISSION WORKING DOCUMENT on the evaluation of data submitted to confirm MRLs following the review of existing MRLs"[11].

The data gaps identified in article 12 review for the core studies (e.g. metabolism study) should be addressed in the approval/renewal dossier and there is no need to repeat those study records in the MRL dossier. However, applicants should use the respective endpoint summaries of the MRL dossier to clearly state which data gaps of the MRL review were addressed or not addressed. This exercise of checking which data gaps of the MRL review have been addressed should be done in the MRL dossier.

The background information linked to the existing MRL in EU shall be reported in Section 11.1 (Assessment from other Authorities: Assessments in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.3 - **Amend existing residue definition** (under the renewal dossier):

If the assessment of the renewal of an active substance triggers the need to modify the previous residue definitions, this should be highlighted directly in the endpoint summary of Section 6.7.1 (proposed residue definitions) **of the renewal dossier.** There is **no need to submit a separate MRL dossier** in IUCLID.

When a change of residue definition is proposed, it highlighted that the existing residue definitions shall be reported in Section 11.1 (Assessment from other Authorities: Assessment in Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

3.4- Include an active substance in **Annex IV** (under the approval/renewal dossier):

If the assessment of the approval/renewal of an active substance leads to a proposal to include an active substance in Annex IV of Regulation 396/2005, this should be highlighted directly in the endpoint summaries (Section 6 and Section 6.7.2) **of the approval/renewal dossier**. In such case, there is **no need to submit a separate MRL dossier** in IUCLID.

[11] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

3.5- Setting **import tolerances** (under the approval/renewal dossier):

The submission of an import tolerance (IT) request **should be done in a separate MRL dossier,** using the relevant purpose of application in the dossier header of the EU PPP MRL application. This option gives the possibility to the applicant to clearly identify the GAPs to be assessed for the IT request and to report specific studies (e.g. residue trials) outside the core active substance dossier.

For IT requests, it highlighted that all background information linked to the assessment in the third country (evidence of registration in the exporting country, residue definition in the exporting country, existing MRL in exporting country, legislation in the third country, etc), shall be compiled in Section 11.1 (Assessment from other Authorities: Assessments outside Europe). See also specific instructions in the dedicated Chapter 11.1 of the present manual.

CASE 4 - MRL dossiers submitted to delete maximum residue level(s):

It is acknowledged that a GAP document might not be necessary to submit a request for deleting MRLs. Nevertheless, for sake of completeness, it is required to create a GAP document and to go through all the endpoints, also for this specific purpose. The study waiver can be used for the non-relevant endpoints.

Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants

a) Categories of IUCLID fields and associated filter rules

Pursuant to Article 38(1)(c) and (d) of Regulation EC No 178/2002, information inserted in IUCLID fields is automatically disclosed by EFSA when the application is deemed admissible, unless a confidentiality request is submitted by applicants on IUCLID fields where this is permitted and the confidential status is granted by EFSA. Confidentiality requests are permitted with regard to fields that correspond to the items listed in Article 39(2) of Regulation EC No 178/2002.

These are:

a. the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;

b. commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;

c. commercial information revealing sourcing, market shares or business strategy of the applicant; and

d. quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

Each IUCLID field has been assigned a **filter rule** which establishes whether the associated information is published or not (*see* column B in the filter rule excel file) available here: https://zenodo.org/record/4627148#.YFig969KiUk. Fields that are published by default are governed by the filter rule "***PUBLISHED***". Fields for which the applicant can submit a confidentiality request are subject to the filter rule "***UNLESS_CONF***".

Please note that fields subject to the "***UNLESS_CONF***" rule will be published on the OpenEFSA Portal, unless a confidentiality request has been submitted by the applicant and accepted by EFSA pursuant to EFSA's Practical Arrangements concerning transparency and confidentiality.

To claim certain fields subject to the filter rule "***UNLESS_CONF***" confidential, the applicant must:

i. set a **confidentiality flag** in the designated field pertaining to the relevant IUCLID entity, summary, record or section (CBI - confidential business information should be selected as this is in alignment with the transparency regulation), and

ii. submit a **justification** for each confidentiality request in compliance with the standards set out in the Practical Arrangements.

More specifically, the applicant must provide at least the following elements:

(a) a clear identification of the relevant parts of the submitted information that the applicant considers eligible for confidential treatment. This implies that the **specific parts of the text actually considered confidential** must be **indicated**;
(b) a text explaining comprehensively and in plain language the reason(s) why the information should be granted confidential status, including whether:

(i) the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons;
(ii) the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree;
(iii) explanation or evidence demonstrating that the harm that may be caused is of a significance corresponding at least to 5% of the total gross annual turnover for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant must provide specific reasons as to why they considered that public disclosure would potentially harm their interests to a significant degree;
(iv) the document, information or data for which confidential treatment is requested is eligible for legal protection and has not been acquired in an unlawful manner;
(v) the document, information or data for which confidentiality status is requested has been finalised in the form submitted to the rapporteur Member State / EFSA up to five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the rapporteur Member State shall ensure that the applicant provides specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree.

Please note that if your confidentiality request has been accepted for an active substance dossier you should mention this in the MRL confidentiality claim and this will be taken into account during the assessment.

The filter rule governing data protection fields is titled "***DATA_PROTECTION***". Confidentiality flags in the data protection field will be published, if they were activated by the applicant. This will allow the public to know that certain information to which the confidentiality flag relates have been claimed confidential by the applicant. A confidentiality flag may relate to a whole IUCLID entity, summary, record or to a (sub-)section thereof. However, the justification associated with the activated confidentiality flag will not be published.

There are four further filter rules applicable to a limited number of fields:

- "***TM_DETAILS_PPP***": fields subject to this filter rule are located in the Test Materials entity. Information contained in these fields is published, unless they have been claimed confidential. To claim fields subject to this filter rule confidential, a **confidentiality flag** must be set in the Administrative data block in the Endpoint Study Record and a **justification** must be provided complying with the standards mentioned above in relation to the filter rule "UNLESS_CONF".

- "***STUDY_REF_AUTH_PPP***": fields subject to this filter rule are located in the Literature entity. If these fields contain names of authors of **unpublished** studies, they are not published to ensure protection of **personal data**.
- "***STUDY_REF_PPP***": fields subject to this filter rule are located in the Literature entity. If these fields concern names and addresses of natural persons **involved in testing on vertebrate animals** or in **obtaining toxicological information,** they are not published to ensure protection of **personal data**.

  "***NOT_PUBLISHED***": information contained in fields subject to this filter rule is not published. This is the case for all fields with the field name "*AttachedDocument*"[12] and "*AttachedStudyReport*". These fields are reserved for the confidential versions of documents and/or study reports pertaining to the relevant IUCLID entity, summary or record. Conversely, fields with the field name "*AttachedSanitisedDocsForPublication*" are published by default, as they are governed by the filter rule "***PUBLISHED***". A document must always be provided under the header for sanitised attachments and, only if there are any differences, a full document can also be attached.

b) General considerations underlying the setting of filter rules

Generally speaking, the number of fields that can be claimed confidential is more limited in endpoint **summaries** compared to flexible/endpoint study **records**. The underlying rationale is that endpoint summaries contain information that is key to the safety assessment and should therefore, in principle, not include a considerable proportion of information that is claimed confidential. Similarly, the possibility for applicants to claim fields confidential is **more restricted** in endpoint study records/flexible records with clear **safety** (e.g. "*ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.*") and/or **environmental implications** (e.g. "*ENDPOINT_STUDY_RECORD.ToxicityToBirds.*"). That being said, information contained in a number of fields, including **open text fields** such as "*Remarks*" or "*AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation*" as well as in **fields allowing for the upload of documents** can **typically always be claimed confidential** – be it in flexible/endpoint study records or endpoint summaries. In other words, for each and every endpoint and data requirement there will be a possibility to claim certain information confidential.

c) Participation in EFSA's confidentiality decision making

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made on their renewal dossiers and to put forward their views and observations, namely:

a. prior to the adoption of a decision rejecting the applicant's confidentiality request in part or in full, by being consulted on the draft decision;

[12] With the exception of the field with the path description "*FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument*" which is published in accordance with the filter rule "***PUBLISHED***", since no corresponding field with the field name "AttachedSanitisedDocsForPublication" exists. This does not mean that information regarding the description of the substance composition cannot be claimed confidential.

b. after the adoption of a confidentiality decision, by making use of the possibility of submitting a confirmatory application;

c. after the adoption of a decision on a confirmatory application, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.[13]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality.

Comparable procedural guarantees are also provided by the responsible RMS for confidentiality requests made on their dossiers for new active substances. For further information, please check EFSA's Practical Arrangements concerning transparency and confidentiality.

d) Publication of dossier

Information not meant to be published, e.g. names of authors of unpublished vertebrate studies, along with information claimed to be confidential, is removed from the dossier, in accordance with the above-mentioned filter rules. The non-confidential version of the dossier is then made available via the OpenEFSA Portal. Dossier filtering is an automated process and it is independent of the text provided in a certain field. Therefore, it is important for applicants to review their dossier before submission via the dissemination preview feature.

Applicants should take note of the fact that a revised version of the dossier will be made available via the OpenEFSA Portal, if EFSA disagrees with one or more confidentiality requests initially submitted.

[13] Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

Dossier Header: EU PPP MRL Application

Purpose:
The dossier header contains administrative data and information about the type and purpose of the application. Information in the dossier header is used by IUCLID tools to process the dossier, for example different validation assistant scenarios could be applied depending of the selection of the purpose of the application.
Note that all the information in the dossier header, including any attachments, will be published.

Field name	Instructions	Field path
Dossier name (given by user)	Short name for the dossier (this should be maintained in all versions). Refer to the active substance name in the text (e.g. "MRL application for *active substance* in *commoditie(s)*" or "Import tolerance for *active substance* in *commoditie(s)*).	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.DossierTemplate.Name
Dossier subject	System information	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.DossierSubject
Submitting legal entity	System information	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.DossierSubject.SubmittingLegalEntity
Dossier creation date/time	System information	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.DossierSubject.DossierCreationDateTime
Dossier submission remark	The EFSA question number if allocated can be reported in this field. e.g. EFSA-Q-2021-00475.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.DossierSubject.DossierSubmissionRemark
European reference number	Contains the unique number to identify all version of a dossier submitted under a regulatory action. From the 1 May it will be possible to generate the UUID within the IUCLID application. Prior to this, a UUID can be generated using this website	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.MRLApplication.DossierSpecificInformation.EUReferenceNumber

	https://www.uuidgenerator.net/ and pasted into this field.	
Purpose of the application	Select the purpose of the application. Optional remarks can be used to specify any useful information to understand the context of the application. 'If the dossier submission is for confirmatory information – State 'Confirmatory Information' in the remarks field'	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.MRLApplication.DossierSpecificInformation.Purpose
Evaluating Member State (EMS)	Indicate the member state assessing the dossier For import tolerance specify in the remark field if the evaluating Member State (EMS) is also the reporting Member State (RMS). If the EMS is not the RMS, please explain why. If the application is not for import tolerance, the rationale for the choice of the EMS may be explained in the remark field below the selection (optional).	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.MRLApplication.DossierSpecificInformation.EMS
Applicant(s) is/are	Category of applicant, more than one category can apply. If the applicant represents the minor use association, indicate this in the remark field below the selection.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.MRLApplication.DossierSpecificInformation.Applicant
Data requirements used to assess the dossier	Indicate the data requirements applied to assess the dossier and indicate in the remark field the rationale for this approach.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.MRLApplication.DossierSpecificInformation.DataRequirements
Pre-application identifiers	List pre-application identifiers which have been issued for the application	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.NotificationOfStudies.PreApplicationId
NoS ID	List all Notification of Studies identifiers which are present in the database linked to the Pre-application identifiers (see	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.NotificationOfStudies.StudiesReqJustification.NoSID

	above) but are not included in the dossier.	
Justification	Justification for the absence of the NoS ID in the dossier	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.NotificationOfStudies.StudiesReqJustification.Justification
Attached information	Attached administrative documents to support the application (e.g. application form). Documents with confidential or personal information should not be attached here (e.g. letters). Remarks are used to indicate the topic/reason for including the attachment The Summary and Evaluation document can also be used for including attachments in the dossier. This is recommended as sanitised and original documents can be uploaded together. Scientific information should be uploaded into documents in the Table of Contents of the dossier	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.NotificationOfStudies.AttachedInformation
Active substance application dossier is submitted simultaneously?	Check box to Indicate whether the MRL application is a part of the active substance approval/renewal of approval dossier.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.OtherSubmissionRelatedInformation.PartOfActiveSubstanceAppl
Submission number of the active substance dossier	If the box above is checked, the European Reference Number of the related active substance approval/renewal of approval dossier must be provided.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS.OtherSubmissionRelatedInformation.SubmissionNumber

Links to support material:
GUIDANCE DOCUMENT ON THE INTERPRETATION OF THE TRANSITIONAL MEASURES FOR THE DATA REQUIREMENTS FOR CHEMICAL ACTIVE SUBSTANCES AND PLANT PROTECTION PRODUCTS ACCORDING TO REGULATION (EU) No 283/2013 AND REGULATION (EU) No 284/2013

EU PPP MRL application - mixture information

Section 1: Identity of the product / active substance information

Purpose:
This document covers the data requirements:
Applicant and contact person
Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate

Mixture		
Field name	**Instructions**	**Field path**
Mixture/Product name	This must be completed; this information is also included in the dossier header as 'Dossier subject'	MIXTURE.MixtureName
Public name	Public name of the mixture	MIXTURE.PublicName
Legal entity owner	This must be completed; this information is also included in the dossier header as 'Submitting Legal Entity'. Links the dossier to the Legal entity of the dossier owner.	MIXTURE.OwnerLegalEntity
Third party	Option to link to the legal entity of a third party	MIXTURE.ThirdParty
Other identifiers	All former and current trade names and proposed trade names and development code numbers of the plant protection product shall be provided. Flags can be used to indicate if the trade name is confidential	
Contact persons	Link to the relevant Contact entity. The primary contact point for the dossier should be provided, name, position, telephone and e-mail address	
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the plant protection product	MIXTURE.RoleInSupplyChain

Links to support material:
Legal entity (including Contact entity)

1.2 Product composition / active substance information

Purpose:
This document covers the data requirements:
Detailed quantitative and qualitative information on the composition of the plant protection product/preparation
Product formulation type and function of component
This document is used to link the active substance dataset (and if relevant the other substance dataset) to the Mixture/product

FLEXIBLE_RECORD.MixtureComposition		
Field name	**Instructions**	**Field path**
Administrative data	See section on Confidentiality of dossiers	FLEXIBLE_RECORD.MixtureComposition.AdministrativeData
Mixture/product name	Name of formulation/preparation reported. In case of multiple formulations more than one document can be completed. Linking to reference substances rather than substances is recommended for the additional documents unless a new component which requires a dataset is included.	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Name
Brief description	Additional information on the formulation/preparation can be added here	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.Description
Formulation type	Indicate the formulation type according the international coding system for pesticides	FLEXIBLE_RECORD.MixtureComposition.GeneralInformation.FormulationType
Components Name	Link to a reference substance or substance. Select substance for the active substance/micro-organism and relevant impurities. This creates other components e.g safeners, synergists, co-formulants, by-	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Reference

Links to support materials

Legal entity

	products, culture medium etc.	
Components Function	Indicate the function of the component in the formulation.	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Function
Components Concentration	Complete the Typical concentration reporting %w/w (or %v/v for gases). For microorgansims, the nominal content of viable material is required and concentration range reporting g/kg (or g/l for liquids). For relevant impurities the maximum content is required. For microorganisms the range - maximum and minimum viable material is required Where relevant, the corresponding content of the variant (such as salts and esters) of the active substances should be included as components.	FLEXIBLE_RECORD.MixtureComposition.Components.Components.TypicalConcentration
Components **Remarks**	Additional information on the quantity of each component in the formulation/preparation which cannot be provided in the other fields	FLEXIBLE_RECORD.MixtureComposition.Components.Components.Remarks
	The additional check boxes in this table are not relevant for European Plant Protection Products	

Links to support materials:
Catalogue of pesticide formulation types and international coding system

Section 2: Good agricultural practices (GAP)

Purpose:
The Good Agricultural Practice (GAP) describes the intended or registered safe use of plant protection products, according to Article 3(2)(a) of Regulation (EC) No 396/2005. The different fields required to define the use of the plant protection product unambiguously are listed in Table 4.
The IUCLID GAP form implements the following data requirements:

- Details of intended use
- Application rate
- Method of application
- Number and timing of applications and duration of protection
- Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

If you click on the red plus sign next to the header 'x Good agricultural practices (GAP)' you can create a new GAP. A name will be assigned automatically to the GAP, containing as default name 'Good agricultural practices (GAP)' followed by a dot and three numbers.
Please note that separate GAP documents need to be created, if the GAPs differ in one or more of the parameters. For some fields multiple options from a picklist can be selected. Please read carefully below the instructions to see whether in a given case a separate GAP document needs to be created or whether it is appropriate to describe the different use options in one form.

FLEXIBLE_RECORD.GAP		
Name	**Instructions**	**Field Path**
Administrative data	The general rules on confidentiality requests apply in setting the flags (Administrative data summary – common block). See section on Confidentiality of dossiers	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary
Product	This field is mandatory. Click on the red plus sign to link the GAP to an existing mixture composition (see Introduction). If no mixture dossier or dataset is available in the inventory, create first a new one and add a mixture composition. In general, the GAP has to be completed for the target a.s., i.e. the a.s. for which the approval/renewal of the approval is requested or for which the MRL application is submitted. If the plant protection product contains a second (non-target) a.s., it is not required to provide a separate GAP form for the second a.s.	FLEXIBLE_RECORD.GAP.AdministrativeDataSummary.Product
Description of key information	The free text field can be used to give a short explanation/description of the GAP. This information is not mandatory. For GAPs that involve different application methods at different growth stages (e.g. drench application at sowing followed by foliar application at a later growth stage), the GAP should be split in separate GAPs (in the example the first GAP being the drench application, the second the foliar use). In this field, the GAPs belonging to a sequential application should be labelled (e.g. GAP 1 of 2, GAP 2 of 2). The field should also be used to label representative uses (relevant for applications on the approval or the renewal of the approval). For existing uses (D2 document), indicate "authorised use" in this field; otherwise the document will be interpreted as for an intended	FLEXIBLE_RECORD.GAP.KeyInformation

	use (D1).	
Crop/treated object	Information on the crop/treated object is mandatory. A picklist is implemented to describe the crop or object to be treated with the plant protection product. The picklist is based on EPPO codes which have been enhanced with additional information to make them more user friendly/self-explanatory. The extended EPPO codes cover the following types of information: • the first 5 digits are the EPPO code (see EPPO Plant Protection Thesaurus at http://eppt.eppo.org) (e.g. PIBSX), • followed by the scientific name of the crop (PIBSX Pisum sativum); • in brackets, the crop name in English is reported (PIBSX Pisum sativum (English pea); • for the most important crops, the corresponding food code of the MRL food classification is reported after a dash (code of Annex I of Regulation (EC) No 396/2005). For some crops, more than one food code is applicable (e.g. PIBSX Pisum sativum (English pea) - 0260030, 0260040, 0300030). In the current version of IUCLID, the link with the food codes of the MRL legislation has been established only for codes listed in Part A of Annex I of Regulation (EC) No 396/2005; food codes listed in Part B of Annex I to, the connection to the crop code has not yet been implemented (the link will be included in the next release of IUCLID). Please note that not for all codes all four name elements are available. To find the codes for the crop/object, the user can either use the hierarchy search tool which requests to choose between crops or treated products. Alternatively, a text string (e.g. the EPPO code, the scientific name) can be directly entered in the search window, resulting in a subset of matching options. In the hierarchy tool, the user should first select between the two highest hierarchy levels 'crops' or 'treated product'. Treated products is relevant only for post-harvest uses and for uses on non-crop objects (e.g. treatment of railways). As a next step, a text string (EPPO code, scientific name, name of the crop in English or the food code of the MRL legislation) can be inserted. EPPO codes matching with the search term are displayed in yellow, and the user should select the relevant one. For post-harvest treatment of food products, two EPPO codes are available (HARFO and HARPO) which were combined with all food codes (Part A) of Annex I of Regulation (EC) No 396/2005: • If the treatment with the plant protection product is intended on the fresh harvested product (e.g. oranges), the code combining HARFO and the respective food code should be selected (e.g. 3HARFO – Oranges – 011020). • For GAPs describing a use on a processed harvested product (e.g. raisins), the code HARPO in combination with the food code should be used (e.g. 3HARPO – Table grapes – 0151010).	FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.Crop

<table>
<tr><td></td><td>In general, codes for crop groups should not be selected. Instead the EPPO codes for the individual crops should be chosen. A multiple selection of crop codes is allowed, only if all parameters of the GAP are identical for all crops selected. If the GAPs differ for the individual crops in one or several fields, a separate GAP form needs to be completed. To facilitate the work to complete separate GAP forms, an existing GAP can be copied and modified for the respective parameters (see 1.3.6).
Further remarks on the crop/treated product can be reported in a free text field, which is created when the user clicks on the symbol  .
Remarks are necessary to specify whether food or feed has been in contact with the plant protection product indirectly if one of the following codes for treated product has been selected:
<table>
<tr><td>3IRRWO</td><td>irrigation water (treatment of)</td></tr>
<tr><td>BULBO</td><td>bulbs, tubers, corms (treatment of)</td></tr>
<tr><td>PLABO</td><td>plant base (treatment of)</td></tr>
<tr><td>SEEDO</td><td>seeds (treatment of)</td></tr>
<tr><td>WOUNO</td><td>wounds (treatment of)</td></tr>
</table></td><td></td></tr>
<tr><td>Genetical modification of crop</td><td>If relevant, describe variety of genetically modified crops on which the use of the plant protection product is intended to be used or authorised.</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.GeneticalModification</td></tr>
<tr><td>Crop destination(s)</td><td>The field is not mandatory.
Please select the relevant EPPO code for crop destination. Multiple selection is allowed (e.g. grown for animal consumption (3ANICD) and grown for human consumption (3HCOND)).
In remarks field more details on the crop destination can be described. See also EPPO code list https://gd.eppo.int/taxon/3CROD.</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.CropDestination</td></tr>
<tr><td>Authorisation zone</td><td>Please select the relevant Authorisation zone from the picklist.
The assignment of countries to the different zones for the authorisation of products can be found in Annex I of Regulation (EC) No 1107/2009.
Please note that multiple selection of codes is not allowed.
Information on the authorisation zone is not mandatory if at least one country has been selected in the field ‘Country or territory’.
If no information is provided in ‘Country or territory’ and in ‘Authorisation zone’, it is assumed that the GAP is relevant for all EU zones.</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.AuthorisationZone</td></tr>
<tr><td>MRL zone</td><td>Select the MRL zone in which the GAP is intended. The assignment of the individual European countries to the zones can be found in the guidance document SANTE/2019/12752 (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-d.pdf) (or a subsequent revision of this document).</td><td>FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.MrlZone</td></tr>
<tr><td>Country</td><td>Select the country or the territory related to the GAP.</td><td>FLEXIBLE_RECORD.</td></tr>
</table>

or territory	The selection of more than one country is possible if the same GAP applies.	GAP.KeyInformation.CropInformation.CountryOrTerritory
Crop location (F/G/I)	This data element is mandatory for GAPs that refer to crops (children codes listed under crops and children codes of '3HARVO harvested crops (treatment of)'. For other GAPs the field should remain empty. The available picklist contains EPPO codes with detailed descriptions of the cases. I: Code to be used for crops grown or stored in closed walk-in buildings. This code includes for example mushroom houses and structures for witloof chicory or rhubarb forcing. G: A walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment. F: Fields and other structures which do not prevent release of plant protection products into the environment. For crops grown outdoor (F), more details can be reported using the more specific subcodes. The detailed description of the subcodes is provided in the picklist.	FLEXIBLE_RECORD.GAP.KeyInformation.CropInformation.CropLocation
Target organisms	Select 'New item' and compile the block consisting of 'Scientific name', 'Common name', 'Development stage of target pest' and 'Development stage of target plant'. See detailed descriptions below.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms
Scientific name	Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). At least one target organism needs to be defined in a GAP. It is possible to select more than one target organism, if the GAP parameters are identical for the different target organisms. If the target organism is not listed, select 'other' and specify. If a scientific name is not relevant or not known, select 'no data'. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required according to a programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. 'I.1.1.1 (EU BPD)'. Please make sure that the scientific name entered in this field matches with the organism described in the field 'Common name'.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.ScientificName
Common name	Please add the common name of the target organism in this field that matches with the Scientific name.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.CommonName
Development stage of target pest	For insecticide and fungicide uses, indicate the developmental stage of the target organism/pest (e.g. development stage of the insect or of the disease for diseases caused by fungi). If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks. If the development stage is not known or not further specified, select 'not specified'. If the development stage is not relevant/applicable, leave field empty.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePest

<table>
<tr><td></td><td>Multiple selection of terms is allowed.</td><td></td></tr>
<tr><td>Development stage of target plant</td><td>For herbicide uses, indicate the developmental stage of the target plant.
In the picklist BBCH codes have been implemented. Although these codes have been developed for describing the development stages of crops, they can be used in analogy for the target plants.
Any remarks can be entered in the supplementary remarks field, for instance an alternative description of the developmental stage which is not available in the picklist.</td><td>FLEXIBLE_RECORD.GAP.PestDiseaseTreated.TargetOrganisms.DevelopmentStagePlant</td></tr>
<tr><td>Major/minor use</td><td>Select the applicable code from the picklist. Minor use according to Art. 51 of Regulation (EC) No 1107/2009 should be flagged as ‘minor use’.
Other EU uses are to be considered as major use (combination of crop/target organism).
Please note that GAPs need to be split in separate documents/GAP forms, if the different crops selected in the field ‘crops/treated object’ would require different the flags (e.g. not all crops are major crops).
The field is not relevant for uses in third countries (e.g. import tolerances).</td><td>FLEXIBLE_RECORD.GAP.PestDiseaseTreated.MajorMinorUse</td></tr>
<tr><td>Application target</td><td>The target to be treated can be selected from a picklist. The following terms are implemented:
<table>
<tr><th>Picklist value</th><th>Description</th></tr>
<tr><td>Foliage/Plant</td><td>Application to a plant or the leaves of a plant.</td></tr>
<tr><td>Seed / Seed Pieces</td><td>Application to a small object produced by a plant from which a new plant can grow.</td></tr>
<tr><td>Propagation Stock</td><td>Application to a specimens of a plant, used for breeding by natural processes from the parent stock.</td></tr>
<tr><td>Root/Bulb</td><td>Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).</td></tr>
<tr><td>Bark</td><td>Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.</td></tr>
<tr><td>Stump / cut stem</td><td>Application to the recently cut of a tree or woody shrub (excludes cut flowers).</td></tr>
<tr><td>Containerized plant</td><td>Application to a plant and soil grown in a movable container.</td></tr>
<tr><td>Agricultural Commodity</td><td>Post-harvest application to an agricultural product that can be bought and sold (e.g., treatment to grain, fibre, cut flowers, packaged animal feed, etc).</td></tr>
<tr><td>Soil (surface)</td><td>Application to the ground in which plants can grow.</td></tr>
<tr><td>Soil (subsurface)</td><td>Application below the ground, or immediately incorporated.</td></tr>
<tr><td>Water</td><td>Application to water in systems, pools, pipes, tanks or other containers, or bodies of water, such as lakes, ponds, bays, estuaries, oceans, reservoirs.</td></tr>
</table></td><td>FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationTarget</td></tr>
</table>

	Air	Application directed to a space, rather than a specific target. Examples of these types of applications include foggers, mosquitocides, ozone generators, knock-down insecticides, etc. This does not include aerial broadcast applications over a crop because the target is the crop, not the air over the crop.	
	Surface	Application to the interior and/or exterior boundaries of an inanimate object. Examples of these types of applications include boat hulls, countertops, hives, nests, etc.	
	Non-porous Surface	Surfaces where liquids will not absorb such as ceramic, porcelain, glass, metal, plastic/vinyl, rubber, stainless steel.	
	Porous Surface	Surfaces where a liquid is likely to absorb such as fabric, drywall, composition board surfaces, paint films and surfaces, plaster surfaces, and wood.	
	other		
	Please select the most appropriate treatment target.		
Method of application	Information on the application method is mandatory. Select the application technique relevant for the GAP from the picklist. Please note that in future releases of IUCLID, EPPO codes will be implemented, which are currently under development. If appropriate, the new EPPO codes (Treatments, 3TREAK) can be reported in the remarks field. More than one term can be selected, if the application techniques belong to the same application type/class. If different application methods are foreseen on a crop (e.g. seed treatment followed by foliar broadcast), two uses should be described as separate GAPs, including in the remarks that the two GAPs are combined.		FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationMethod
Growth stage and season	Click on 'New item' and compile the block of fields that comprises the following fields: Growth stage of crop (first application), Growth stage of crop (last application), Treatment season. If the GAP foresees treatments at different treatment windows (e.g. first treatment window before flowering, second treatment window after flowering), the block can be repeated. Information on the growth stage is mandatory if the GAP refers to a crop; if the GAP refers to treatment of non-crop objects (children of 3NOCFO), it is not required; if the GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be entered; if the GAP refers to children codes of 3CRPAO (treatment of crop parts),it is not required. If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory.		FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason

Growth stage of crop (first application)	This field is intended to describe the growth stage of the crop at the first treatment with the plant protection product. The picklist offers the BBCH codes which describe the phenomenologically similar growth stages of all mono- and dicotyledonous plant species (source: BBCH Monograph edited by Uwe Meier, Julius Kühn-Institut, 2018, doi: 10.5073/20180906-074619). Select the growth stage of the crop at first application. If a treatment is foreseen at one specified growth stage, select the BBCH code only in this field (Growth stage of crop (first application)). For a range, also select the relevant BBCH code in the field 'Growth stage of crop (last application)'. If necessary, more details on the treatment timing shall be reported in remarks (e.g. a description of the timing/growth stage at the application to specify more detailed the timing of the application (e.g. pre-plant, before transplant, etc.). The letters in bracket after the description of the crop development show to which plant group the respective definition refers. (D = Dicotyledons, M = Monocotyledons, G = Gramineae, P = Perennial plants, V = Development from vegetative parts or propagated organs). Please note that BBCH codes 71 to 79 is not used, if the main fruit growth happens in principal growth stage 8.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropFirst
Growth stage of crop (last application)	Please select from the picklist the growth stage of crop at last application. See above (Growth stage of crop (first application)) for further details.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.GrowthStageCropLast
Treatment season	For autumn/winter sown crops, report whether the treatment is foreseen in autumn/winter or in spring/summer. Multiple selection is allowed. If necessary, any other restrictions for the treatment season can be reported in the remarks field, selecting the option 'other:'	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.GrowthStageAndSeason.TreatmentSeason
Number of applications (range)	Information on the number of applications is mandatory. Report the number of applications (e.g. 1 – 3). If only one treatment is foreseen, report '1' in the lower numeric field.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationsRange
Re-treatment interval (in days)	Enter the interval between treatments (re-treatment interval); if relevant, a range for minimum interval and maximum interval between treatments, expressed in days, can be reported.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.RetreatmentInterval
Application rate per treatment (product) – range	Mandatory information. For reporting the application rate, follow the recommendations on dose expression for plant protection products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate (for the formulation) per treatment.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRatePerTreatment

	Use the second numeric field to report the upper application rate per treatment. Select the most appropriate unit to express the application rate. For applications on crops, the application rate should preferably be expressed as application rate per hectare. See also below application rate per treatment for target a.s. (range).	
Remarks on application rate	Any further explanations related to the application rate can be provided in this field. For 3-dimensional crops, the application rate expressed on leaf wall area can be reported in addition to the application rate reported per hectare.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.RemarksOnApplicationRate
Water amount per treatment / spray volume	For products applied after dilution with water, the minimum and maximum amount of water used in spray application (spray volume) should be reported.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.WaterAmountPerTreatment
Concentration of formulation in dilution	For products applied after dilution with water, report the concentration of the formulation in the solution.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ConcentrationFormulationDilution
Safener/ synergist/ adjuvant added	Is a safener/synergist/adjuvant intended to be added to the tank mix? If yes, the information on the type and the amount of safener/synergist/adjuvant is mandatory. Please indicate whether the addition of the safener/synergist/adjuvant is mandatory or whether it is only recommended. Indicate the safener/synergist/additive type, the name and the amount added to the tank mix (volume (%)). See also EPPO standard PP1/291(1).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.SafenerSynergistAdjuvant
Application rate per treatment for target a.s. (range)	It is mandatory to report the application rate for the target a.s. The field is intended to specify the application rate for the target active substance (i.e. the a.s. defined in the active substance dataset (EU PPP Active substance information) of the IUCLID dossier). For reporting the application rate, follow the recommendations on dose expression for plant protection products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate per treatment. Use the second numeric field to report the upper application rate per treatment. If the formulation contains a variant of the active substance (e.g. an ester), the application rate should be expressed for the a.s. (not for the variant!). Example for a variant: the formulation contains quizalofop-P-terfuryl which is a variant of the a.s quizalofop-P. In the field defining the application rate for the target a.s. the application rate	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ApplicationRateForTarget

	should be expressed as quizalofop-P. The factor to recalculate the application rate of quizalofop-P-terfuryl (molecular weight 428.9) to quizalofop-P (molecular weight 344.7) is derived as the ratio of the molecular weight (344.7/428.9=0.804).	
Maximum seasonal application rate (a.s.)	Please note that in the current version of IUCLID the field name might be misleading: in the future release the name will be changed to 'Maximum annual application rate' to avoid any confusion. If restrictions need to be defined for the annual application rate (in case of crops which have more than one harvest per season), please report the maximum annual application rate for the active substance. The application rate should be reported for the a.s. (not the variant).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.SeasonalAplication
Treatment window (for dispensers)	For dispensers or similar application forms, the duration of treatment window needs to be reported.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.TreatmentWindowDispensers
Seeding rate (maximum)	Field relevant for seed treatments only. Enter the seeding rate: For crops where the seeds are usually sold by number of units (e.g. sugar beet, maize, sunflower), the seeding rate should be expressed as unit/ha (unit is usually 100.000 individual kernel). For seeds sold by weight (e.g. cereals the seeding rate is normally expressed in kg or g seeds /ha or m^2. If 'other:' is selected as unit, describe the seeding rate unit in the remarks.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.MaxSeedingRate
Planting density	The field is not mandatory. Describe the planting density (number of plants per ha or m^2).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.PlantingDensity
Pre-harvest interval	Mandatory field. Specify the minimum pre-harvest interval (PHI) in days (i.e. the minimum time between the last treatment of a crop and the harvest). This field should also be used to describe the time between post-harvest treatment of a food/feed item and the placement on the market. Enter a single numeric value. The qualifier '>' can be used together with a PHI to describe treatments at early development stages of the crop where the PHI cannot be specified more accurately. 'Not applicable' can be selected where the pesticide is applied to empty storage rooms, or for treatment of fields after harvest. In case 'not applicable' is selected, further clarifications need to be provided in the field 'additional information'.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.PreharvestInterval
Re-entry period livestock	The field is not mandatory. This field should be used to describe the minimum re-entry period (hours/days) for livestock, i.e. the time that needs to elapse before animals may enter treated pastures.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ReentryPeriodLivestock
Withholding period animal	The field is not mandatory. This field is intended to define the minimum time (in days) between harvest of a feed crop and the use of the feed.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetail

feed		s.WithholdingPeriod
Re-entry period	The field is not mandatory. Describe the minimum re-entry period (in days or hours) for workers in the field/room treated with pesticide, in order to safeguard human health. If no re-entry period is defined/required, select 'not applicable'.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.ReentryPeriod
Waiting period handling treated product	The field is not mandatory. This field is intended to describe the minimum waiting periods (hours/days) that need to be respected between treatment and handling of treated products (e.g. handling of products after fumigation).	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.WaitingPeriod
Ventilation practices	The field is not mandatory. If relevant, please describe the ventilation practices to be carried out after indoor treatments, to safeguard human health.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.VentilationPractices
Plant-back interval	The field is not mandatory. If relevant, please describe the plant-back interval (expressed as days) that has to be respected (e.g. in case of crop failure) before the planting of succeeding crops is allowed.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.PlantbackInterval
Restrictions	The field is not mandatory. If relevant, please report any relevant restrictions that would have an impact on the risk assessment e.g.: - geographical restrictions, - restriction related to use of other a.s., - maximum number of applications per season for a.s. belonging to the same group (e.g. dithiocarbamates, triazoles), - restrictions for rotational crops, - PPE, - buffer zones, - temperature range at application, - soil incorporation depth and time, - restricted soil type, - restriction to crops grown in artificial substrate, - restriction to be used only in crops grown in hydroponic systems, - restriction to crops grown in pots/no connection to natural soil, - restrictions to be used in crops up to a certain crop height, - minimum percent soil organic matter, - restrictions to protect pollinators, - restriction regarding application equipment.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.Restrictions
Type of user	The field is not mandatory. Please select one or several terms from the picklist (professional/non-professional/other:). If other is selected, please provide more details in the remark filed.	FLEXIBLE_RECORD.GAP.PestDiseaseTreated.ApplicationDetails.TypeOfUser
Additional information	Any relevant information on the GAP that cannot be reported in any of the data fields above should be entered in this field.	FLEXIBLE_RECORD.GAP.AdditionalInformation

EU PPP MRL application - active substance information

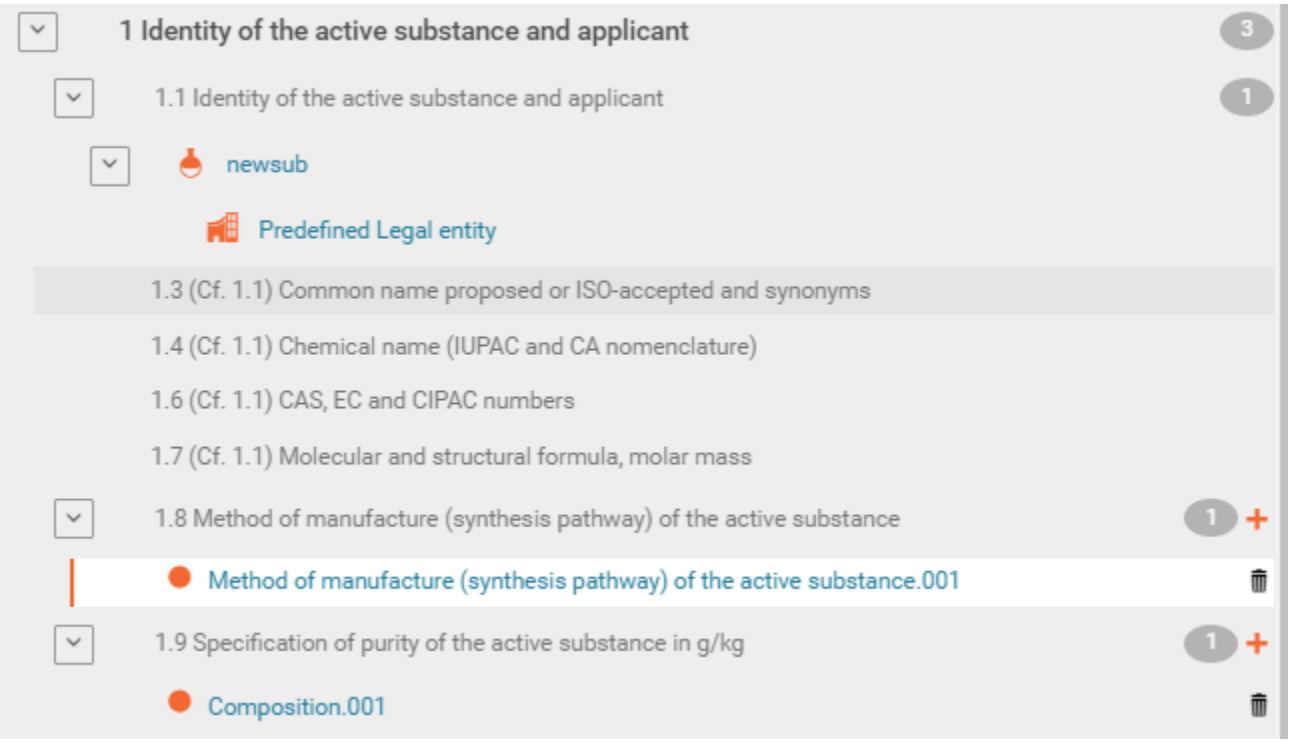
Section 1: Identity of the active substance and applicant

The following documents are located under section 1 "Identity of the active substance and applicant"

1.1 Identity of the active substance and applicant: Substance

1.8 Method of manufacture (synthesis pathway) of the active substance: Manufacturer EU_PPP - Flexible record

1.9 Specification of purity of the active substance in g/kg: Substance Composition – Flexible record



1.1 Identity of the active substance and applicant

Purpose:
This document facilitates the creation of a substance dataset when completing a mixture/product dossier. It also links to a reference substance in a mixture composition document. This document should be completed for active substance and relevant metabolites and impurities
Note: if there are no studies for a component of mixture link directly to a reference substance.

Substance			
Name	**Instructions**	**Type**	**Field Path**
Substance	The International Organization for Standardization (ISO)	Multi-	SUBSTANCE.Chemica

name	common name, or proposed ISO common name	line text	lName
Public name	Public name of the active substance	Multi-line text	SUBSTANCE.PublicName
Other substance identifiers	Code numbers used to identify the active substance, during development work, shall be reported. For each code number reported, the material to which it relates, the period for which it was used should be reported in the Remarks field The Member States or other countries in which it was used and is being used, should be reported in the Country field		SUBSTANCE.OtherNames
Flags	See confidentiality	Confidentiality	SUBSTANCE.OtherNames.DataProtection
Identifier		Open list	SUBSTANCE.OtherNames.NameType
Identity		Multi-line text	SUBSTANCE.OtherNames.Name
Country		Multi select open list	SUBSTANCE.OtherNames.Country
Relation		Open list	SUBSTANCE.OtherNames.Relation
Remarks		Text area	SUBSTANCE.OtherNames.Remarks
Other substance identifiers			
Legal entity flags		Confidentiality	SUBSTANCE.OwnerLegalEntityProtection
Legal entity	Include the name of the legal entity i.e. Company name for the applicant	Entity reference field	SUBSTANCE.OwnerLegalEntity
Third party flags		Confidentiality	SUBSTANCE.ThirdPartyProtection
Third party	Option to link to the legal entity of a third party. This is to be filled in by consultants if they are working on the dossier.	Entity reference field	SUBSTANCE.ThirdParty
Contact persons	Contact entity		SUBSTANCE.ContactPersons
Person flags		Confidentiality	SUBSTANCE.ContactPersons.DataProtection
Person		Entity reference field	SUBSTANCE.ContactPersons.ContactPerson
Contact persons			
Identificat		Header	SUBSTANCE.Referen

ion of substance		1	ceSubstance
Reference substance flags		Confidentiality	SUBSTANCE.ReferenceSubstance.Protection
Reference substance	Link to the reference substance Reference substance v.6.4 (Final)	Entity reference field	SUBSTANCE.ReferenceSubstance.ReferenceSubstance
Type of substance		Header 1	SUBSTANCE.TypeOfSubstance
Type of substance	For Microorganism dossiers 'microorganism or toxin produced by microorganism' must be selected. The other types can be used for chemicals	Open list	SUBSTANCE.TypeOfSubstance.Composition
Origin	Picklist to indicate class of active substance e.g organic or inorganic	Open list	SUBSTANCE.TypeOfSubstance.Origin
Role in the supply chain	Check 'Manufacturer' to indicate the applicant is the Producer of the active substance	Header 1	SUBSTANCE.RoleInSupplyChain
Role flags		Confidentiality	SUBSTANCE.RoleInSupplyChain.RoleProtection
Manufacturer		Check box	SUBSTANCE.RoleInSupplyChain.Manufacturer
Importer		Check box	SUBSTANCE.RoleInSupplyChain.Importer
Only representative		Check box	SUBSTANCE.RoleInSupplyChain.OnlyRepresentative
Downstream user		Check box	SUBSTANCE.RoleInSupplyChain.DownstreamUser

Links to support materials
Legal entity
ISO/TC 81

1.8 Method of manufacture (synthesis pathway) of the active substance

Purpose:
To describe the method of manufacture (synthesis pathway) of the active substance. For each manufacture plant, describe, the purity of the starting materials, chemical pathways involved and identity of impurities present in the final product.

FLEXIBLE_RECORD.Manufacturer_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data		Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary

	See section on Confidentiality of dossiers	Confidentiality	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.DataProtection
Related compositions	Link to one or more compositions of the substance can be made which will then dis-play the corresponding name(s). This link enables to transparently identify which composition of the substance is relevant for which use during its life cycle (from manufacture to service life).	Endpoint reference list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdministrativeDataSummary.RelatedCompositions
Description of key information	Describe the manufacturing process e.g. chemical pathways involved. Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilised. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.KeyInformation
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.KeyInformation.field4764
Additional information	State the manufacturing plant if separate documents are provided for each manufacturing plant	Header 1	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation
	This text will be published.	Rich text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.field782

			1
Grounds for confidential file	Select one or more of the grounds for confidentiality to justify the claim. Please see section on Confidentiality of dossiers	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.GroundsForConfidentialFile
Justification	Provide additional information to support the claim	Text area	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Justification
Conditions	Select condition/s that apply to the confidentiality claim **Public availability**: the document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons; **Potential harm**: the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree and that the harm that may be caused is of a significance corresponding at least to 5% of their total gross turnover for legal persons, or earnings for natural persons, in the year preceding that of the submission of the confidentiality request. If the harm is quantified as not reaching this	Multi select open list with remarks	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.Conditions

	percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant should provide a specific reason in the form of a free text in the respective Justification box on why they considered that any public disclosure would potentially harm their interests to a significant degree. **Worthiness of legal protection**: the document, information or data for which confidentiality treatment is requested is eligible for legal protection in the form of the award of the confidentiality status. **Environmental Protection**: the document, information or data for which confidentiality status is requested does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation. **Novelty**: the document, information or data for which confidentiality status is requested has not been finalised in the form submitted to EFSA more than five years prior to the submission of the confidentiality request. If the document,		

	information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason in the form of a free text in the respective Justification on why public disclosure of that information would still potentially harm its interests to a significant degree.		
Document J	Document J can be uploaded here, this file will not be published. The filled-in "IUCLID templates for PPP Risk Assessment - Template 1.1 - Template for presentation the assessment for the equivalence of batches" (https://doi.org/10.5281/zenodo.4557366) shall be included in Document J.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.DocumentJ
Sanitised Document J	If relevant, a sanitised version can be uploaded.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.SanitisedDocumentJ
Attached background material	Additional background material can be uploaded here, use remarks to indicate the contents of the uploaded files		FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial
Attached document	Upload supporting material (e.g. Excel files) as described in regulatory guidance. Click the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Single file attachment	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short	Text	FLEXIBLE_RECORD.Manufacturer_EU_PPP.Additi

	description of the content of the attached document if the file name is not self-explanatory.		onalInformation.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of any submitted background material must be uploaded here, these will be published	Attachments list	FLEXIBLE_RECORD.Manufacturer_EU_PPP.AdditionalInformation.AttachedSanitisedDocsForPublication

Links to support materials:
Transparency Regulation: Practical Arrangements
https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

1.9 Specification of purity of the active substance in g/kg

Purpose:
The minimum content in g/kg of pure active substance in the manufactured material used for production of plant protection products, shall be reported. A justification shall be provided for the minimum content proposed in the specification; this shall include a statistical analysis of the data on at least five representative batches, as referred to in point 1.11. Additional supporting data may be provided to further justify the technical specification.
Where the required information is provided for a pilot plant production system, that information shall again be provided once industrial scale production methods and procedures have stabilized. Where available, industrial scale data shall be provided before approval under Regulation (EC) No 1107/2009. Where data on industrial scale production are not available, a justification shall be provided.
For microorganisms; the identity and maximum content of all contaminating micro-organisms, expressed in the appropriate unit, must be reported, where relevant detailed information on all components such as condensates, culture medium, etc. must be provided, identity and content should also be reported for impurities and additives
If the active substance is manufactured as technical concentrate (TK), the minimum and maximum content of the pure active substance shall be given, along with its content in the theoretical dry weight material.
If the active substance is a mixture of isomers, the ratio or the ratio range of the content of isomers shall be provided. The relative biological activity of each isomer, both in terms of efficacy and toxicity, shall be reported.
For plant extracts, a different approach may be taken if adequately justified.

FLEXIBLE_RECORD.SubstanceComposition			
Name	**Instructions**	**Type**	**Field Path**
General Information	To report the analytical profile of batches a substance composition document should be completed for each batch	Header 1	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation
Name	Indicate a name representative of the composition.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.Name
Type of composition	Select the type of composition as appropriate. - A 'legal entity composition of the substance' refers to a composition specific to the party carrying out the application/notification/registration.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.TypeOfComposition
State / form	Indicate the physical state and form of the composition. The picklist is not exhaustive, but aims to reflect states and forms that may influence the properties of the substance. If none of pre-defined picklist items appropriately describe your composition, select 'other:'. A text field is then activated next to the list field in which you can enter the state and form of the composition. If multiple options apply, please create a separate composition for each.	Open list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.StateForm
Description	Include in this field, as appropriate, additional information on the composition. Such information	Text templ	FLEXIBLE_RECORD.SubstanceComposition.GeneralInf

	is important especially when multiple compositions are reported in section 1.2, to clarify the differences and reasons for such compositions. For a complex substance, the description should enable the understanding of the process that led to the particular composition. Free-text templates are available to support the user in providing a suitable description.	ate	ormation.DescriptionOfComposition
Justification for deviations	Provide in this field, if relevant, the justification for deviating from agreed conventions when reporting the composition. Such deviations can for example relate to the definitions of substance types (e.g. mono-constituent substance), or the level to which a composition has been described in terms of separate constituents, impurities and additives. Consult any programme-specific guidance on how to use this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.JustificationForDeviations
Attached description / justification	Attach in this table supporting information to describe the composition, e.g. schematics for relevant chemical reactions or process steps that take place in the generation of the composition.		FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription
Attached document	Upload a file by clicking the upload icon. Documents with confidential material should not be uploaded in this field.	Single file attachment	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.AttachedDocument
Remarks	Provide information about the contents of the attached document.	Text	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.AttachedDescription.Remarks
Attached description / justification			
Related composition (s)		Header 2	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions
Related composition	Use this field, where relevant, to link compositions of the type 'legal entity composition of the substance' to other compositions in the same dataset. Typically, this field is used to link a legal entity composition to the boundary composition that encompasses that legal entity composition. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple links between the same compositions. Related compositions in other datasets or dossiers should be referred to textually in the field 'Reference to related composition(s)'.	Endpoint reference list	FLEXIBLE_RECORD.SubstanceComposition.GeneralInformation.RelatedCompositions.RelatedComposition
Reference	Use this field, where relevant, to refer	Multi-	FLEXIBLE_RECORD.Substa

to related composition (s)	compositions of the type 'legal entity composition of the substance' to compositions in other datasets. Typically, this field is used to provide a textual reference from a legal entity composition to the boundary composition that encompasses the legal entity composition, when the boundary composition is provided in another dataset. The field is active only for compositions of the type 'legal entity composition of the substance' to prevent multiple referencing between the same compositions. Related compositions located in the same dataset should be linked in the field 'Related composition'.	line text	nceComposition.GeneralInformation.RelatedCompositions.ReferenceToRelatedCompositions
Degree of purity		Header 1	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.DataProtection
	Indicate the degree of purity; give the purity with the upper and lower limit for typical commercial batches of the substance. For providing only a single numeric value; enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.DegreeOfPurity.Purity
Constituents	This part is a repeatable block subsection enabling to provide detail on all constituents of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one constituent, add a new block to describe each constituent.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Constituents
			FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.DataProtection
Reference substance	Assign here the reference substance that identifies the constituent. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.ReferenceSubstance
Typical concentratio	Indicate the typical concentration of the constituent in the selected composition of the	Half-boun	FLEXIBLE_RECORD.SubstanceComposition.Constitue

n	substance.	ded with open list (Decimal)	nts.Constituents.ProportionTypical
Concentration range	Indicate the concentration range of the constituent the selected composition of the substance. If only providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.Concentration
Remarks	Provide additional information about the constituent, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Constituents.Constituents.Remarks
Impurities	This part is a repeatable block subsection enabling to provide detail on all impurities of a specific composition of the substance. Click the Plus button to open the repeatable block. If the composition contains more than one impurity, add a new block to describe each impurity.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Impurities
			FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.DataProtection
Reference substance	Assign here the reference substance that identifies the impurity. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.ReferenceSubstance
Typical concentration	Indicate the typical concentration of the impurity in the selected composition of the substance. Ensure to follow regulatory guidance on what constitutes an impurity.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.ProportionTypical
Concentration range	Indicate the concentration range of the impurity the selected composition of the substance. If only providing a single numeric value:	Range with	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Concentration

	-Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	open list (Decimal)	
Remarks	Provide additional information about the impurity, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.Remarks
This impurity is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the impurity has an impact on the classification and labelling of the substance.	Check box	FLEXIBLE_RECORD.SubstanceComposition.Impurities.Impurities.RelevantForClassificationLabeling
Additives	This part is a repeatable block subsection enabling to provide detail on all additives of a specific composition of the substance. Click the Plus button <image> to open the repeatable block. If the composition contains more than one additive, add a new block to describe each additive.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.Additives
			FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives
	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DataProtection
Reference substance	Assign here the reference substance that identifies the additive. Click the Arrow button to access a linked reference substance and modify it as appropriate. Click the Link button to link/change the reference substance. If the desired reference substance is not present in your database, click the New button at the bottom of the Query window and insert the information of the reference substance in the available fields. For further information on reference substances, see chapter 10 of 'Functionalities of IUCLID', in the left pane of the Help system window.	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ReferenceSubstance
Typical concentration	Indicate the typical concentration of the additive in the selected composition of the substance.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.ProportionTypical
Concentration range	Indicate the concentration range of the additive the selected composition of the substance. If only	Range	FLEXIBLE_RECORD.SubstanceComposition.Additives.

	providing a single numeric value: -Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	with open list (Decimal)	Additives.Concentration
Function	Indicate the function of the additive in the composition of the substance. Ensure to follow regulatory guidance on what constitutes an additive.	Open list	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Function
Details of function in composition	Provide further information related to the function of the additive in the composition of the substance. In particular, if selecting a less specific entry in the previous 'Function' field, it is recommended to include more details on the function in this field.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.DetailsOfFunctionInComposition
Remarks	Provide additional information about the additive, as relevant.	Text area	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.Remarks
This additive is considered relevant for the classification and labelling of the substance	Select the checkbox to indicate that the additive has an impact on the classification and labelling of the substance.	Check box	FLEXIBLE_RECORD.SubstanceComposition.Additives.Additives.RelevantForClassificationLabeling
Characterisation of nanoforms	The remaining fields would only be completed if the active substance is a nanoform or a polymer.	Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms
Type of information reported	Select the type of information reported as appropriate. A 'single nanoform' refers to an individual nanoform. A 'set of nanoforms' refers to a group of similar nanoforms. Consult any programme-specific guidance on how to use this field.	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.TypeOfInformationReported
Nanoform name flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.NameDataProtection
Name of nanoform	Indicate the name of the nanoform. Provide a name that describes the chemical composition and the key physicochemical characterisers of the nanoform, as relevant. The name should allow the unique identification of the nanoform.	Text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.NanoformName
Nanoform set flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SetDataProtection
Name of set of	Indicate a name representative of the set of similar nanoforms. Provide a name that describes the	Text	FLEXIBLE_RECORD.SubstanceComposition.Characteri

nanoforms	chemical composition and the key physicochemical characterisers of the nanoforms within the set, as relevant. The name should allow the unique identification of each individual set of nanoforms.		sationOfNanoforms.NanoformSetName
Justification for reporting set of similar nanoforms	Provide in this field, if relevant, the justification to demonstrate why the hazard, exposure and risk assessment can be performed jointly for the nanoforms within the set of nanoforms based on the size distribution, shape, aspect ratio and other morphological characterisers, surface functionalisation or treatment and surface area of the particles of the nanoforms. The justification can be provided based on the available free text template. Please note: Any additional information that can support the justification can be attached in the field 'Attached justification' or linked to the relevant record via the 'Cross-reference' feature.	Text template	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.JustificationForReportingSetOfSimilarNanoforms
Attached information	Attach supporting information for reporting set of similar nanoforms, e.g. scientific reports or literature references.		FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.AttachedInformation2
Attached information		Single file attachment	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.AttachedInformation2.AttachedInformation
Attached information			
Cross-reference	The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done by creating a link to the relevant record in the field 'Related information'. The field 'Reason / purpose' allows for selecting a reason from the picklist and optionally to add free text explanation in the related supplementary text field.		FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.CrossReference
Reason / purpose		Open list with remarks	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.CrossReference.ReasonPurpose
Related information		Endpoint reference field	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.CrossReference.RelatedInformation
Remarks		Text area	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.CrossReference.Remarks
Cross-reference			

Shape		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape
Shape flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeFlags
Shape description			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription
Shape category	Indicate the shape category of the particles by selecting a value in the picklist.	Closed list with remarks	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.ShapeCategory
Shape	Indicate the shape of the particles using the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate shape.	Open list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.Shape
Pure shape	Indicate, if the nanoform consists of particle with a single shape or different shapes by selecting a value in the picklist. For a nanoform consisting of particles with a single shape select 'yes'. For a nanoform consisting of particles with more than one shape select 'no' and provide further information on the fraction of different shapes in this table.	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.PureShape
Typical composition	Indicate, if relevant, the typical fraction of the shape present in percentage. For a nanoform consisting of particles with a single shape this value is not provided.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.TypicalComposition
Range	Indicate the range of the fraction of the shape present in percentage. For a nanoform consisting of particles with a single shape this value is not provided. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.Range
Remarks	Provide additional information about the shape, as relevant.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.ShapeDescription.Remarks
Shape description			
Justification for set containing multiple	Provide, if relevant, the justification to demonstrate that the hazards of nanoforms covered by the set can be assessed jointly.	Text area	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Shape.JustificationForSetContaini

shape categories or shapes			ngMultipleShapeCategoriesOrShapes
Particle size distribution and range		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange
Particle size distribution and range flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.ParticleSizeDistributionRangeFlags
Particle size distribution and range	This part is a repeatable block subsection enabling to provide detail on particle size distribution. Click the 'New item' to open the repeatable block. If the nanoform(s in a set) contain particles falling under more than one shape category (multimodal shapes), add a new block to describe each shape category.		FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable
Shape category	Indicate the shape category of the particles by selecting a value in the picklist.	Closed list with remarks	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.ShapeCategory
Percentile			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.Percentile
Percentile	Indicate, as minimum, the values d10, d50 and d90 with the unit of measurement. In addition to the required values, provide any other relevant percentile values. If none of pre-defined percentiles apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate value.	Open list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.Percentile.Percentile
Typical value	Indicate, if relevant, the typical value of the percentile with the unit of measurement.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.Percentile.TypicalValue
Range	Indicate the range values of percentile with the unit of measurement. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' - Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Deci	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.Percentile.Range

		mal)	
Remarks	Provide additional information about the percentile, as relevant.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.Percentile.Remarks
Percentile			
Typical length	Indicate, if relevant, the typical length of the particles with the unit.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.TypicalLength
Range of length	Indicate, if relevant, the range values of the length with the unit. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.RangeOfLength
Typical lateral dimension 1	Indicate, if relevant, one of the orthogonal external dimensions other that thickness.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.TypicalLateralDimension1
Range of lateral dimension 1	Indicate, if relevant, the range values of one of the orthogonal external dimensions other that thickness. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.RangeOfLateralDimension1
Typical lateral dimension 2	Indicate, if relevant, second of the orthogonal external dimensions other that thickness.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.TypicalLateralDimension2
Range of lateral dimension 2	Indicate, if relevant, the range values of second of the orthogonal external dimensions other that thickness. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Deci	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.RangeOfLateralDim

		mal)	ension2
Typical aspect ratio (:1)	Indicate, if relevant, the typical aspect ratio of the particles that is calculated as the length (or the longest dimension) to width (or the smallest dimension).	Half-bounded with closed list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.TypicalAspectRatio
Range of aspect ratio (:1)	Indicate, if relevant, the range of the aspect ratios of the particles that are calculated as the length (or the longest dimension) to width (or the smallest dimension).	Precise range (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.RangeOfAspectRatio
Additional information	Provide additional information on assembly structure and/or on rigidity, if applicable. This information can be provided based on the available free text template.	Text template	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.AdditionalInformation
Fraction of constituent particles in the size range 1-100 nm	Indicate the number fraction of the constituent particles with at least one of the external dimensions in the size range 1 nm to 100 nm.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.ParticleSizeDistributionAndRange.PartSizeDistribRangeRepeatable.FractionOfConstituentParticlesInTheSizeRange
Particle size distribution and range			
Crystallinity		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity
Crystallinity flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.CrystallinityFlags
Structures			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures
Structure	Indicate the structure of the particles by selecting a value in the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate structure.	Open list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.Structure
Name	Indicate, if applicable, a name for the reported crystal structure.	Text	FLEXIBLE_RECORD.SubstanceComposition.Characteri

			sationOfNanoforms.Crystallinity.Structures.Name
Pure structure	Indicate, if the nanoform(s) consist of particles with only one crystalline or only amorphous structure by selecting 'yes' in the picklist. In all the other cases select 'no' and provide further information on the percentage of each crystal structure present in the nanoform(s).	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.PureStructure
Typical composition	Indicate, if relevant, the percentage of the crystal structure present. For the nanoform(s) consisting of particles with only one crystalline or only amorphous structure, this value is not provided.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.TypicalComposition
Range	Indicate the range of percentage of the crystal structure present. For the nanoform(s) consisting of particles with only one crystalline or only amorphous structure, this value is not provided. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.Range
Crystal system	Indicate, if relevant, the crystal system by selecting values in the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate particle shape.	Multi select open list with remarks	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.CrystalSystem
Bravais lattice	Indicate, if relevant, the Bravais lattice by selecting values in the picklist.	Multi select closed list with remarks	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Structures.BravaisLattice
Structures			
Description	Include in this field, as appropriate, additional information on the crystallinity.	Text area	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Crystallinity.Description
Specific surface area		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea
Specific surface area flags		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.Specifi

			cSurfaceArea.SpecificSurfaceAreaFlags
Typical specific surface area	Indicate, if relevant, the typical specific surface area of the nanoform(s) by weight.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.TypicalSpecificSurfaceArea
Range of specific surface area	Indicate the range of specific surface area by weight. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.RangeOfSpecificSurfaceArea
Typical volume specific surface area	Indicate, if relevant, the typical specific surface area of the nanoform(s) by volume. When reporting the volume specific surface area, provide information also on the skeletal density.	Half-bounded with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.TypicalVolumeSpecificSurfaceArea
Range of volume specific surface area	Indicate the range of volume specific surface area. When reporting the volume specific surface area, provide information also on the skeletal density. If only providing a single numeric value: Enter the value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.' -Use the second numeric field if the qualifier is '<' or '<='.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.RangeOfVolumeSpecificSurfaceArea
Skeletal density	Indicate, if relevant, the range of the skeletal density.	Range with open list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.SkeletalDensity
Remarks	Provide additional information about the specific surface area, as relevant.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SpecificSurfaceArea.Remarks
Surface functionalisation / treatment		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment
Surface functionalisation / treatment flags	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.DataProtection

Surface treatment applied	Indicate, if the surface functionalisation/treatment has been applied to the nanoform(s). If you select 'yes' provide more information on the surface functionalisation/treatment by creating a repeatable block.	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatmentApplied
Does the set contain both treated and non-surface treated nanoforms?	Indicate if the set contains both treated and non-treated nanoforms.	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SetContainTreatedNon-surfaceTreatedNanoforms
Surface treatments	This part is a repeatable block subsection enabling to provide detail on all surface functionalisation/treatment applied. Click the New item to open the repeatable block. If one more than one surface treatment has been applied on a set of nanoforms add a new block to describe each of them.		FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments
Surface treatment name	Indicate, if applicable, a name for the surface treatment.	Text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatmentName
Surface treatment			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment
Order	Indicate the surface treatment layers, starting from the core particle	Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.Order
Surface treatment agent flag		Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.SurfaceTreatmentAgentFlag
Surface treatment agent	Indicate the surface treatment agent, by assigning the reference substance that identifies the surface treatment agent. Click the 'Select' button to link the reference substance. If the desired reference substance is not present in your database, click the 'Create' button and insert the information of the reference substance in the available fields. A reference substance linked to each layer must be specified with IUPAC name. In addition, if	Entity reference field	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.SurfaceTreatmentAgent

	available, the EC number and CAS number should be provided.		
Typical weight-by-weight contribution, % (w/w)	Indicate, if applicable, the typical weight-by-weight contribution of each surface treating agent applied on the particle.	Half-bounded with closed list (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.TypicalWeightbyWeightContributionWW
Range of weight–by-weight contribution, % (w/w)	Indicate the range of weight-by-weight contribution of each surface treating agent applied on the particle.	Range (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.RangeWeightByWeightContributionWW
Remarks	Provide additional information about the surface treatment agent, as relevant.	Text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.SurfaceTreatment.Remarks
Surface treatment			
External layer	Indicate the nature of the external layer of the particle by selecting a value in the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated below the list field in which you can enter the appropriate value.	Open list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.ExternalLayer
Description	Provide in this field the description of the process that has been applied on the nanoform. The description should contain the type of process/reaction, together with relevant process parameters. The description can be provided based on the available free text template.	Text template	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.Description
Percentage of coverage of particle surface, %	Indicate the percentage of coverage of particles surface that refers to the percentage of the core particle relative to the total weight of the surface-treated particle.	Range (Decimal)	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.PercentageOfCoverageOfParticleSurface
Attached information	Provide any further information on the surface functionalisation/treatment of the particle, e.g. schematic illustrations of the applied layers, further details on the process applied for the surface treatment etc.		FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.AttachedInformation
Attached document		Single file	FLEXIBLE_RECORD.SubstanceComposition.Characteri

		attachment	sationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.AttachedInformation.AttachedDocument
Remarks		Text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfNanoforms.SurfaceFunctionalisationTreatment.SurfaceTreatments.AttachedInformation.Remarks
Attached information			
Surface treatments			
Characterisation of polymers		Header 1	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers
Polymer molecular weight	This part is a subsection enabling to provide detail on characterisation of the polymer molecular weight.	Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight
Polymer molecular weight flags	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.DataProtection
Number average molecular weight (NAMW)	The number average molecular weight (NAMW) is the arithmetic mean of the molecular weight of all molecules in a polymer.	Integer	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.NumberAverageMolecularWeight
Weight average molecular weight (WAMW)	The weight average molecular weight (WAMW) is the arithmetic mean of the molecular weight of all molecules in a polymer that has been weighted according to the weight fractions of the molecules in the polymer.	Integer	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.WeightAverageMolecularWeight
Polydispersity index	The polydispersity index is the WAMW/NAMW.	Decimal	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.PolydispersityIndex
Percentage of low molecular weight species (< 1,000 g/mol)	The percentage fraction of the substance with a molecular weight less than 1,000 g/mol, as determined by GPC (or other approved method).	Decimal	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.PercentLowMolecularWeightSpecies1000
Percentage of low molecular weight	The percentage fraction of the substance with a molecular weight less than 500 g/mol, as determined by GPC (or other approved method).	Decimal	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.PolymerMolecularWeight.PercentL

species (< 500 g/mol)			owMolecularWeightSpecies 500
Reactive functional groups		Header 2	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups
Reactive functional groups flags	Set confidentiality and regulatory programme flags.	Confidentiality	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.DataProtection
Polymer contains only low concern reactive functional groups	Low concern reactive functional groups include: (a) aliphatic hydroxyls (b) blocked isocyanates (including ketoxime-blocked isocyanates) (c) butenedioic acid groups (d) carboxylic acids (e) conjugated olefinic groups contained in naturally occurring fats, oils and carboxylic acids (f) halogens (other than reactive halogen-containing groups such as benzylic or allylic halides) (g) imidazolidinone groups (h) imides (i) organic phosphate esters (j) thiols (k) unconjugated nitriles (l) unconjugated olefins that are not specifically activated by being part of a larger functional group or by other activating influences.	Check box	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.PolymerRFGOnlyLowConcern
Reactive functional groups - moderate concern		Header 3	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsModerateConcern
Reactive functional group			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsModerateConcern.ReactiveFunctionalGroup
Functional group		Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsModerateConcern.ReactiveFunctionalGroup.FunctionalGroup
Functional group equivalent	Enter the FGEW for the reactive functional group, if required.	Integer	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.Reactive

weight (FGEW)			FunctionalGroups.ReactiveFunctionalGroupsModerateConcern.ReactiveFunctionalGroup.FGEW
Remarks	Provide a summary of the calculation method used to determine the FGEW, or any other information relevant to the FGEW calculation for this reactive functional group.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsModerateConcern.ReactiveFunctionalGroup.Remarks
Reactive functional group			
Reactive functional groups - high concern		Header 3	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsHighConcern
Reactive functional group			FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsHighConcern.ReactiveFunctionalGroup
Functional group		Closed list	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsHighConcern.ReactiveFunctionalGroup.FunctionalGroup
Functional group equivalent weight (FGEW)	Enter the FGEW for the reactive functional group, if required.	Integer	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsHighConcern.ReactiveFunctionalGroup.FGEW
Remarks	Provide a summary of the calculation method used to determine the FGEW, or any other information relevant to the FGEW calculation for this reactive functional group.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.ReactiveFunctionalGroupsHighConcern.ReactiveFunctionalGroup.Remarks
Reactive functional group			
Combined functional		Header 3	FLEXIBLE_RECORD.SubstanceComposition.Characteri

group equivalent weight			sationOfPolymers.ReactiveFunctionalGroups.CombinedFunctionalGroupEquivalentWeight
Combined functional group equivalent weight (FGEWcombined)	The combined FGEW of all the moderate and high concern functional groups present in the polymer.	Integer	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.CombinedFunctionalGroupEquivalentWeight.FGEWcombined
Remarks	Provide a summary of the calculation method used to determine the FGEW, or any other information relevant to the FGEW calculation for the combined functional group equivalent weight.	Multi-line text	FLEXIBLE_RECORD.SubstanceComposition.CharacterisationOfPolymers.ReactiveFunctionalGroups.CombinedFunctionalGroupEquivalentWeight.Remarks

Section 2: Physical and chemical properties of the active substance

The following document is located under section 2. "Physical and chemical properties of the active substance':

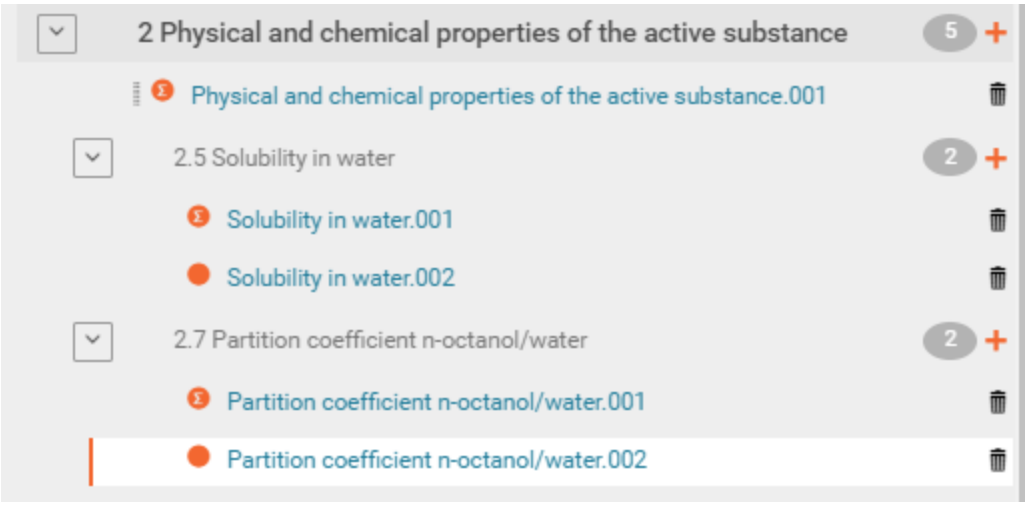
- Physical and chemical properties – Endpoint summary

  2.5 Solubility in water

  - Endpoint summary
  - Endpoint study record

  2.7 Partition coefficient n-octanol/water

  - Endpoint summary
  - Endpoint study record



2. Physical and chemical properties of the active substance – Endpoint summary

Purpose:
Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details for:

- Solubility in water
- Partition coefficient

(according to (Regulation (EU) N° 283/2013, Annex Part A, point 2)

ENDPOINT_SUMMARY.PhysicalChemicalProperties - v5.0 (Final) [July 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: - Solubility in water (state temperature, state purity and pH) - Partition coefficient (state temperature, pH and purity) If there is no additional information to be reported this field may	Header 1	ENDPOINT_SUMMARY.PhysicalChemicalProperties.Discussion

	be left empty.		

2.5 Solubility in water – Endpoint summary

Purpose:
Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be the structural formula, vapour pressure, dissociation constant and hydrolysis as a function of pH.
(COMMISSION REGULATION (EC) No 440/2008)

ENDPOINT_SUMMARY.WaterSolubility – v.5.0 (Final) [July 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Report Information to support solubility in water for example: - the structural formula - vapour pressure - dissociation constant - temperature - purity and pH	Header 1	ENDPOINT_SUMMARY.WaterSolubility.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.WaterSolubility.KeyValueForChemicalSafetyAssessment
Water solubility	Report solubility in water in mg or g/L	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.WaterSolubility.KeyValueForChemicalSafetyAssessment.WaterSolubility
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.WaterSolubility.KeyValueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for	Header 1	ENDPOINT_SUMMARY.WaterSolubility.Discussion

	differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.		

2.5 Solubility in water – Endpoint study record

Purpose:
The water solubility of purified active substances under atmospheric pressure shall be determined and a value reported for 20 °C. These water solubility determinations shall be made in the neutral range (that is to say in distilled water in equilibrium with atmospheric carbon dioxide). If the pKa is between 2 and 12, water solubility shall also be determined in the acidic range (pH 4 to 5) and in the alkaline range (pH 9 to 10). Where the stability of the active substance in aqueous media is such that water solubility cannot be determined, a justification based on test data shall be provided.
(COMMISSION REGULATION (EU) No 283/2013)

ENDPOINT_STUDY_RECORD.WaterSolubility– v.5.0 (Final) [July 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.DataSource
Materials and methods	Material and methods – common block Guideline: OECD 105.	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarksIn the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods including analytical method, method validation data and all relevant chromatograms (attach as appropriate) particularly if no guideline was used. If the test substance appears 'insoluble' in water, provide the detection limit of the	Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.StudyDesign.DetailsOnMethods

	analytical method. Also provide the purity of water used. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the water solubility.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubility.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion
Water solubility	Enter mean water solubility or range if reported so and indicate the temperature and pH conditions in the respective subfields. If necessary, copy this block of fields for each temperature and pH conditions at which the water solubility was determined. If the pH value was measured with another test substance concentration than the given water solubility concentration, specify the concentration with unit in field 'Details on remarks'.		ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.KeyResult
Water solubility	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Solubility
Conc. based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.), or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.ConcBasedOn
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.LoadingOfAqueousPhase

		(Decimal)	
Incubation duration	Specify the time until equilibrium was reached in the test.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.IncubationDuration
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.Ph
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.WaterSolubility.RemarksOnResults
Water solubility			
Solubility of metal ions in aqueous media	If the concentration of dissolved metal ions in aqueous media was tested in a transformation / dissolution test, indicate the type of test and the concentrations measured after a distinct incubation period, together with the loading, element analysed and test conditions (temperature, pH and oxygen) in the respective subfields. If necessary, copy this block of fields for different test runs, conditions or several metals released in the case of multi-metallic (e.g. UVCB) substances.		ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.KeyResult
Type of test	Select from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TypeOfTest

Mean dissolved conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.MeanDissolvedConc
Element analysed	Specify the element analysed.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.ElementAnalysed
Loading of aqueous phase	Indicate the loading, i.e. concentration of massive forms and/or powders introduced into the aqueous medium. Select from drop-down list.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.LoadingOfAqueousPhase
Incubation duration	Specify the duration of incubation for the loading applied. Select from drop-down list.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.IncubationDuration
Test conditions	Briefly describe the temperature, pH, oxygen conditions and time interval to determine the concentrations of dissolved metal ions in the water.	Multi-line text	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.TestConditions
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.SolubilityOfMetalIonsInAqueousMedia.RemarksOnResults
Solubility of metal ions in aqueous media			
Details on results		Text area	ENDPOINT_STUDY_RECORD.WaterSolubility.ResultsAndDiscussion.DetailsOnResults
Any other informati	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.WaterSolubi

on on results incl. tables			lity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.WaterSolubility.ApplicantSummaryAndConclusion

2.7 Partition coefficient n-octanol/water– Endpoint summary

Purpose:
Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be:
- the results of the preliminary estimation
- all information relevant for the interpretation of the results, especially with regard to impurities and physical state of the substance;
- POW values and their mean for each set of test conditions and the overall mean (if there is the suggestion of concentration dependence of the partition coefficient, this should be noted);
- the standard deviation of individual POW values about their mean;
- the overall mean expressed as its logarithm to base 10;
- the theoretical POW when it has been calculated or when the measured value is above 104 .

(OECD Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method)

ENDPOINT_SUMMARY.PartitionCoefficient – v.5.0 (Final) [July 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Report Information to support the partition coefficient, for example state: temperature, pH and purity	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment
Log Kow (Log Pow)		Decimal	ENDPOINT_SUMMARY.PartitionCoefficient.KeyValueForChemicalSafetyAssessment.LowKow
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.PartitionCoefficient.KeyVa

			lueForChemicalSafetyAssessment.TemperatureOf
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.PartitionCoefficient.Discussion

2.7 Partition coefficient n-octanol/water– Endpoint study record

Purpose:
The n-octanol/water partition coefficient (Kow or log Pow) of purified active substance and of all components of the residue definition for risk assessment shall be determined and reported for 20 °C or 25 °C. The effect of pH (4 to 10) shall be investigated when the active substance has a pKa value between 2 and 12.

ENDPOINT_STUDY_RECORD.Partition			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.DataSource
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline, e.g. OECD 117 Method A.8 Partition coefficient (Annex to Regulation (EC) No 440/2008). For surface active comounds method A.8 can be applicable if no problems occurr (e.g. phase separations). The HPLC method described in Method A.8 is not applicable to surface active compounds.	Header 1	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods
Partition coefficient type	Indicate the type of partition coefficient, normally 'octanol-water'. Select 'other:' and specify as appropriate. Note: Data on the Henry's law constant (air - water partition)	Open list	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.PartitionCoefficientType

	should be entered in the respective chapter; data on Kd values (e.g., partition / distribution coefficients for soil or sediment) should be recorded in chapters 'Adsorption / desorption' or 'Other distribution data'.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.TestMaterials
Study design		Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks. In the supplementary remarks field, provide method validation. As appropriate attach all relevant chromatograms.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on methods	Provide details on the methods. If an estimation method was used (to be indicated in field 'Test result type') state the equation(s) applied to calculate the value. For experimental studies, use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.StudyDesign.DetailsOnMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Partition.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and		Header 1	ENDPOINT_STUDY_REC

discussion			ORD.Partition.ResultsAndDiscussion
Partition coefficient	Enter overall mean partition coefficient or lower and upper value in case of range determined at the temperature and pH conditions indicated in the respective subfields. Copy this block of fields for each temperature and pH conditions at which the partition coefficient was determined or for indicating both Pow and log Pow values.		ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.KeyResult
Type	Indicate if Pow or log Pow is given.	Closed list	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Type
Partition coefficient	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Partition
Temp.	Enter numeric value and unit.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Temp
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use	Range (Decimal)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.Ph

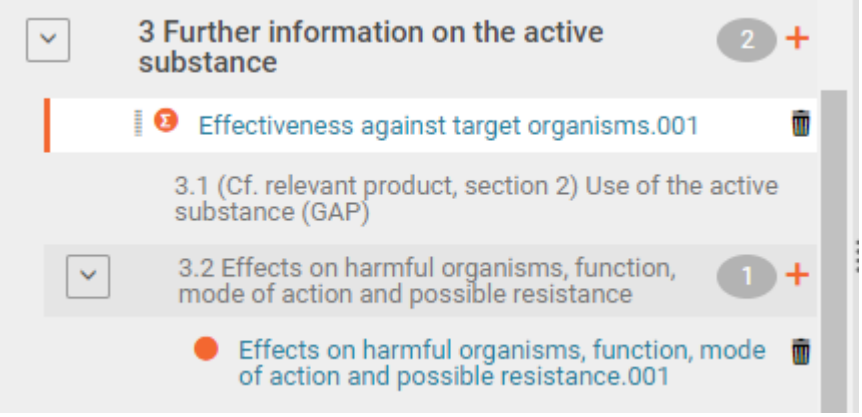
	both numeric fields together with the appropriate qualifier(s) if applicable.		
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any remarks by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.Partcoeff.RemarksOnResults
Partition coefficient			
Details on results	Give any further relevant information. As appropriate include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If requested by the regulatory programme, also attach a chart of relation and fitted regression equation (which includes a correlation coefficient) in field 'Attached background material'.	Text area	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Partition.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Partition.ApplicantSummaryAndConclusion

Section 3: Further information on the active substance

The following document is located under section 3 'Further information on the active substance':

- Effectiveness against target organisms – Endpoint summary
  - 3.1 (Cf. relevant product, section 2) Use of the active substance (GAP)
  - 3.2 Effects on harmful organisms, function, mode of action and possible resistance – Endpoint study record



3. Effectiveness against target organisms – Endpoint summary

Purpose:
Summary information of the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be: active substance (ISO name), function (*e.g.* fungicide), Rapporteur Member State, co-Rapporteur Member State

ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganism			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.AdministrativeDataSummary

	information: Enter information describing the intended purposes for which plant protection products containing the active substance are used, or are to be used and the dose and manner of their use or proposed use. State whether the representative uses (GAPs) are supported by the information provided in the Effectiveness against target organism studies		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EffectivenessAgainstTargetOrganisms.Discussion

3.2 Effects on harmful organisms, function, mode of action and possible resistance – Endpoint study record

Purpose:
The information provided shall include the endpoints Function, Effects on harmful organisms, Mode of action and Info on the (possible) occurrence of resistance development and appropriate management strategies

ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms [September 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.DataSource
General information		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation

Background information	Use this field to include any background information, if required, or any relevant introductory remark. Leave field empty if not applicable. Do not include information for which specific fields are provided. PURPOSE OF THIS TEMPLATE: This template can be used for recording general information on the effectiveness of an active substance or a product, together with its active substances (as required by the relevant legislation). For products, efficacy studies should be reported using the corresponding template 'Efficacy data'. For active substances, the effectiveness achieved or claimed should be briefly described in this template. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. As appropriate, the general information can be provided in one record or in several individual records. For instance, one record may be sensible if several target organisms, but same function and product type are addressed. Separate records may be sensible for addressing different	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.BackgroundInformation

	types of target organisms and functions.		

Pest / target organisms to be controlled		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled
Target organisms	Specify the target organism(s) to be controlled. Repeat this block of fields as necessary. Due to the great number of possible target organisms this picklist is not exhaustive. If the species name is not listed, choose an appropriate superior term (e.g. 'Acaridae:') and specify by entering free text in the related field. If organism is not listed at all, choose 'other:' and enter the name or several names in a row in the related text field.		ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms
Scientific name	Select appropriate scientific name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.ScientificName
Common name	Select appropriate common name from picklist. If not listed, select 'other' and specify. If not given/known, select 'no data'. See also instructions on this block of fields. Any remarks can be entered in the	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.CommonName

	supplementary remarks field.		
Developmental stage of target pest	Indicate the developmental stage of the target organism. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStage
Developmental stage of target plant	Indicate the developmental stage of the target plant. If not listed, select 'other' and specify. If not given/known, select 'no data'. If not applicable, leave field empty.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.PestTargetOrganismsToBeControlled.TargetOrganisms.DevelopmentalStageOfTargetPlant
Target organisms			
Products, organisms or objects to be protected / under study		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy
Organisms (to be protected) or treated materials	Describe and specify the organism(s) or materials(s) / object(s) to be protected.	Multi-line text	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.ProductsOrganismsOrObjectsToBeProtectedUnderStudy.OrganismsToBeProtectedOrTreatedMaterials
Information on intended use and application		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication
Function addressed	Indicate the function of the substance. Multiple selection is possible for indicating additional functions provided they relate to the same product type indicated in the next field. However, it may be sensible or required according to legislation-specific guidance to use separate records for each function.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FunctionAddressed

	Any remarks can be entered in the supplementary remarks field.		
Product type	Indicate the product type in which the active substance is intended to be included. In case of multiple product types use separate records for each of them. Note that only product types related to EU BPD are listed. For other legislations, choose 'other:' and specify in the related text field.	Open list	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.ProductType
Field of use envisaged / User	The fields of use, existing and proposed, for plant protection products containing the active substance shall be specified e.g. agriculture, horticulture, forestry and viticulture; protected crops; amenity; weed control on non-cultivated areas; home gardening; house plants; plant products storage practice; other.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnIntendedUseAndApplication.FieldOfUseEnvisagedUser
Information on application of product		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct
Method of application	For the product, indicate the method of application. Multiple selection is possible for indicating more than one method. If not listed, select 'other' and specify.	Multi select open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct.MethodOfApplication
Details on application	Outline the descriptions using the freetext template as appropriate (delete/add elements). You may summarise data on application and	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.InformationOnApplicationOfBiocidalProduct.DetailsOnAp

	geographical or climatic variations in tabular form. Upload predefined table(s) in the rich text field 'Overall remarks'. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: If the information or part of the information required by the legislation is provided in another section, it is sufficient to include a cross-reference to that section / record. Explanations: - DESCRIPTION OF APPLICATION SYSTEM USED: Give name of substances used for dilution including their concentration in the product. State any other substance(s) added including purpose and concentration in the product. Describe the application technique(s). Particularly if more than one product type or application method is applicable, you may summarize these data in tabular form. - APPLICATION RATE: For each product type and application technique give the recommended dose of the product and the active substance per object (e.g. per surface area of the material to be protected or as a concentration in a water system). LIKELY / FINAL CONCENTRATION AT WHICH ACTIVE SUBSTANCE OR		plication

	PRODUCT WILL BE USED: self-explanatory - NUMBER AND TIMING OF APPLICATIONS: Indicate the recommended number and timing, i.e. duration of application and possible reapplications as well as waiting periods considered necessary. Particularly if more than one product type or application method is applicable, you may summarize these data in tabular form. - GEOGRAPHICAL VARIATIONS: Where relevant, describe how the application should be varied in different parts of the Community. - CLIMATIC VARIATIONS: Where relevant, describe how the application should be varied at different climatic conditions. - WAITING PERIODS TO PROTECT MAN AND ANIMALS: Where relevant, specify any waiting periods.		
General information on effectiveness		Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness
Effects on target organisms	The effects on the target organisms required for the claimed efficacy should be described and specified if possible for each use and method of application if these have different effects, including any effect-concentration dependences or the	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.EffectsOnTargetOrganisms

	possible existence of a threshold concentration of the active substance. In case of a submission of an active substance the effectiveness achieved or claimed should be briefly described. If required or sensible such description can be supported by including summary table(s) which give an overview of relevant efficacy studies performed with a product or products. Upload predefined table(s) in the rich text field 'Overall remarks'. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). To show possible differences, the use, i.e. product type and method of application of the product(s) envisaged should also be given. For products, efficacy studies should be reported using the corresponding template 'Efficacy data'.		
Mode of action	Indicate the principles of the mode of action for the function indicated in above field, e.g. 'acute toxin: contact poison'. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ModeAction
Details on mode of action	For the function indicated in above field, indicate the principles of the mode of action; e.g. 'contact poison' or	Text template	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiven

	'stomach poison'. Briefly describe the biochemical and physiological mechanisms, e.g. 'cholinesterase inhibition' and the biochemical pathway and specify any time delay between application and effect. Use the freetext template as appropriate (delete/add elements).		ess.DetailsOnModeOfAction
(Possible) Occurrence of resistance	Indicate whether resistance can possibly develop including cross-resistance. As appropriate include an appraisal of the information gained from the efficacy studies.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.PossibleOccurrenceOfResistance
Management strategies to avoid resistance	Describe any appropriate management strategies towards the minimization of the development of resistance.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.ManagementStrategiesToAvoidResistance
Any other known limitations and management strategies	As applicable describe any other known limitations and relevant management strategies towards them.	Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.GeneralInformation.GeneralInformationOnEffectiveness.AnyOtherKnownLimitationsAndManagementStrategies
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion
Details on results		Text area	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.DetailsOnResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgain

	block		stTargetOrganisms.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms.ApplicantSummaryAndConclusion

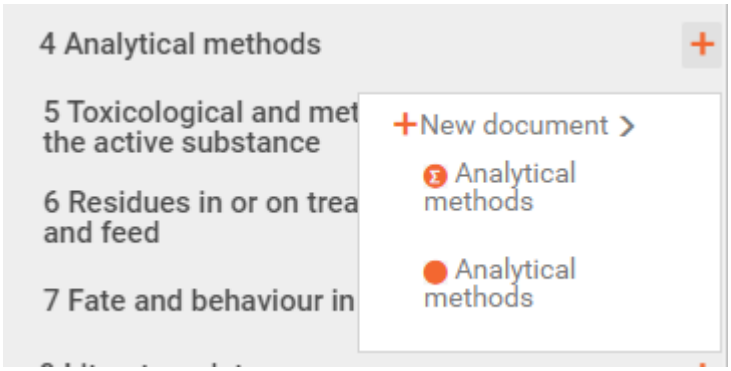
Links to support material:
EPPO (2017) EPPO Global Database. Database available online: https://gd.eppo.int

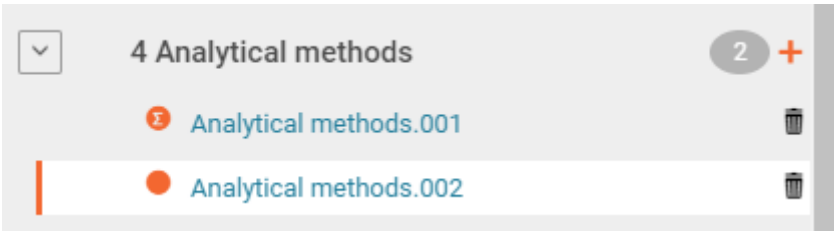
EPPO database on PP1 standards https://pp1.eppo.int/

Section 4: Analytical methods

The following documents are located under section 4. 'Analytical methods':

- 'Analytical methods' – Endpoint summary
- 'Analytical methods' – Endpoint study record





Analytical methods - Endpoint Summary

Purpose:
Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be: recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection (LOD), and limit of quantitation (LOQ).
(http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)

ENDPOINT_SUMMARY.AnalyticalMethods			
Label	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide an assessment of the suitability of the proposed methods for monitoring and enforcement. Note Further information on residue definitions and LOQs can be provided in Proposed residue definitions document and Proposed maximum residue levels document in the Residues Section	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block Attached (sanitised) documents for publication: The filled-in " IUCLID templates for PPP Risk Assessment - Template 4.1 - Template for the overview table for analytical methods for risk assessment" (https://doi.org/10.5281/zenodo.4556992) shall be uploaded here.	Header 1	ENDPOINT_SUMMARY.AnalyticalMethods.Discussion

Analytical methods - Endpoint study record

Purpose:
The provisions of this Section cover analytical methods used for the generation of pre-approval data and required for post-approval control and monitoring purposes. Descriptions of methods shall be provided and include details of equipment, materials and conditions used. On request, the following shall be provided:(a) analytical standards of the purified active substance; (b) samples of the active substance as manufactured; (c) analytical standards of relevant metabolites and all other components included in all monitoring residue definitions; (d) samples of reference substances for the relevant impurities. Where possible, the standards referred to in points (a) and (c) shall be made commercially available and, on request, the distributing company shall be named.

ENDPOINT_STUDY_RECORD.AnalyticalMethods			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.DataSource.Reference
Background		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.Background
Background information	Use this field to include any background information, if required, or any relevant introductory remarks on the study summary. Leave field empty if not applicable. Do not include information for which specific fields are provided. For instance, include any background information on the test substance in fields on 'Test materials'. PURPOSE OF THIS TEMPLATE: This template can be used for summarising analytical methods for determining a given substance in various matrices. Depending on the requirements of the relevant legislation, methods for the following matrices may have to be recorded: soil, sediment, suspended particulates, air, water (including drinking water), animal and human body fluids and tissues, plants, plant products, food and feedingstuffs, formulated product, other.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.Background.BackgroundInformation
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline, e.g. EU guidance document on analytical methods for the analysis of technical material and preparation	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods

	(SANCO/3030/99 rev. 4) Residues: EU guidance document on analytical methods for the determination of residues (Post-registration monitoring and control) (SANCO/825/00 rev. 8.1, 2010) EU guidance document for generating and reporting methods of analysis in support of pre-registration data requirements (SANCO/3029/99 rev. 4). OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39. In OECD Harmonised Template 87: Analytical methods a huge list is provided'.		
Matrix / medium	Indicate the medium for which the analytical method is described. In the supplementary remarks field, you can add explanations as appropriate. Note: The picklist is not descriptive as to whether analytical methods have to be submitted for each of the matrices provided in the picklist. If the methods for several matrices can be summarised in one record, you can copy this field for indicating the respective matrices.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.MatrixMedium
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.TestMaterials
Principles of analytical methods		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods
Instrument / detector	Indicate the instrument / detector used for the quantitative analysis of the parent compound / transformation products including the type of detector, e.g. 'HPLC-UV'. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on analytical data collection method'. Note: If a residue analytical method is recorded, the instrument/detector used for the so-called data collection or data-gathering method should be specified here. Data collection method is the analytical method used to collect quantitative residue data by analysing the analyte(s) in the matrices. This method can be identical with or differ from the so-called enforcement method which has to be recorded under the heading 'Enforcement method (if applicable)'. Enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.PrinciplesOfAnalyticalMethods.InstrumentDetector
Details on	Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g.	Text temp	ENDPOINT_STUDY_RECORD.AnalyticalMethods.

analytical method	'parent compound', 'parent and transformation products' or 'transformation product: .....') in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	late	MaterialsAndMethods.PrinciplesOfAnalyticalMethods.DetailsOnAnalyticalMethod
Enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable
Instrument / detector for enforcement method	If no enforcement method is proposed or required, ignore this field. An enforcement method is a validated analytical method which can be applied by the regulatory agency for enforcing the proposed tolerance, i.e. maximum residue limits (MRL) for pesticides. If such a method is proposed indicate the instrument / detector used in the enforcement method. Multiple selection is possible if more than one method needs to be specified. Give any further details in field 'Details on data enforcement method'.	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.InstrumentDetectorForEnforcementMethod
Details on enforcement method	'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product: .....") in matrices. Use freetext template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms "data collection method" and "enforcement method" see help text for field "Instrument / detector". Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.EnforcementMethodIfApplicable.DetailsOnEnforcementMethod
Confirmatory method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable

Instrument / detector for confirmatory method	'If not applicable, ignore this field. If a confirmatory method was used (i.e. applying techniques to demonstrate specificity in case the original method is not highly specific), indicate the instrument / detector used. Note: Not all picklist items may be relevant for a confirmatory technique. Multiple selection is possible if more than one method needs to be specified. Give any further details in field "Details on data confirmatory method".'	Multi select open list	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.InstrumentDetectorForConfirmatoryMethod
Details on confirmatory method	Briefly describe further details on the principles of the confirmatory method if any. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.ConfirmatoryMethodIfApplicable.DetailsOnConfirmatoryMethod
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion
Recovery results and characteristics of analytical method		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod
Recovery results	Indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.') Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.RecoveryResults

	Note: Specific tables may be required.		
Characteristics of analytical method	For each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....'), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio. Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms 'data collection method' and 'enforcement method' see help text for field 'Instrument / detector'. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.RecoveryResultsAndCharacteristicsOfAnalyticalMethod.CharacteristicsOfAnalyticalMethod
Results using enforcement method (if applicable)		Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod
Recovery results (enforcement method)	If not applicable, ignore this field. If an enforcement method is proposed which is different from the analytical method described as general analytical method (or 'data-gathering method' in residue analysis), indicate the compound (analyte) addressed (e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....'). Report the recovery rates at each level (e.g. at spiking level 1, spiking level 2 etc.) at the limit of quantification and give the mean % recovery and the relative standard deviation in % including the number of recovery studies. Include a brief evaluation of the repeatability of the method (e.g. 'These values demonstrate that the method has satisfactory repeatability.') Use freetext template and delete/add elements as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.ResultsUsingEnforcementMethod.RecoveryResults
Characteristics of	If not applicable, ignore this field. If an enforcement method is proposed which is different from the	Text temp	ENDPOINT_STUDY_RECORD.AnalyticalMethods.R

enforcement method	analytical method described as general analytical method (or 'data-gathering method' in residue analysis), report both the limit of quantitation (LOQ) and limit of detection (LOD), and the criteria used to determine the LOD or LOQ, i.e., the lowest fortification/spiking level or S/N ratio for each compound (analyte) addressed (to be specified, e.g. 'parent compound', 'parent and transformation products' or 'transformation product: .....'). Use freetext template, delete/add elements and edit text set in [...] as appropriate, or include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	late	esultsAndDiscussion.ResultsUsingEnforcementMethod.CharacteristicsOfEnforcementMethod
Independent laboratory validation (if applicable)	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation
Independent laboratory validation	If not applicable, ignore this field. If applicable (as for enforcement methods), discuss the independent laboratory validation (ILV) in terms of whether or not it was conducted according to guideline specifications. Discuss any method modifications that may impact the analyses of the residues (e.g., altered LOQ) that are suggested by the independent laboratory. Alternatively, include a table (particularly for comprehensive data) in rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.IndependentLaboratoryValidation.IndependentLaboratoryValidation
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall	Overall remarks, attachments – common block	Head	ENDPOINT_STUDY_REC

remarks, attachments		er 1	ORD.AnalyticalMethods.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AnalyticalMethods.ApplicantSummaryAndConclusion

Links to support material:

OECD GUIDANCE DOCUMENT ON PESTICIDE RESIDUE ANALYTICAL METHODS
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en

Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013.
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_phys-chem-ana_3030.pdf

Section 5: Toxicological and metabolism studies on the active substance and their metabolites

Introduction

For EU pesticides, when compiling the dossier for active substances the applicant should consult programme-specific guidance under Commission Communication on list of test methods and guidance documents for active substances available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013XC0403(02) [Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market Text with EEA relevance]

It is expected that under MRL application the applicant will submit *in vivo* toxicological studies mainly by the oral route of exposure, relevant for consumer exposure. Therefore, under the MRL application the applicant is not expected to fill in data fields relevant for other routes of exposure such as inhalation and dermal exposure.

It is important than when presenting the results in tabular format for mammalian toxicology studies the applicant follows the recommendations of the IUCLID templates for PPP Risk Assessment - Template 5.1 - Template for presentation of results in tabular format for mammalian toxicology studies. [http://doi.org/10.5281/zenodo.4557274].

In cases that there are not specific study records fit for purposes please consider the use of the study record for intermediate effects if the aim of the study is mechanistic or the study record for other toxicological studies if the aim is not mechanistic (e.g. hazard identification), both under 5.8.

In cases QSARs are submitted please also attached in the respective study record a summary assessment report of a QSAR. See IUCLID templates for PPP Risk Assessment - Template 5.2 - Summary assessment report of a QSAR and example. [http://doi.org/10.5281/zenodo.4557311].

Toxicological reference values – Flexible record

Purpose
To report Health-based guidance values than under the pesticides peer review are called toxicological reference values. These are the Acceptable operator exposure level (AOEL), Acceptable daily intake (ADI), Acute reference dose (ARfD) and Acute Acceptable operator Exposure Level (AAOEL) values derived for the active substance or metabolite (if applicable).

FLEXIBLE_SUMMARY.ToxRefValues			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	See Confidentiality request	Header 1	FLEXIBLE_SUMMARY.ToxRefValues.Administrativ

			eDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ToxRefValues.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation
	Rational for the derivation of the reference values reported below, plus specific information which should be considered when assessing the reported values.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.KeyInformation.KeyInformation
Human health hazard characteristics		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics
AOEL (Acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel
Not allocated	Check the box if an AOEL is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.NoAllocated
Justification	Justification for the non-derivation of an AOEL	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.Justification
AOEL	Report the AOEL value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.Aoel
Study retained	Type of study used to derive the AOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AOEL	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value	Oral absorption value	Decimal	FLEXIBLE_SUMMARY.To

(%)	derived from the toxicokinetic studies expressed as a percentage		xRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.OralAbsorption
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationOverallUf

	exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableOperatorExposureLevel.JustificationAndComments
ADI (Acceptable daily intake)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.

			AcceptableDailyIntake
Not allocated	Check the box if an ADI is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.NoAllocated
Justification	Justification for the non-derivation of an ADI	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.Justification
ADI	Report the ADI value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.Adi
Study retained	Type of study used to derive the ADI (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.StudyRetained
Route of original study	Route of exposure in the study used to derive the ADI. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.RouteOfOriginalStudy
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences). Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AOEL derivation is a LOAEL	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.OverallUncertainty

	instead of a NOAEL, the uncertainty factor should be between 2 and 10. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental NOAEL will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.		
Justification of the overall UF	Justification for the uncertainty factor applied considering	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.

	intra/inter species extrapolation		AcceptableDailyIntake.JustificationOverallUf
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcceptableDailyIntake.JustificationAndComments
ARfD (Acute reference dose)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose
Not allocated	Check the box if an ARfD is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.NoAllocated
Justification	Justification for the non-derivation of an ARFD	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Justification
ARfD	Report the ARfD value and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.Arfd
Study retained	Type of study used to derive the ARfD (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.StudyRetained
Route of original study	Route of exposure in the study used to derive the ARfD. It should be by default: oral.	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.RouteOfOriginalStudy
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used.	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.OverallUncertainty

	The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).		
Justification of the overall UF	Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be given to the uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for ARfD derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during ARfD derivation. In that case, it should be considered issues related to completeness	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationOverallUf

	and consistency of the available data and issues related to reliability of alternative data if those have been used. e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis. Justification for the uncertainty factor applied considering intra/inter species extrapolation		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteReferenceDose.JustificationAndComments
AAOEL (Acute acceptable operator exposure level)		Header 2	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel
Not allocated	Check the box if an AAOEL is not necessary for the application	Check box	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.NoAllocated
Justification	Justification for the non-derivation of an AAOEL	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealt

			hHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.Justification
AAOEL	Report the AOEL and select the relevant units	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.Aaoel
Study retained	Type of study used to derive the AAOEL (species and duration)	Multi select open list with remarks	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.StudyRetained
Route of original study	Route of exposure in the study used to derive the AAOEL	Closed list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.RouteOfOriginalStudy
Oral absorption value (%)	Oral absorption value derived from the toxicokinetic studies expressed as a percentage	Decimal	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.OralAbsorption
Overall uncertainty factor (UF)	The overall assessment factor is the product of all the assessment factors used. The default UF is 100 (10 for intraspecies differences and 10 for interspecies differences).	Text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.OverallUncertainty
Justification of the overall UF	Justification for the uncertainty factor applied considering intra/inter species extrapolation. Please detail if additional UF are applied e.g.: - UF for dose response relationship i.e. consideration should be given to the	Multi-line text	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.JustificationOverallUf

	uncertainties in the dose descriptor as the surrogate for the true no-adverse-effect-level. For instance, in case the starting point for AAOEL derivation is a LOAEL instead of a NOAEL, the uncertainty factor should be between 2 and 10. However, by using the BMD approach instead of NOAEL/LOAEL approach there would be not need to apply an additional UF in this case. - UF for differences in duration of exposure i.e. need to be considered taking into account that, in general, the experimental dose descriptor will decrease with increasing exposure times and that other and more serious adverse effects may appear with increasing exposure times. - UF for the quality of the whole database i.e. may be applied to compensate for the potential remaining uncertainties during AAOEL derivation. In that case, it should be considered issues related to completeness and consistency of the available data and issues related to reliability of alternative data if those have been used.		

	e.g. In case some studies are missing, additional UF can be added. - UF for remaining uncertainties. In that case, the assessment factor should where relevant be applied and justified on a case-by-case basis.		
Dose descriptor starting point	Critical endpoint value, type (e.g. NOAEL, BMDL05), value and units	Open list	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.DoseDescriptorStartingPoint
		Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.field8204
Justification and comments	Provide additional information related to the derivation of this specific toxicological reference value.	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.HumanHealthHazardCharacteristics.AcuteAcceptableOperatorExposureLevel.JustificationAndComments
Additional information		Header 1	FLEXIBLE_SUMMARY.ToxRefValues.Discussion
	Provide additional information related to the endpoint, for example: previous Reference Values set for the substance	Rich text area	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.Discussion
Attached background material	Upload any additional information related to the derivation of toxicological reference values and provide an indication of the content in the remarks		FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.To

			xRefValues.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	For any attached background material a sanitised version for publication must be provided.	Attachments list	FLEXIBLE_SUMMARY.ToxRefValues.Discussion.AttachedSanitisedDocsForPublication

Links to support materials

Guidance for the setting of an acute reference dose (ARfD)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_acute-ref-dose.pdf
GUIDANCE FOR THE SETTING AND APPLICATION OF ACCEPTABLE OPERATOR EXPOSURE LEVELS (AOELs)
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_accpt-exp-levs-2006.pdf
Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2579
Update: use of the benchmark dose approach in risk assessment
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4658

5.1 Studies on absorption, distribution, metabolism and excretion in mammals

The following documents are located under section 5.1 'Studies on absorption, distribution, metabolism and excretion in mammals':

- 'Toxicokinetics, metabolism and distribution' – Endpoint summary
- 'Basic toxicokinetics' – Endpoint study record

Toxicokinetics, metabolism and distribution - Endpoint Summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Absorption, distribution, metabolism and excretion (toxicokinetics):

- Rate and extent of oral absorption/systemic bioavailability
- Toxicokinetics (Cmax, Tmax, Plasma T1/2
- Distribution (indicate which organs have the highest levels
- Rate an extent of excretion
- Provide statement on comparative in vitro metabolism interspecies differences between human and test species.

The document should contain the information needed to be reported according to the list of end points for ADME (SANCO/12592/2012-rev. 2, 22 March 2019).
Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)
PBPK modelling including results, if available, should be summarised under this section. Modeling codes and results can be uploaded as attachments.

ENDPOINT_SUMMARY.Toxicokinetics			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Study name / type: Provide the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Currently comparative in vitro metabolism studies should be reported under **5.8 Other toxicological studies** (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3). Description of key information: Provide a brief description of toxicity studies and effects. The information provided for absorption, distribution, metabolism and excretion, or observations based on physicochemical properties should be	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.AdministrativeDataSummary

	described. The interpretation of the result should be done considering: - a discussion on potential data gaps, - the relevant of the results for the risk assessment (e.g. the extent to which the results from an animal study are relevant for human health).		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue
Bioaccumulation potential	This information is usually based on physicochemical properties (e.g. log Kow, molecular structure and molecular weight) and on metabolism. The rationale for the indicated value should be explained in the "Description of key information" field.	Closed list	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.Bioaccumulation
Absorption rate - oral (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionOral
Absorption rate - dermal (%)		Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionDerm
Absorption rate - inhalation (%)	This information can be obtained experimentally or generated considering physicochemical properties (e.g. water solubility, log Kow, molecular structure, molecular weight)	Decimal	ENDPOINT_SUMMARY.Toxicokinetics.KeyValue.AbsorptionInhal
Additional information	Discussion(Header 1) – common block Provide additional information related to	Header 1	ENDPOINT_SUMMARY.Toxicokinetics.Discussion

	the endpoint, for example: Rate and extent of oral absorption/systemic bioavailability; Toxicokinetics (Cmax, Tmax, Plasma T1/2; for parent and metabolites if available); Distribution (indicate which organs have highest levels); Rate and extent of excretion; In vitro metabolism (mention key findings, especially human:test species comparison); Toxicologically relevant compounds		

Basic toxicokinetics – Endpoint study record

Purpose:
Provide information on Absorption, distribution, metabolism and excretion (ADME) properties.

Currently comparative in vitro metabolism studies should be reported under "5.8 Other toxicological studies" (ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation - v.6.3 (Final) [September 2020]

Specific considerations for the reporting of metabolism studies in IUCLID:
An endpoint study record should be created for each metabolism study, filling out the standard fields of the template. In addition, metabolism studies should be entered via the DER-composer (part of the Metapath software package).

ENDPOINT_STUDY_RECORD.BasicToxicokinetics			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource
Reference	Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'. If you entered in the study in the DER composer, the XML-files created with the DER-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data	Literature reference list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.DataSource.Reference

	fields on material and methods and on results and discussions that were not directly reported in the present study record. In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE OBJECT. If you did not enter yourself the study in the DER composer because the XML-files linked to this study record are already in the list of "DER-composer XML-files" available to the Regulatory Authorities, the attachment of the XML-files is not mandatory. In such a case, please simply report the "MAP-number(s)" or the XML-file(s) in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding XML-file(s) in the database.		
Materials and methods	Material and methods – common block Applicable test guideline: According to the provisions in Article 62(1) of Regulation (EC) No 1107/2009, in vivo methods can only be used where alternative methods are not suitable Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics (* Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013) Guideline: Guideline: Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods
Objective of study	Indicate the purpose of the study. The field is repeatable. Select the respective toxicokinetic aspect(s) investigated. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.ObjectiveOfStudyPick
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'. In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestMaterials.Radiolabelling
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Sex: If different sexes were used in multiple test runs recorded in the same record, select 'male/female' and differentiate in field 'Doses / concentrations'.	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.TestAnimals

Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Duration and frequency of treatment / exposure	Indicate duration and frequency of application, e.g. 'single application' or 'multiple application: 14 days, 2 doses per day, 5 days per week'.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DurationAndFrequencyOfTreatmentExposure
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values / pilot study / main study.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentr			

ations			
No. of animals per sex per dose / concentration	Enter value or specify according to dose if different number of animals per dose / concentration, e.g. '4 in each dose / concentration group with single application; 2 f and 4 m in multiple application group'. In case of a robust study summary, include animal numbers per sex in table on animal assignment.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Positive control reference chemical	Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.PositiveControl
Details on study design	Include further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Details on dosing and sampling	Include details on dosing and sampling. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.DetailsOnDosingAndSampling
Statistics	List parameters that were analysed by which statistical methods, computer programme used.	Multi-line text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion

Preliminary studies	Briefly describe the results of preliminary / pilot study or studies if any.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PreliminaryStudies
Main ADME results	Briefly describe the most relevant results with regard to absorption, distribution, metabolism, excretion and any other aspects related to toxicokinetics. Further details can be given in the below fields 'Details on absorption', 'Details on distribution in tissues', 'Details on excretion' and/or 'Any other information on results incl. tables'. If required, copy block of fields to include several parameters. Absorption: Include degree of absorption in %. In case of a robust study summary, include a function relating excretion of radioactivity (in urine, feces, etc.) to sampling time. Distribution: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues/organs. Excretion: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues and excreta including total recovery. Material balance: Indicate mass balance of study. Metabolism including clearance: describe any decrease of the test chemical concentration from the incubation vial measured to determine the clearance in vitro.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults
Type	Select either 'absorption', 'distribution', 'metabolism', 'excretion' or 'other:' from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Type
Results	Briefly describe the most relevant results.	Text	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MainAdmeResults.Results
Main ADME results			
Toxicokinetic / pharmacokinetic studies		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies
Details on	In case of a robust study summary, describe further details on absorption. As appropriate include a detailed	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinet

absorption	table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		ics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnAbsorption
Details on distribution in tissues	In case of a robust study summary, describe further details on distribution including organs with highest levels. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnDistribution
Transfer into organs	Indicate the transfer of the radiolabelled test substance into organs. Copy this block of fields for each transfer type and/or different test runs if applicable.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TestNo
Transfer type	Select type of transfer (e.g. 'blood/brain transfer') from picklist.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.TransferType
Observation	Select the qualitative description (e.g. 'distinct transfer') that characterises the observed transfer of radiolabelled test substance into the brain or spinal cord or into the placenta and on the secretion of radioactivity via the gastric mucosa, respectively. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.TransferIntoOrgans.Observation
Transfer into organs			
Details on excretion	In case of a robust study summary, describe further details on excretion. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.DetailsOnExcretion

	the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Toxicokinetic parameters	Select toxicokinetic parameter from picklist and enter the corresponding value(s) with unit in the related text field. Examples: (i) Half-life 1st: 23.4 hrs (male, single administration study); (ii) C(time): 88 µg/l at 40 hrs Copy this block of fields for each parameter. If multiple test runs are recorded, enter test numbers in subfield 'Test No.'.		ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.KeyResult
Test no.	Select a consecutive test number from drop-down list if more than one test runs are reported.	Closed list	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.TestNo
Toxicokinetic parameters	Select parameter from drop-down list. Explanations: - AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration	Open list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.PharmacokineticStudies.ToxicokineticParameters.ToxicokineticParameters
Toxicokinetic parameters			
Metabolite characterisation studies		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies
Metabolites identified	Indicate whether metabolites were identified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.MetabolitesIdentified
Details on metabolites	List the metabolites identified, include percent of radioactive dose given, where they were identified, when, if applicable, how they were identified, if applicable, how much parent was present in the excreta. In case of a robust study summary, also include a detailed table in the rich text field 'Any other information	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.MetaboliteCharacterisationStudies.DetailsOnMetabolites

	on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). When available, include summary of metabolic pathways and attach figures in field 'Attached background material'. Mention which are major vs. minor pathways. Attach the submitter's postulated pathway as a figure. Note: Specific tables may be required.		
Enzymatic activity		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity
Enzymatic activity measured	Indicate the results of any enzymatic activity measured (induction, inhibition or biotransformation of test material). Identify enzyme(s) involved, rate of activity, time points measured, data from individual vials, time point for each independent run, calculated clearance and summary statistics, and method used to follow the activity. Specify whether measurements were done in vivo or in vitro, in main study or supplemental approach.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.EnzymaticActivity.EnzymaticActivityMeasured
Bioaccessibility (or Bioavailability)		Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.Bioaccessibility
Bioaccessibility (or Bioavailability) testing results	Indicate the results of the bio-accessibility (or bio-availability) tests, if applicable.	Text area	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.Bioaccessibility.BioaccessibilityTestingResults
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BasicToxicokinetics.ApplicantSummaryAndConclusion

Links to support material:
Test guideline: Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013

Please find specific instructions on who to structure the results of mammalian toxicology metabolism studies under the following link:

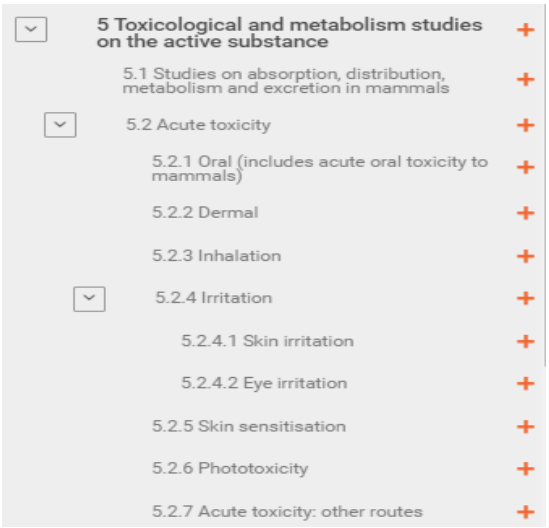
https://www.efsa.europa.eu/en/applications/pesticides/tools

5.2 Acute toxicity

The following documents are located under section 5.2 'Acute toxicity'

- 5.2 Acute toxicity – Endpoint Summary
  - 5.2.1 Oral (Includes acute oral toxicity to mammals' – Endpoint study record
  - 5.2.2 Dermal – Endpoint study record
  - 5.2.3 Inhalation – Endpoint study record
  - 5.2.4 Irritation – Endpoint Summary
    - 5.2.4.1 Skin irritation – Endpoint study record
    - 5.2.4.2 Eye irritation – Endpoint study record
  - 5.2.5 Skin sensitisation
    - Endpoint Summary
    - Endpoint study record
  - 5.2.6 Phototoxicity
    - Endpoint Summary
    - Endpoint study record
  - 5.2.7 Acute toxicity: other routes – Endpoint study record

The applicant is adviced to present the results of acute toxicity studies in a tabular format as additional information and background material.



Acute toxicity – Endpoint Summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2):

- Rat LD50 oral
- Rat LD50 dermal
- Rat LC50 inhalation

The document should contain the information needed to be reported according to the list of end points for acute oral, dermal and inhalation toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).

ENDPOINT_SUMMARY.AcuteToxicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment
Acute toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (quality of database) – common block Dose descriptor: LD50 should usually be chosen. However, if the	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaOralRoute.EndpointConclusion

	acute toxicity was established by determining the discriminating dose, that should be chosen.		
Acute toxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (quality of database) – common block Dose descriptor: LC50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating concentration, that should be chosen.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion
Physical form	Indicate in what physical form the test material was administered.	Open list	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaInhalationRoute.EndpointConclusion.PhysicalForm
Acute toxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.LinkToRelevantStudyRecords

	(e.g. Klimisch score, duration of the study, whether or not the study is GLP		
Endpoint conclusion	Endpoint conclusion (quality of database) – common block Dose descriptor: LD50 should usually be chosen. However, if the acute toxicity was established by determining the discriminating dose, that should be chosen.	Header 3	ENDPOINT_SUMMARY.AcuteToxicity.KeyValueForChemicalSafetyAssessment.AcuteToxicityViaDermalRoute.EndpointConclusion
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: Rat LD50 oral Rat LD50 dermal Rat LC50 inhalation Skin irritation Eye irritation Skin sensitisation	Header 1	ENDPOINT_SUMMARY.AcuteToxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.AcuteToxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.AcuteToxicity.JustificationForClassificationOrNonClassification.JustifClassifAcuteTox

5.2.1 Oral (includes acute oral toxicity to mammals)– Endpoint study record

Purpose:
Provide summary data on acute toxicity via oral, dermal and inhalation routes.

ENDPOINT_STUDY_RECORD.AcuteToxicityOral			
Name	**Instructions**	**Typ**	**Field Path**

		e	
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.DataSource
Materials and methods	Material and methods – common block Guideline: Select the applicable test guideline: - Method B.1 bis Acute oral toxicity - fixed dose procedure (Annex to Regulation (EC) No 440/2008). - Method B.1 tris Acute oral toxicity - Acute toxic class method (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 420: Acute oral toxicity: fixed dose procedure - OECD Test Guideline 423: Acute oral toxicity: acute toxic class method - OECD Test Guideline 425: Acute oral toxicity: up-and-down procedure Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods
Test type	If possible, indicate whether the acute toxic class method, fixed dose procedure, up-and-down procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species Select name of species. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.TestAnimals

	human exposure.		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Indicate details of oral exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Doses	Include the doses including unit administered to the test animals, '5, 50, 500 and 2000 mg/kg bw'. As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi	ENDPOINT_STUDY_R

		-line text	ECORD.AcuteToxicityOral.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If the test was conducted according to the fixed dose procedure, include the discriminating dose, i.e. the highest out of the four fixed dose levels which can be administered without causing compound-related mortality (including human kills). If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.Endpoint

	and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	In the case of a fixed dose study, summarise evidence of toxicity and mortality of any preliminary sighting study at the fixed doses administered.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.ClinicalSigns

	because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings. If the fixed dose method was used, indicate if animals appeared to recover completely and state if there were no obvious substance-related signs of toxicity.		
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block Attached document: Detailed results in the different dose groups can be reported in Appendix F format either as an attachment and in the 'Any other information on results incl. tables'	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOral.ApplicantSummaryAndConclusion

5.2.2 Dermal – Endpoint study record

Purpose:
The acute dermal toxicity of the active substance shall be reported unless waiving is scientifically justified (for example where oral LD50 (2) is greater than 2 000 mg/kg). Both local and systemic effects shall be investigated. Findings of severe skin irritation (Grade 4 erythema or oedema) in the dermal study shall be used instead of performing a specific irritation study.

ENDPOINT_STUDY_RECORD.AcuteToxicityDermal			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: - Method B.3 Acute toxicity (dermal) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 402: Acute Dermal Toxicity	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods
Test type	If possible, indicate whether the fixed dose procedure or standard acute method was used. The latter method should not be used any more. However, it may apply to existing studies. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure. Sex: Testing in one sex (usually females) is generally considered sufficient. Provide rationale for use of males (if applicable), in field 'Details on test animals and environment conditions'.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.TestAnimals

Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on dermal exposure	Indicate details of exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnDermalExposure
Duration of exposure	Indicate total duration of exposure in hours, e.g. '4 hrs'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Doses	Include the doses including unit administered to the test animals, e.g. 50, 200, 1000 and 2000 mg/kg bw', or mention the doses after '- other:'. As appropriate include notes in parentheses, e.g. '(male)'. For a robust study summary also indicate the analytical concentrations of the test substance in the vehicle in the results table (see field 'Mortality').	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals

Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate. If TG 402 (9 October 2017) was used, see flowchart for the testing procedure in its Annex 2.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other, if applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Preliminary
Effect levels			ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose procedure was used, select 'discriminating dose', i.e the dose causing evident toxicity but not mortality. With the up-and-down procedure an 'approximate LD50' may be derived. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.Endpoint

	'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. For GHS classification, see 'Interpretation of results' under section 'Applicant's summary conclusion' below.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If the fixed dose method was used, tabulate the evidence of toxicity and mortality (number of animals) for each sex and dose group. 'Evidence of toxicity' describes clear signs of toxicity following administration of test substance, which should be such that an increase in the exposure concentration can be expected to result in the development of severe toxic signs and probable mortality. Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDi

	recovered. Distinguish between effects at the site of application (local) and systemic effects. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.		scussion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityDermal.ApplicantSummaryAndConclusion

5.2.3 Inhalation – Endpoint study record

Purpose:
The acute inhalation toxicity of the active substance shall be reported where any of the following apply:
- the active substance has a vapour pressure > 1 × 10–2 Pa at 20 °C;
- the active substance is a powder containing a significant proportion of particles of a diameter < 50 µm (> 1 % on weight basis);
- the active substance is included in products that are powders or are applied by spraying.

The head/nose only exposure shall be used, unless whole body exposure can be justified.

ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: - Method B.2 Acute toxicity (inhalation) (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 403: Acute Inhalation Toxicity - OECD Test Guideline 436: Acute Inhalation Toxicity – Acute Toxic Class Method	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods
Test type	If possible, indicate which method was used in the study. If neither of these test types applies, either leave field empty or use 'other:'. Note: This field may be redundant with the information given in field 'Guideline', but is considered useful for searching reasons.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure. Sex: Provide rationale for use of females (if applicable),in field 'Details on test animals and environment conditions'.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.TestAnimals

Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. This field can be used for giving an additional information by selecting 'other:' or selecting a pre-defined reason why no numeric value is provided, e.g. 'not measured/tested' or 'not determinable' and entering free text explanation in the supplementary remarks field.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remark on MMAD/GSD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Indicate details of inhalation exposure. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt (i.e. diagram as pdf/jpeg etc.) from the study report.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical	Indicate whether the test atmosphere concentrations and the particle size were analytically verified.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhal

verification of test atmosphere concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. If any problems occurred, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.	with remarks	ation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfTestAtmosphereConcentrations
Duration of exposure	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfExposure
Remarks on duration	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnDuration
Concentrations	Provide rationale for the selection of the starting concentration. Include the nominal concentrations the test animals were exposed to, e.g. '100, 500, 2500 and 20000 ppmV(gas)' or '0.5, 2.0, 10, 20 mg/L air (dust/mist)'. As appropriate include notes in parentheses, e.g. '(male)'. For robust study summaries, also provide the analytical concentrations in the results table (see field 'Mortality').	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Concentrations
No. of animals per sex per dose	Enter number or state numbers for different groups if varying, e.g. '10 (controls), 5 (in test groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the GHS category. LC50 or other, if applicable.	Multi-line	ENDPOINT_STUDY_RECORD.AcuteToxicityInhal

		text	ation.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Information on the test atmosphere characteristics can be provided e.g. Nominal concentration and Temperature	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion
Preliminary study	Summarise evidence of toxicity and mortality of any preliminary sighting study (if performed).	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Preliminary
Effect levels	Provide the LC50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. Where there are significant differences in response between the sexes, include the effect levels for both. If no LC50 or other endpoint available from picklist is reported, but only a concentration level, specify this concentration using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. If a fixed dose concentration was used, select 'discriminating conc.', i.e the dose causing evident toxicity but not mortality. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LC50 >10 mg/m³ air or LC50 <10 mg/m³ air. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.Endpoint

Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. For GHS classification, see 'Interpretation of results' under section 'Applicant's summary conclusion' below.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if relevant available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.cl
Exp. duration	Enter numeric value. If exposure cannot be described by a single (integer) number, calculate hours and minutes reported to a decimal number, preferably based on the unit 'h (hour)', e.g. 4.15 h for 4 h, 9 min.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.ExposureDuration
Remarks on result	This field can be used for: - giving a qualitative description of results where required and in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Summarise evidence of toxicity and mortality of any preliminary sighting study.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.Mortality
Clinical signs	Choose the corresponding clinical sign and briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the	Open list with	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscuss

	major clinical signs and time when most animals recovered. (For non TG 433 inhalation studies, do not dwell on effects that are most likely due to agonal death.) Focus on any important findings, i.e. compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. If another clinical sign should be reported, choose option – other: and mention the sign as contained in the comprehensive Clinical sign lexicon provided as Table 2 in the publication by Sewell F. et al. (2015), "A global initiative to refine acute inhalation studies through the use of 'evident toxicity' as and endpoint: Towards adoption of the Fixed Concentration Procedure", Regul Toxicol Pharmacol, Vol. 73, pp. 770-779. Note if there was a reference point (e.g. NOAELs) for clinical findings.	remarks	ion.ClinicalSigns
Body weight	Briefly describe whether animals gained or lost weight. Indicate if body weight loss was greater than 10%.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables)		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.OverallRemarksAttachments
Applicant's summary	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummary

and conclusion			AndConclusion
Executive summary		Rich text area	ENDPOINT_STUDY_RECORD.AcuteToxicityInhalation.ApplicantSummaryAndConclusion.ExecutiveSummary

5.2.4 Irritation – Endpoint summary

Purpose:
Indicate whether Skin irritation, Eye irritation is observed.
The document should contain the information needed to be reported according to the list of end points for skin and eye irritation (SANCO/12592/2012-rev. 2, 22 March 2019).
Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

ENDPOINT_SUMMARY.IrritationCorrosion			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of irritation studies and effects	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment
Skin irritation / corrosion		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCo

			rrosion.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (irritating)" should be chosen if the substance meets the classification criteria for skin irritation (Category 2). "Adverse effect observed (corrosive)" should be chosen if the substance meets the classification criteria for skin corrosion (Categories 1A, 1B or 1C). "No adverse effect observed (not irritating)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.SkinIrritationCorrosion.EndpointConclusion.EndpointConclusion
Eye irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (irritating)" should be chosen if the substance meets the classification criteria for	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.EyeRespirationIrritation.EndpointConclu

	eye irritation (Category 2). "Adverse effect observed (irreversible damage)" should be chosen if the substance meets the classification criteria for irreversible effects on the eye (Category 1). "No adverse effect observed (not irritating)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.		sion.EndpointConclusion
Respiratory irritation		Header 2	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (irritating)" should be chosen if the substance is found to cause respiratory irritation. "Adverse effect observed (irreversible damage)" should be chosen if the substance does not cause respiratory irritation. "No study available" should be chosen if there is no data to conclude on respiratory irritation.	Closed list	ENDPOINT_SUMMARY.IrritationCorrosion.KeyValueForChemicalSafetyAssessment.RespiratoryIrritation.EndpointConclusion.EndpointConclusion
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example:	Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.Discussion

	skin/eye irritant or non-irritant		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.IrritationCorrosion.JustificationForClassificationOrNonClassification.Remarks

5.2.4.1 Skin Irritation – Endpoint study record

Purpose:
The results of the study shall provide information on the potential for skin irritancy of the active substance including, where relevant, the potential reversibility of the effects observed.
Before undertaking in vivo studies for corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data. Where insufficient data are available, they can be developed through application of sequential testing.
The testing strategy shall follow a tiered approach:
(1) the assessment of dermal corrosivity using a validated in vitro test method;
(2) the assessment of dermal irritation using a validated in vitro test method (such as human reconstituted skin models);
(3) an initial in vivo dermal irritation study using one animal, and where no adverse effects are noted;
(4) confirmatory testing using one or two additional animals.

ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.4 Acute toxicity: dermal irritation/corrosion (Annex to Regulation (EC) No 440/2008). OECD TG 430 / Method B.40 In vitro skin corrosion: transcutaneous electrical resistance test (TER) (Annex to Regulation (EC) No 440/2008). OECD TG 431 / Method B.40 bis In vitro skin corrosion: human skin model test (Annex to Regulation (EC) No 440/2008).	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods

	OECD Test Guideline 404: Acute Dermal Irritation/Corrosion OECD Test Guideline 431: In vitro Skin Corrosion: Human Skin Model Test OECD Test Guideline 430: In vitro Skin Corrosion: Transcutaneous Electrical Resistance Test OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method OECD TG 439 / Method B.46 In vitro skin irritation: reconstructed human epidermis model test (Annex III of Regulation (EC) No 761/2009 (7).		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem
Test system	Select as appropriate. If not available from picklist, select 'other:' and specify. Further information can be given in the supplementary remarks field. Use of other than the test systems recommended by the test guidelines is to be considered as deviation from guideline and should be noted and justified in the field "Test guideline - Deviations".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.TestSystem
Source species	Select as appropriate. Indicate the species used as source of the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.SourceSpecies
Cell type	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the cell type used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellType
Cell source	For in vitro tests, e.g. according to OECD Guidelines 431 and 439, indicate the source of the cells used to construct the in vitro test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.CellSource
Source strain	For in vitro tests, e.g. according to OECD Guideline 430, indicate the strain used as source of the test system. If not available from picklist, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMe

	Use of other than the strain recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields.		thods.InVitroTestSystem.SourceStrain
Details on animal used as source of test system	For in vitro tests, e.g. according to OECD Guideline 430, give details on the animal used as source of the skin discs. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnAnimalUsedAsSourceOfTestSystem
Justification for test system used	Provide a justification for the test system used	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.JustificationForTestSystemUsed
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.Vehicle
Details on test system	For in vitro tests, e.g. according to OECD Guidelines 430, 431, 435 or 439, indicate details on the test system used including test conditions. Select freetext template for the respective type of study (i.e. Transcutaneous electrical resistance test (TER) (e.g OECD TG 430) or Artificial membrane barrier test method (e.g OECD TG 435) or Human skin model test (e.g OECD TG 431) or Reconstructed human epidermis test method) (e.g OECD TG 439)) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - SKIN DISC PREPARATION (if Transcutaneous electrical resistance test): Summarise the procedure used to prepare the skin discs and, for each animal skin used as source for skin discs, indicate the electrical resistances obtained with two of the isolated skin discs before testing (should be ³ 10 kΩ) - RECONSTRUCTED HUMAN EPIDERMIS (RHE) TISSUE: For human skin model tests, e.g. according to OECD Guidelines 431 and 439, indicate the Reconstructed human Epidermis (RhE) tissue model used, batch number(s) used, the production date, the shipping date, the delivery date, and the date of initiation of testing. - TEMPERATURE USED FOR TEST SYSTEM: Indicate the	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DetailsOnTestSystem

	temperature used during treatment / exposure (e.g. room temperature, 25°C, 37°C, etc). If more than one temperature was used, indicate the different sequential temperatures used and the exact exposure time at each temperature. - REMOVAL OF TEST MATERIAL AND CONTROLS: Indicate the volume (if applicable) and number of washing steps used to remove the test item from the test system after treatment / exposure. Indicate if any observable damage was induced by the washing procedure. Indicate any modification to the validated SOP introduced in the washing procedure. - FUNCTIONAL MODEL CONDITIONS WITH REFERENCE TO HISTORICAL DATA (if human skin model test): Provide details on viability (negative control OD values of each tissue batch in comparison to historical acceptability ranges); barrier function (for each tissue batch, indicate the IC50 obtained with 18 h treatment with SDS or the ET50 obtained with treatment with 1% Triton X-100 in comparison to historical acceptability ranges); morphology (number and type of viable epithelial cell layers (basal layer, stratum spinosum, stratum granulosum) and the approximate number of layers of the stratum corneum, as assessed by histological examination); contamination (indicate if the tissue batches used were free of contamination by bacteria, viruses, mycoplasma or fungi, reproducibility (indicate the reproducibility of the negative and positive controls over time) - PREDICTION MODEL / DECISION CRITERIA: Describe and justify the prediction model / decision criteria used to derive the corrosion/irritation classification		
Control samples	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information. Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control, a concurrent negative control, non-specific colour controls and non-specific MTT reduction controls.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.ControlSamples
Amount/ concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with test system, e.g. '3 min. ' or '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DurationOfTreatmentExposure

Duration of post-treatment incubation (if applicable)	Indicate length of post-treatment incubation period as applicable.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.DurationOfPostTreatmentIncubationIfApplicable
Number of replicates	Indicate the number of replicate tissues/skin discs used in each treatment / exposure and control groups.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.InVitroTestSystem.NumberOfReplicates
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section 'Skin irritation / corrosion', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestAnimals
Test system		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem
Type of coverage	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.TypeOfCoverage
Preparation of test site	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.PreparationOfTestSite
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the	Multi select	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMe

	control substance and other identifiers (e.g. CAS number, the physical state, lot/batch No. including expiration date, purity and any other relevant information). Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control.	open list with remarks	thods.TestSystem.Controls
Amount / concentration applied	Give the amount(s) of substance applied (volume or weight with unit) and the concentration of the substance and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with test animal, including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.ObservationPeriod
Number of animals	Indicate number of animals used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	For in vivo tests, e.g. according to OECD Guideline 404, give details on study design. Describe the method of calculation of maximum average score given in the results table used (if applicable). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro

Results	Indicate the overall irritation / corrosion results for the test substance in terms of tissue viability, transcutaneous electrical resistance, penetration time or other. Copy this block of fields as appropriate. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results
Irritation / corrosion parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field, e.g. "based on optical density measurement".	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.IritationCorrosionParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 2 hours); Run 1, replicate 1 (duration of exposure: 2 hours), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of iritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known iritation/corrosion in the test conducted. Relevant remarks can be given in the	Open list with	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscu

	supplementary remarks field.	remarks	ssion.InVitro.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.Results.RemarksOnResults
Results			
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system, no visible damage on test system, direct-MTT reduction, colour interference with MTT, etc). Discuss the applicability of the test method to test colorants and/or direct MTT-reducers in reference to the %NSC and/or %NSMTT values reported in the block of fields above. - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults
In vivo		Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo
Results	For in vivo test results, provide individual time point scores per animal and mean scores. If reported or required by the relevant legislation, indicate overall irritation / corrosion results in terms of an Overall irritation score, Primary dermal irritation index or other (specify). Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'In vivo, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by		ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results

	entering the adequate qualitative description of the prediction. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:' An explanation should be provided when there was a	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.Results.RemarksOnResults

	need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.		
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time up to removal of each animal from the test (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined table(s) if any in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). In field "Details on study design (in vivo)", describe the method of calculation used. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Use freetext template and delete/add elements as appropriate. For in vivo tests, e.g. according to OECD Guideline 404, describe any other adverse local (e.g. defatting of skin) and systemic effects in addition to dermal irritation or corrosion.	Text template	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinIrritationCorrosion.ApplicantSummaryAndConclusion

5.2.4.2 Eye Irritation – Endpoint study record

Purpose:
The eye irritancy of the active substance shall always be tested, except where it is likely that severe effects on the eyes may be produced based on criteria listed in the test methods.The results of the study shall provide the potential of eye irritancy of the active substance including, where relevant, the potential reversibility of the effects observed. Before undertaking in vivo studies for eye corrosion/irritation of the active substance, a weight-of-evidence analysis shall be performed on the existing relevant data. Where available data are considered insufficient, further data may be developed through application of sequential testing. The testing strategy shall follow a tiered approach: (1) the use of an in vitro dermal irritation/corrosion test to predict eye irritation/corrosion; (2) the performance of a validated or accepted in vitro eye irritation study to identify severe eye irritants/corrosives (such as Bovine Corneal Opacity and Permeability (BCOP) assay, Isolated Chicken Eye (ICE) assay, Isolated Rabbit Eye (IRE) assay, Hen's Egg Test - Chorio-Allantoic Membrane assay (HET-CAM)), and where negative results are obtained, the assessment of eye irritation using an in vitro test method for identification of nonirritants or irritants, and where not available; (3) an initial in vivo eye irritation study using one animal, and where no adverse effects are noted; (4) confirmatory testing using one or two additional animals.

ENDPOINT_STUDY_RECORD.EyeIrritation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.5 Acute toxicity: eye irritation/corrosion OECD 405 OECD 437 OECD 438 Method B.47 Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants (Method B.48 Isolated chicken eye test method for identifying ocular corrosives and severe irritants	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestMaterials
Test animals / tissue source		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals

Species	Select as appropriate. For in vitro / ex vivo tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fields NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in section Irritation / corrosion', that human data are provided by creating a record and referring to the human data in block 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.Strain
Details on test animals or tissues and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestAnimals.OrganismDetails
Test system		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Vehicle
Controls	Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable. In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lo/batch No. including expirations date, purity and any other relevant information. Multiple selection is possible if more than one type of	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.Controls

	control was used, e.g. a concurrent positive control and a concurrent negative control.		
Amount / concentration applied	Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.AmountConcentrationApplied
Duration of treatment / exposure	Indicate length of time test material was in contact with animal/cell/tissue including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfTreatmentExposure
Observation period (in vivo)	Indicate length of observation period.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.ObservationPeriod
Duration of post-treatment incubation (in vitro)	Indicate length of post-treatment incubation period as appropriate.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DurationOfPostTreatmentIncubationInVitro
Number of animals or in vitro replicates	Indicate number of animals used (if in vivo) or, in the case of in vitro tests, the number of replicate tissues used in each treatment / exposure and control group.	Multi-line text	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.NumberOfAnimals
Details on study design	Select freetext template for the respective type of study (i.e. In vivo test method, In vitro test method (BCOP) or In vitro test method (ICE) and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.TestSystem.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion
In vitro		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro

Results	Indicate the overall irritation / corrosion results for the test substance in terms of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). Copy this block of fields for reporting several scores, e.g. means of individual replicates. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy
Irritation parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. For instance, in the case of morphological effects, specify if and to what severity pitting of corneal epithelial cells, loosening of epithelium, roughening of the corneal surface and sticking of the test substance to the cornea occurred.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.IrritationParameter
Run / experiment	Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 10 min.); Run 1, replicate 1 (duration of exposure: 10 min.), Mean of three runs with two replicates each.	Text	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.RunExperiment
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.Value
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. vehicle only without test substance) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) demonstrated lack of irritation/corrosion of the known non-irritant/non-corrosive substance, and/or that the negative control falls within the acceptance criteria range as	Open list with rema	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOf

	described in the TG. Relevant remarks can be given in the supplementary remarks field.	rks	ExVivoInVitroStudy.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) demonstrated irritation/corrosive effects of the known irritant/corrosive substance and/or that positive control results fall within the acceptance criteria as described in the TG. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.ResultsOfExVivoInVitroStudy.RemarksOnResult
Results			
Other effects / acceptance of results	Select freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative and positive control) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVitro.OtherEffectsAcceptanceOfResults
In vivo		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo
Results	Indicate the scores of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). In subfield "Basis of irritation parameter" indicate if the score is an average value (i.e. mean), or for a give animal, or other. Copy this block of fields for reporting several scores, e.g. means or for individual animals. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field		ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults

	"Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro' or 'in vivo', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		
Irritation parameter	Select type of parameter from picklist. Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Parameter
Basis	Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3').	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Basis
Time point	Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit.	Open list	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.TimePoint
Score	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Score
Max. score	Provide the numeric value of the total possible score depending on the scale used.	Decimal	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Scale
Reversibility	Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility.	Open list with remarks	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResults.Reversibility
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is	Open list with rema	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationC

	provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	rks (2000)	orrosionResults.RemarksOnResults
Results			
Irritant / corrosive response data	For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Describe the method of calculation of maximum average score given in the results table. Note: Specific tables may be required.	Text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.IrritationCorrosionResponseData
Other effects	Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable.	Text template	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.InVivo.OtherEffects
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.EyeIrritation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EyeIrritation.ApplicantSummaryAndConclusion

5.2.5 Skin sensitisation – Endpoint Summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details e.g. Sensitising (state method, e.g. LLNA).
The document should contain the information needed to be reported according to the list of end points for skin sensitisation (SANCO/12592/2012-rev. 2, 22 March 2019).
Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

ENDPOINT_SUMMARY.Sensitisation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the study and the potential of the active substance to provoke skin sensitisation reactions.	Header 1	ENDPOINT_SUMMARY.Sensitisation.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment
Skin sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessm

	substance meets the classification criteria for skin sensitisation. "No adverse effect observed (not sensitising)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.		ent.SkinSensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.SkinSensitisation.EndpointConclusion.AdditionalInformation
Respiratory sensitisation		Header 2	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected:	Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.LinkToRelevantStudyRecords

	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (sensitising)" should be chosen if the substance meets the classification criteria for respiratory sensitisation. "No adverse effect observed (not sensitising)" should be chosen if the substance does not meet the criteria for classification. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.EndpointConclusion
Additional information	Provide additional information related to the endpoint, for example: sensitising (state method, e.g. LLNA)	Rich text area	ENDPOINT_SUMMARY.Sensitisation.KeyValueForChemicalSafetyAssessment.RespiratorySensitisation.EndpointConclusion.AdditionalInformation
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Sensitisation.JustificationForClassificationOrNonClassification.Remarks

5.2.5 Skin sensitisation – Endpoint Study record

Purpose:
The study shall provide sufficient information to assess the potential of the active substance to provoke skin sensitisation reactions. The study shall always be carried out, except where the active substance is a known sensitiser. The local lymph node assay (LLNA) shall be used, including where appropriate the reduced variant of the assay. In case the LLNA cannot be conducted, a justification shall be provided and the Guinea Pig Maximisation Test shall be performed. Where a guinea pig assay (Maximisation or Buehler), meeting OECD guidelines and providing a clear result, is available, further testing shall not be carried out for animal welfare reasons. Since an active substance identified as a skin sensitiser can potentially induce hypersensitivity reaction, potential respiratory sensitisation should be taken into account when appropriate tests are available or when there are indications of respiratory sensitisation effects.

ENDPOINT_STUDY_RECORD.SkinSensitisation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 406 Method B.42 Skin sensitisation: Local lymph node assay (Annex to Regulation (EC) No 440/2008). Method B.6 Skin sensitisation (Annex to Regulation (EC) No 440/2008). OECD 429 OECD 442A + 442B.	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods
Type of study	Select type of study as appropriate. If another than the LLNA test system was used, a justification may be required in the following field.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TypeOfStudy
Justification for non-LLNA method	Provide a justification for the use of another than the LLNA test system (if in vivo), if the relevant legislation so requires. For instance it could be argued that the LLNA method was not available yet by the time the study was conducted or that the LLNA test is not suitable for that substance or that an appropriate guinea pig maximisation test is available which would not justify conducting an additional LLNA due to animal welfare. Refer to the relevant legislation-specific guidance document.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.JustificationForNonLLNAMethod
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.TestMaterials
In vitro test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem
Details of test system	If standard cell lines not used, please select 'other:' and specify in the freetext field exact details of the cell line used.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.DetailsTestSystem
Details on the study	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.In

design	(EC/CAS, purity, treatment of the material) etc. If stable dispersion is not obtained and the test solution is still used, add an explanation why this is not considered to affect the validity of the study. DOSE RANGE FINDING ASSAY: describe the highest concentration used for the dose range finding assay and how appropriate doses were selected taking solubility and cytotoxicity into account. Specify which solvents were used and finally selected and how cytotoxicity assessment was performed. APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical and control substance exposure conditions in detail. SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted. MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY: describe the steps taken to ensure the suitability of the cell surface marker expression/luciferase activity measurements for the test chemical, including solvents used LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used.		VitroTestSystem.DetailsOnStudyDesign
Vehicle / solvent control	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.VehicleSolventControl
Negative control	Select the negative control as appropriate. If no negative control required (Keratinosens), select 'not applicable'. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.NegativeControl
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVitroTestSystem.PositiveControl
In chemico test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem
Details of test system	Indicate the purity of the peptides used in the 'remarks' field. If standard peptides are not used, please select 'other:' and specify in the freetext field the exact details of the peptide used and supporting information on the scientific validity of their use.	Multi select open list with remar	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.DetailsTestSystem

		ks	
Details on the study design	PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. INCUBATION: describe the incubation conditions and whether precipitation was noted. PREPARATION OF THE HPLC: describe the steps taken to ensure the suitability of the HPLC for the test chemical, including solvents used DATA EVALUATION: report the UV wavelength used for peptide/derivative detection.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.DetailsOnStudyDesign
Vehicle / solvent	Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.VehicleSolvent
Positive control	Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InChemicoTestSystem.PositiveControl
In vivo test system		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem
Test animals		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals
Species	Select as appropriate. For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify. NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Sensitisation data'. It can be useful to document, in section 'Skin sensitisation', that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify. In the supplementary remarks field, also specify the substrain if not specified by picklist item. Provide rationale for choice of strain and substrain if deviating from the ones recommended by the test guideline used.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.Strain
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	Closed list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAni

			mals.Sex
Details on test animals and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.TestAnimals.DetailsOnTestAnimalsAndEnvironmentalConditions
Study design: in vivo (non-LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA
Induction	Record the vehicle, test substance concentrations used for induction exposure(s), the total amount of substance applied and the day(s) and duration of the induction. Copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction
Route	Indicate the route of induction exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.Vehicle
Concentration / amount	Provide the test substance concentrations used for induction exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Induction.DaySDuration
Adequacy of induction	Indicate if the test concentration used for the induction exposure was well-tolerated systemically and the highest to cause mild-to-moderate skin irritation, or if the	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.In

	highest technically applicable concentration used. If the substance is a non-irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation.		VivoTestSystem.StudyDesignInVivoNonLLNA.Induction.AdequacyOfInduction
Induction			
Challenge	Record the vehicle, test substance concentrations used for challenge exposure(s), the total amount of substance applied and the day(s) and duration of challenge. Copy this block of fields as appropriate. Consecutive numbers can be entered in the subfield "No." for indicating multiple challenges.		ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge
No.	For indicating multiple challenges or rechallenge select a consecutive number from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.No
Route	Indicate the route of challenge exposure.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Route
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.Vehicle
Concentration / amount	Provide the test substance concentrations used for challenge exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.ConcentrationAmount
Day(s)/duration	Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8).	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.DaySDuration
Adequacy of challenge	Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.Challenge.AdequacyOfChallenge
Challenge			

No. of animals per dose	Provide number of animals per dose or range if different numbers were used, e.g. '10 (controls), 10-20 (in test groups)'.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.NoOfAnimalsPerDose
Details on study design	For in vivo non-LLNA sensitisation tests, describe any range finding tests (pilot study) and for the main study the induction and challenge procedures including the type of information given in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406): - A. INDUCTION EXPOSURE - No. of exposures: 5 - Exposure period: - - Test groups: TS in FCA - Control group: FCA only - Site: R flank - Frequency of applications: every 2nd day - Duration: 0-8 d - Concentrations: same throughout B. CHALLENGE EXPOSURE - No. of exposures: 2 - Day(s) of challenge: 22 & 35 - Exposure period: - - Test groups: TS - Control group: TS - Site: L flank - Concentrations: 4 different - Evaluation (hr after challenge): 24, 48, 72	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.DetailsOnStudyDesign
Challenge controls	Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.ChallengeControls
Positive control substance(s)	Indicate if positive control substance(s) was/were used. If yes, describe the positive control(s) in supplementary field as appropriate. If no, describe any periodic or historic positive control(s).	Closed list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoNonLLNA.PositiveControlSubstances
Study design: in vivo (LLNA)		Header 3	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle	Open list with	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.In

	used is not from the list provided in the test guideline, a rationale must be provided.	remarks	VivoTestSystem.StudyDesignInVivoLLNA.Vehicle
Concentration	Describe dose selection, i.e. at least 3 consecutive concentrations (100%, 50%, 25% 10%, 5%, 2.5%, 1%, 0.5% etc.) of the test substance. Adequate scientific rationale should accompany the selection of the concentration series used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Concentration
No. of animals per dose	Provide number of animals per dose or range if different numbers were used.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.NoOfAnimalsPerDose
Details on study design	For LLNA, LLNA:DA or LLNA:BrdU-ELISA, describe details on materials and methods as indicated in the freetext template. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. - Details on radio isotope: to be included in field 'Details on test material' - RANGE FINDING TESTS: Briefly describe compound solubility, irritation and lymph node proliferation response if significant. - PRE-SCREEN TESTS: Briefly describe compound solubility, irritation, systemic toxicity (changes in: nervous system function, behaviour, respiratory patterns, food and water consumption), ear thickness measurements, erythema scores (0-3 on any day of measurement). MAIN STUDY - ANIMAL ASSIGNMENT AND TREATMENT: Indicate name of test method used. Comment on criteria used to consider a positive response. - TREATMENT PREPARATION AND ADMINISTRATION: Describe dose preparation and administration. (e.g. for LLNA:BrdU-ELISA 25 µl of compound x was applied to the entire dorsal surface of each ear of each mouse. The application was repeated on days 2 and 3). On day 5 an injection of 0.5 ml (5mg/mouse) of BrdU (10 mg/ml) solution was made inter-peritoneally for each experimental mouse. Twenty-four hours later, the draining auricular lymph node of each ear was excised into PBS (indicate individual animal approach or pooled animal approach). A single cell suspension of lymph node cells was prepared from each mouse (describe method of cell suspension).	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.DetailsOnStudyDesign
Positive control substance(s)	Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate, e.g. the concentration used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Positiv

		remarks	eControlSubstances
Statistics	Provide the statistical procedures employed (e.g., linear regression analysis or William's test to assess dose-response trends; Dunnett's test to make pairwise comparisons).	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.InVivoTestSystem.StudyDesignInVivoLLNA.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion
Positive control results	Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers.	Multi-line text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.PositiveControlResults
In vitro / in chemico		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico
Results	Indicate the test results. Copy this block of fields as appropriate. In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction. Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.KeyResult
Group		Open	ENDPOINT_STUDY_RE

		list	CORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Group
Run / experiment	Indicate the run / experiment the measurement relates to.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.RunExperiment
Parameter	Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. Please include EC150 and EC200 values, if those can be calculated.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Parameter
Value	Indicate also the unit of measurement e.g. µM, mM, µg/ml, mg/ml etc.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.Value
At concentration		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.AtConcentration
Cell viability		Text area	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.CellViability
Vehicle controls validity	Indicate whether test(s) with vehicle control(s) (i.e. without test substance, with/without solvent) is/are valid. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.VehicleControlsValid
Negative controls validity	Indicate whether test with negative control(s) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.NegativeControlsValid
Positive controls validity	Indicate whether test with positive control(s) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. Relevant remarks can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.Results.PositiveControlsValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived;	Open list with	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.I

	- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	remarks (2000)	nVitroInChemico.Results.RemarksOnResults
Results			
Outcome of the prediction model	For DPRA, the mean peptide % depletion values have been specified for each reactivity group in the test guideline for each prediction model.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.PredictionModelOutcome
Other effects / acceptance of results	Use freetext template and delete/add elements as appropriate. Provide the following information as appropriate: - OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system) - DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'. - ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative control, positive control, and variability between replicate measurements) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVitroInChemico.OtherEffectsAcceptanceOfResults
In vivo (non-LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest
Results	Record the results of in vivo non-LLNA tests at the different readings for each test or control group used. Copy this block of fields as appropriate. Present the scores from the challenge responses in a table. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.T

			raditionalSensitisationTest.ResultsOfTest.KeyResult
Reading	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Reading
Hours after challenge	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.HoursAfterChallenge
Group	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.Group
Dose level	If more than one concentration was tested at challenge, specify the concentration(s) the reading refers to, e.g. '0.15 g of a 10% aqueous solution'. Several dose levels can be given if the results reported in this block of fields is the same for all challenge groups, e.g. '0.15 or 0.3 g of a 10% aqueous solution'.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.DoseLevel
No. with + reactions	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.NoWithReactions
Total no. in group	Enter numeric value.	Integer	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.TotalNoInGroup
Clinical observations	Briefly describe relevant clinical observations.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.ClinicalObservations
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.TraditionalSensitisationTest.ResultsOfTest.RemarksOnResults

Results			
In vivo (LLNA)		Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA
Results	Indicate the cell proliferation results for the test substance, i.e. either ATP (measured adenosine triphosphate content of lymphocytes) or BrdU (measured 5-bromo-2-deoxyuridine content in DNA of lymphocytes) or DPM (incorporated radioactivity as disintegrations per minute) or other. Copy this block of fields as appropriate. (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field 'Remarks on result' should be completed by entering the adequate qualitative description of the prediction.In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Cellular proliferation data / Observations" and/or upload a table in the field "Any other information on results incl. tables". Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results.		ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.KeyResult
Parameter	Select type of parameter from picklist, if applicable, i.e. either SI (stimulation index) or EC3 (estimated concentration of a test substance needed to produce a stimulation index of three) or ECt (estimated concentration of a test substance needed to produce a stimulation index that is indicative of a positive response) or other (specify). Further details can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Parameter
Value	Provide the numeric value or a range of values if reported so. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.Value
Variability	Indicate the standard deviation or other appropriate measure of variability that takes into account the inter-animal variability in both the test substance and control	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.I

	groups when using the individual animal approach.		nVivoLLNA.Results.Variability
Test group / Remarks	Indicate the concentration of the test material, the run / experiment number the calculated value relates to and any other relevant information. Examples: Exp. 1 (0%); Exp. 1 (0.5%); Exp. 1 (1%), etc. or Mean of three runs (0%), etc.	Text	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.TestGroupRemarks
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.Results.RemarksOnResults
Results			
Cellular proliferation data / Observations	For robust study summaries or as requested by the regulatory programme, tabulate the raw data (unless these data are given in above block of fields 'Stimulation index / EC value') and indicate any relevant observations. Use freetext template and delete/add elements as appropriate. Alternatively or in addition refer to appropriate table(s), which were uploaded in the rich text field 'Any other information on results incl. tables'. Use predefined table if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). Provide the results of cellular proliferation measurements (DPM values for conventional LLNA or ATP content values for LLNA: DA or BrdU content values for LLNA: BrdU-ELISA). Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean measurements compared to control. Indicate whether results are from the individual animals or pooled. Indicate whether the overall result is positive or negative. Note: Specific tables may be required.	Text template	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.InVivoLLNA.CellularProliferationDataObservations
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.SkinSensitisation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.OverallRemarksAttachments
Applicant's summary and	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.SkinSensitisation.ApplicantSummaryAndConclusion

conclusion			

5.2.6 Phototoxicity – Endpoint Summary

Purpose:
State if 'not required' or 'not phototoxic/probably phototoxic/phototoxic'
The document should contain the information needed to be reported according to the list of end points for phototoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

ENDPOINT_SUMMARY.Phototoxicity - v.1.2 (Final) [August 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the phototoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Phototoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa
Results		Open list	ENDPOINT_SUMMARY.Phototoxicity.KeyValueCsa.Results
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: state 'not required' or 'not phototoxic/probably phototoxic/phototoxic'	Header 1	ENDPOINT_SUMMARY.Phototoxicity.Discussion

5.2.6 Phototoxicity – Endpoint Study record

Purpose:
The study shall provide information on the potential of certain active substances to induce cytotoxicity in combination with light, for example active substances that are phototoxic in vivo after systemic exposure and distribution to the skin, as well as active substances that act as photo-irritants after dermal application. A positive result shall be taken into account when considering potential human exposure. The in vitro study shall be required where the active substance absorbs electromagnetic radiation in the range 290- 700 nm and is liable to reach the eyes or light-exposed areas of skin, either by direct contact or through systemic distribution. If the Ultraviolet/visible molar extinction/absorption coefficient of the active substance is less than 10 L × mol–1 × cm–1, no toxicity testing is required.

ENDPOINT_STUDY_RECORD.PhototoxicityVitro			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.DataSource
Materials and methods	Material and methods – common block Type of study: Indicate whether an in vitro 3T3 NRU phototoxicity test or a reactive oxygen species (ROS) assay was performed. Applicable test guideline: OECD 432, OECD 101, Method B.41 In vitro 3T3 NRU phototoxicity test '.	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestMaterials
Test system		Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain.SpeciesStrainCell
Details on mammalian cell type (if applicable)	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.SpeciesStrain.MammalianCellDetails
Species / strain			
Controls	Indicate whether vehicle, true negative and/or positive controls were tested.		ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls

Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.NegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.PositiveControls
Positive control substance	If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification. Final concentration, conditions and durations of treatment and recovery periods. Note that the list of substances provided is not exhaustive.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.PositiveControlSubstance
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.TestSystemExpConditions
Vehicle	Indicate whether vehicle was used to emulsify or mix the experimental test material to enhance its solubility. If yes, specify in field 'Details on test solution'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Vehicle
Vehicle / solvent	Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation. Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle. Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.VehicleSolvent

	vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.		
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.MaterialsAndMethods.TestSystem.Statistics
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.KeyResult
Results	Include the main test results.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.Results
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.RemarksOnResult
Results with reference substance (positive control)	If reference substance(s) was/were tested, indicate whether the results with it/them are valid and provide relevant effect levels and other relevant information. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.ResultsReferenceSubstance
Reported statistics and error estimates	Indicate the parameters analysed, the statistical method used and the statistical test performed. If probit analysis was used, indicate the intercept and probit slope. As appropriate state any relevant error estimates associated with the determination of concentration-response relationship.	Multi-line text	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.StatisticsErrorEstimates

Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhototoxicityVitro.ApplicantSummaryAndConclusion

5.2.7 Acute toxicity: Other routes

Purpose:
Provide information:
- For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.
- For volatile active substances (vapour pressure >10–2 Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestMate

			rials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Species: NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'. It can be useful to document, in the section on acute toxicity, that human data are provided by creating a record and referring to the human data in field 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Briefly describe details of exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Doses	Include the doses including unit administered to the test animals, '5, 50, 500 and 2000 mg/kg bw'. As appropriate include notes in parentheses, e.g. '(male)'.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Doses
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 (controls), 5 (in dose groups)'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

Control animals	Indicate whether concurrent control group was used.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design, i.e. observation period, frequency of observations/weighing, necropsy of survivors and other examinations performed. Use freetext template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	Indicate the method of calculating the LD50 or other.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion
Effect levels	Provide the LD50 with confidence limits if available and/or other effect levels reported. Copy this field block for each effect level. If both sexes were tested at each dose level, then the combined effect level should be stated. If no LD50 or other endpoint available from picklist is reported, but only a dose level, specify this dose using 'other' and indicate the effects observed in subfield 'Remarks on result'.		ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Sex
Dose descriptor	Select the relevant dose descriptor from drop-down list, i.e. the exposure level that corresponds to a quantified level of effects. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.Endpoint

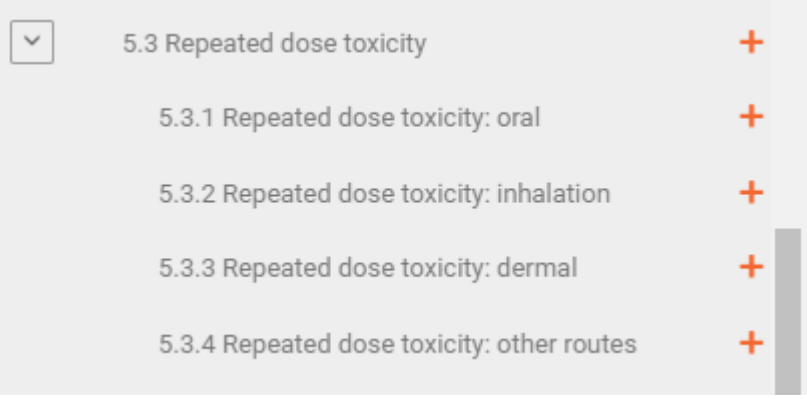
	relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. LD50 >10 mg/kg bw or LD50 <10 mg/kg bw. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.BasedOn
95% CL	For robust study summaries or as requested by the regulatory programme, provide the 95% confidence limits if available. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.cl
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.EffectLevels.RemarksOnResults
Effect levels			
Mortality	Include raw data on mortality and evident toxicity for each sex and approximate time of deaths. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.Mortality
Clinical signs	Briefly describe significant effects found, including the numbers of animals showing signs, time of onset, duration of the major clinical signs and time when most animals recovered. Do not dwell on effects that are most likely due to agonal death. Focus on any important findings, i.e.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.ClinicalSigns

	compound-related or suspected related effects. In case particular effects are considered control-related e.g. because of abnormal control values, this should be specifically addressed. Note if there was a reference point (e.g. NOAELs) for clinical findings.		
Body weight	Briefly describe whether animals gained or lost weight.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.BodyWeight
Gross pathology	Briefly describe whether there were any treatment related effects. Do not stress effects due to agonal death.	Multi-line text	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.GrossPathology
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Text template	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.OtherFindings
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AcuteToxicityOtherRoutes.ApplicantSummaryAndConclusion

5.3 Repeated dose toxicity

The following documents are located under section 5.3 'Repeated dose toxicity'

- 5.3 Repeated dose toxicity – Endpoint Summary
  - 5.3.1 Repeated dose toxicity:oral – Endpoint study record
  - 5.3.2 Repeated dose toxicity: inhalation – Endpoint study record
  - 5.3.3 Repeated dose toxicity: dermal – Endpoint study record
  - 5.3.4 Repeated dose toxicity: other routes – Endpoint study record



5.3 Repeated dose toxicity – Endpoint Summary

Purpose:
Provide consolidated information across the four routes (oral/inhalation/dermal/other) in both rodent and non-rodent species. The studies, data and information to be provided and evaluated, shall be sufficient to permit the identification of effects following repeated exposure to the active substance, and in particular to further establish, or indicate:

- Target organ / critical effect
- Relevant oral reference point (e.g. NOAELs).
- Relevant dermal reference point (e.g. NOAELs).
- Relevant inhalation reference point (e.g. NOAELs).

The document should contain the information needed to be reported according to the list of end points for short-term toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

ENDPOINT_SUMMARY.RepeatedDoseToxicity			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block Description of key information: Provide brief description of the toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the magnitude of the toxic effect, i.e. dose-dependent, or whether	Closed list	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ToxicEffectType

	the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.		
Repeated dose toxicity: via oral route - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects
Link to relevant study records	For relevant study record – common block Study name / type: The study giving rise to the highest concern should be chosen e.g. most sensitive species. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityViaOralRouteSystemicEffects.EndpointConclusion

	chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. The organ in which adverse effects were observed should be specified here. If		

	adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Repeated dose toxicity: inhalation - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)"	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationSystemicEffects.EndpointConclusion

	should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is		

	associated with the dose descriptor.		
Repeated dose toxicity: inhalation - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level).	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityInhalationLocalEffects.EndpointConclusion

	The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Repeated dose toxicity: dermal - systemic effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects

Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalSystemicEffects.EndpointConclusion

	day, µg/ kg per day or mg/ kg per day. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Repeated dose toxicity: dermal - local effects		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected:	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords

	quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.		
Results		Read-only	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.LinkToRelevantStudyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (90-day study), "No study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg per day, µg/ kg per day or	Header 3	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.RepeatedDoseToxicityDermalLocalEffects.EndpointConclusion

	mg/ kg per day. Study duration: The duration of the selected robust study summary. Species: The species reported in the selected robust study summary should be chosen here. The system in which adverse effects were observed should be specified here. If adverse effects were observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework
	A discussion about the mode of action and the relevance of the data for human health should be provided here.	Rich text area	ENDPOINT_SUMMARY.RepeatedDoseToxicity.KeyValueForChemicalSafetyAssessment.ModeOfActionAnalysisHumanRelevanceFramework.ModeOfActionAnalysis
Additional	Discussion(Header 1) –	Header 1	ENDPOINT_SUMMARY.R

information	common block Provide information on short-term toxicity studies in other species that the most sensitive species (described under study name / type, see above). Please provide: -Target organ/toxicity -Relevant dose descriptor (e.g. NOAEL)		epeatedDoseToxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.RepeatedDoseToxicity.JustificationForClassificationOrNonClassification.Remarks

5.3.1 Repeated dose toxicity: oral– Endpoint study record

Purpose:
Provide data related to the short-term oral toxicity of the active substance to rodents (90-day), usually the rat, a different rodent species shall be justified, and non rodents (90-day toxicity study in dogs), shall always be reported.
Where available, 28-day studies shall be reported.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: 90 d OECD 408 OECD 409 Method B.26 Sub-chronic oral toxicity test. Method B.27 Sub-chronic oral toxicity test.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods

	28 d OECD 407 Method B.7 Repeated dose (28 d).		
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on	For robust study summaries or as requested by the regulatory programme, include a short description on	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxic

analytical verification of doses or concentrations	the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.		ityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DosesConcentrations

			.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations
Observations and	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate	Text templ	ENDPOINT_STUDY_RECORD.RepeatedDoseToxic

examinations performed and frequency	the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	ate	ityOral.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.SacrificeAndPathology
Optional endpoint(s)	Describe any other optional endpoint(s).	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.OptionalEndpointS
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results		Head	ENDPOINT_STUDY_REC

and discussion		er 1	ORD.RepeatedDoseToxicityOral.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOral.ApplicantSummaryAndConclusion

5.3.2 Repeated dose toxicity: inhalation– Endpoint study record

Purpose:
For volatile active substances (vapour pressure $>10^{-2}$ Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.8 repeated dose (28 days) Method B.29 sub-chronic inhalation toxicity study 90-d OECD 413 (90 d) OECD 412 (28 d).	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure
Route of administration	Specify the route of administration by indicating in what physical form the test material was administered.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure	Indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposure

Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on inhalation exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnInhalationExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual concentration was acceptable. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration	Indicate total duration of exposure in days, weeks or	Multi-	ENDPOINT_STUDY_REC

of treatment / exposure	months, e.g. '104 weeks', '90 days' or '28 days'.	line text	ORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '6 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, e.g. mg/L air (nominal), mg/L air (analytical), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationE

		with remarks	xposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.SacrificeAndPathology

	the respective regulatory programme.		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.TargetSystemOrganToxicity

Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityInhalation.ApplicantSummaryAndConclusion

5.3.3 Repeated dose toxicity: dermal– Endpoint study record

Purpose:
For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal - v.7.5 (Final) [September 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 411 (90 d) OECD 410 (28 d) Method B.9 Repeated dose (28 days) Method B.28 Sub-chronic dermal toxicity test: 90-day. Limit test: Indicate if the experiment was a limit test.	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure
Type of coverage	Select type of coverage used. For robust study summaries or as requested by the regulatory programme, specify the area of application in field 'Details on dermal exposure'.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.TypeOfCoverage
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMe

	the respective regulatory programme.		thods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit meas	ENDPOINT_STUDY_RECORD.RepeatedDoseToxici

		ure with Open List (Decimal)	tyDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinat		Head	ENDPOINT_STUDY_REC

ions		er 2	ORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results		Head	ENDPOINT_STUDY_REC

and discussion		er 1	ORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block Body weight and weight changes: The effects should be also considered in relation to organ weights.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Record the available effect levels for NO(A)EL(s), LO(A)EL(s) and other relevant dose descriptors. Copy this block of fields for entering different effect levels, based on different endpoints and/or separated for each sex. Dose descriptor: Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.EffectLevels.Efflevel.RemarksOnResults
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block Dose response relationship: Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

incl. tables			
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityDermal.ApplicantSummaryAndConclusion

5.3.4 Repeated dose toxicity: other routes– Endpoint study record

Purpose:
For human risk assessment additional dermal studies shall be considered on a case by case basis, unless the active substance is a severe irritant.
For volatile active substances (vapour pressure >10–2 Pascal) expert judgement (for example based on route-specific kinetic data) shall be required to decide whether the short term studies have to be performed by inhalation exposure.

ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure

Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate total duration of exposure in days, weeks or months, e.g. '104 weeks' or '90 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., '8 hours/day, 7 days/week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration	Multi-	ENDPOINT_STUDY_REC

	values.	line text	ORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to test group if different number of animals per group, e.g. '10 in each test group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

	If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof.	Text template	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Dose descriptor: Select the relevant dose descriptor,	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxici

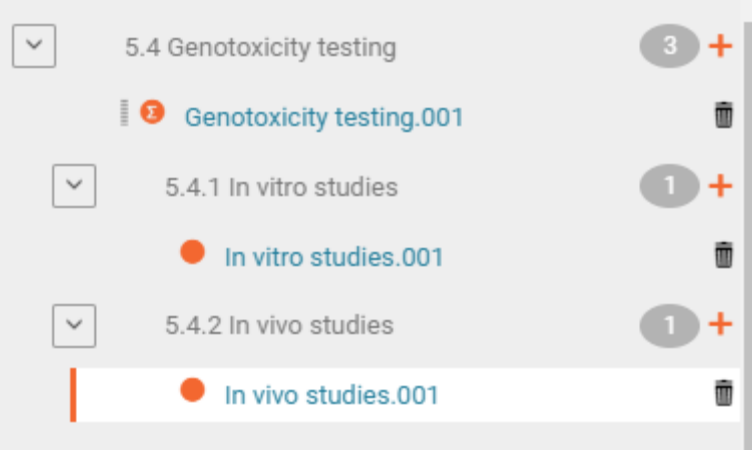
	i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		tyOther.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.Organ

Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.TargetSystemOrganToxicity.TargetSystemOrganToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.RepeatedDoseToxicityOther.ApplicantSummaryAndConclusion

5.4 Genotoxicity testing

The following documents are located under section 5.4 'Genotoxicity testing'

- 5.4 Genotoxicity testing– Endpoint Summary
  - 5.4.1 In vitro studies – Endpoint study record
  - 5.4.2 In vivo studies – Endpoint study record



5.4 Genotoxicity testing – Endpoint Summary

Purpose:
State the available in vitro and in vivo studies and the results, as well the overall genotoxic potential.
State the photomutagenicity potential, if required.
In the case of metabolites, where available information on genotoxicity can come from additional sources such as QSAR and read-across there is the need to summarize and integrate all available evidence for genotoxicity in a summary table. For that purpose a template has been created. See IUCLID templates for PPP Risk Assessment - Template 5.3 - Template Summary table integrating experimental evidence on genotoxicity for metabolites. [http://doi.org/10.5281/zenodo.4557333]
The document should contain the information needed to be reported according to the list of end points for genotoxicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

ENDPOINT_SUMMARY.GeneticToxicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Description of key information: Provide a brief description of the genotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.GeneticToxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment
Genetic toxicity in vitro		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro
Link to relevant study records	For relevant study record – common block The following factors, among others, should	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInV

	be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.		itro.LinkToRelevantStudyRecords
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (positive)" should be chosen if the outcome of the study was positive. "No adverse effect observed (negative)" should be chosen if the outcome of the study was negative. If "No study available" is chosen, a justification needs to be provided.	Closed list	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVitro.EndpointConclusion.EndpointConclusion
Genetic toxicity in vivo		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo
Description of key information	Report Information to support the genetic toxicity in vivo.	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study	Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.LinkToRelevantStudyRecords

	summary is selected: quality of the study (e.g. Klimisch score), duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant.		
Endpoint conclusion		Header 3	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion
Endpoint conclusion	"Adverse effect observed (positive)" should be chosen if the outcome of the study was positive. "No adverse effect observed (negative)" should be chosen if the outcome of the study was negative. If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for genetic toxicity in vivo, "No study available (further information necessary)" should be chosen.	Closed list	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.GeneticToxicityInVivo.EndpointConclusion.EndpointConclusion
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be	Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework.MoAHumanRelevanceFramework

	easily uploaded in this textarea where relevant		
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: - In vitro studies (state the available in vitro studies and the results), - In vivo studies (state the available in vivo studies and the results) Provide an statement on the photomutagenicity potential: e.g. -Not required -Unlikely to be photomutagenic Attached background material: Provide the original version of any document that contains confidential material. For metabolites, please attach the summary table integrating available evidence for genotoxicity on metabolites. See "IUCLID templates for PPP Risk Assessment - Template 5.3 - Template summary table integrating experimental evidence on genotoxicity for metabolites". [http://doi.org/10.5281/zenodo.4557353]	Header 1	ENDPOINT_SUMMARY.GeneticToxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.GeneticToxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling	Rich text area	ENDPOINT_SUMMARY.GeneticToxicity.JustificationForClassificationOrNonClassification.Remarks

	or not fulfilling the classification criteria should be presented.		

5.4.1 In vitro studies – Endpoint study record

Purpose:
The following in vitro mutagenicity tests shall be performed: bacterial assay for gene mutation, combined test for structural and numerical chromosome aberrations in mammalian cells and test for gene mutation in mammalian cells. However, if gene mutation and clastogenicity/aneuploidy are detected in a battery of tests consisting of Ames and in vitro micronucleus (IVM), no further in vitro testing needs to be conducted. If there are indications of micronucleus formation in an in vitro micronucleus assay further testing with appropriate staining procedures shall be conducted to clarify if there is an aneugenic or clastogenic response. Further investigation of the aneugenic response may be considered to determine whether there is sufficient evidence for a threshold mechanism and threshold concentration for the aneugenic response (particularly for non-disjunction). Active substances which display highly bacteriostatic properties as demonstrated in a range finding test shall be tested in two different in vitro mammalian cell tests for gene mutation. Non performance of the Ames test shall be justified. For active substances bearing structural alerts that have given negative results in the standard test battery, additional testing may be required if the standard tests have not been optimised for these alerts. The choice of additional study or study plan modifications depends on the chemical nature, the known reactivity and the metabolism data on the structurally alerting active substance.

ENDPOINT_STUDY_RECORD.GeneticToxicityVitro			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.13/14 Mutagenicity - reverse mutation test using bacteria Method B.10 Mutagenicity - In vitro mammalian chromosome aberration test Method B.17 – Mutagenicity – In vitro mammalian cell gene mutation test OECD 471 OECD 473 OECD 476 OECD 487	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.TypeOfAssay
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMe

			thods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method
Target gene	Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TargetGene
Species / strain	Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain
Species / strain / cell type	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.SpeciesStrain
Details on mammalian cell type (if applicable)	For robust study summaries, describe relevant details on cell cultures if applicable. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.DetailsOnMammalianCellLinesIfApplicable
Additional strain / cell type characteristics	For robust study summaries, indicate additional strain characteristics (e.g. 'DNA-Polymerase-A-deficient') only if necessary to characterise the test system. Otherwise, leave this subfield empty.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.SpeciesStrain.AdditionalStrainCharacteristics
Species / strain			
Cytokinesis block (if used)	If a cytokinesis blocking substance (e.g. cytoB) was used, indicate its identity and its concentration and duration of cell exposure.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.CytokinesisBlockIfUsed
Metabolic activation	Indicate whether metabolic activation was applied or not. Select 'not applicable' for mammalian cell lines when no exogenous metabolic system is required.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivation
Metabolic activation system	For robust study summaries, specify metabolic activation system, if any. Indicate the type and composition of and acceptability criteria for the metabolic activation system used. Alternatively or in addition refer to appropriate table(s), which can be uploaded in the rich text field "Any other information on materials and methods incl. tables". Use predefined table or adapt table(s) from study report.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.MetabolicActivationSystem

	Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Test concentrations with justification for top dose	Indicate the test concentrations without and with metabolic activation, and for the different treatment harvest schedules. For robust study summaries or as requested by the regulatory programme, include a justification for the maximum dose level used, for instance if maximum recommended concentration for the test, limited by solubility (in solvent and/or culture medium, and presence of precipitates) or cytotoxicity indicating the parameter measured and the targeted level of cytotoxicity, and a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.TestConcentrationsWithJustificationForTopDose
Vehicle / solvent	Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation. Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle. Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Vehicle
Controls	Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as necessary, particularly if controls or different substances were used for tests with and without metabolic activation or cytokinesis block. If necessary, indicate so in the supplementary remarks field or in subfield 'Remarks'.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls
Untreated negative controls	Indicate whether untreated negative controls (i.e. consisting of culture medium without solvent / vehicle or test substance, and otherwise treated in the same way as the treatment groups) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used . Any explanations can be given in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.NegativeControls
Negative solvent / vehicle controls	Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.SolventControls

	concentration (and/or volume) of vehicle added.		
True negative controls	Indicate whether true negative control(s) (i.e. substances with known lack of genotoxicity) was/were tested and specify the substance(s) and concentration (and/or volume) in the supplementary remarks field.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.TrueNegativeControls
Positive controls	Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field "Positive control substance".	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControls
Positive control substance	If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. If different substances were used for tests with and without metabolic activation or for different tester strains or for the different treatment harvest schedules, include a remark in subfield 'Remarks'. If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification. Final concentration, conditions and durations of treatment and recovery periods. Note that the list of substances provided is not exhaustive.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.PositiveControlSubstance
Remarks	Enter any remarks related to the recorded controls as appropriate.	Text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Controls.Remarks
Controls			
Details on test system and experimental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.DetailsOnTestSystemAndConditions
Rationale for test conditions	Provide the rationale for selection of concentrations and number of cultures, including cytotoxicity data and solubility limitations, if available.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.RationaleForTestConditions
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.Method.Statistics

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion
Test results	Include the main test results in this block of fields for each tester strain and metabolic activation system used. Multiply this block of fields as often as required. (Note: If only one strain was tested, subfield 'Species/strain' may be left empty.) In case of a robust study summary or as requested by the regulatory programme, also provide the relevant raw data including statistical analysis and p-values if any, in field 'Additional information on results' and/or refer to detailed tables on the genotoxicity and cytotoxicity results, which can be uploaded in the rich text field 'Any other information on results incl. tables'. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). For instance, results for each strain ± metabolic activation (e.g. S9 mix) in an Ames test should be tabulated.		ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.KeyResult
Species / strain	Indicate the species/strain or cell type tested. Multiply this block of fields for each tester strain.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Organism
Metabolic activation	Indicate whether metabolic activation was applied or not.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.MetActIndicator
Genotoxicity	Indicate result of the test conducted with the tester strain(s), or cell types and the metabolic activation system specified. If positive or equivocal, include concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Genotoxicity

Cytotoxicity / choice of top concentrations	Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the supplementary remarks field and provide details on the cytotoxicity measurement. Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '… see Table 1'). Note: Specific tables may be required.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.Cytotoxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. vehicle without test substance,) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.VehContrValid
Untreated negative controls validity	Indicate whether test with untreated controls, if applicable (i.e. no vehicle and no test substance) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.NegContrValid
True negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.TrueNegativeControlsValidity
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.TestRs.PosContrValid
Test results			
Additional information on results	Enter any additional information that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.ResultsDetails
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.RemarksOnResults
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was	Rich text area	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ResultsAndDiscussion.AnyOtherInfor

	converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.		mationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVitro.ApplicantSummaryAndConclusion

5.4.2 In vivo studies – Endpoint study record

Purpose:
If all the results of the in vitro studies are negative, at least one in vivo study shall be done with demonstration of exposure to the test tissue (such as cell toxicity or toxicokinetic data), unless valid in vivo micronucleus data are generated within a repeat dose study and the in vivo micronucleus test is the appropriate test to be conducted to address this information requirement.

ENDPOINT_STUDY_RECORD.GeneticToxicityVivo			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: Method B.12 - Mutagenicity - In vivo mammalian erythrocyte micronucleus test Method B.11 - Mutagenicity – In vivo mammalian bone-marrow chromosome aberration test OECD 474 OECD 475 OECD 486 OECD 488 Method B.39 Unscheduled DNA synthesis (UDS) - Test with mammalian liver cells in vivo In vivo Comet assay.	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods
Type of assay	As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Studytype

Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Indicate whether vehicle(s)/solvent(s) was/were used and specify the substance(s) or state 'none' if no vehicle/solvent was used or 'no data' if not available from the study report or publication. Provide a justification for the choice of solvent/vehicle. Provide further details as appropriate. Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week').	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PostExp

			osurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level or for the pilot, range-finding and main study. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.ControlGroup
Positive control(s)	Indicate what substance(s) was/were used as positive control(s) or state 'none' if no positive controls were used or 'no data' if not available from the study report or publication. If other than the reference substance(s) specified in the test guidelines was/were used include a brief justification. Also provide information on the route of administration and doses either under separate headings or in parentheses after the control substance(s) specified.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AdministrationExposure.PositiveControls

	Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive.		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations
Tissues and cell types examined	Indicate tissues and cell types examined including the number of cells analysed per animal. Also note if examinations were not performed with tissues or cells from all animals studied. For robust study summaries or as requested by the regulatory programme, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.TissuesAndCellTypesExamined
Details of tissue and slide preparation	Indicate any relevant details to characterise the test system and test protocol used. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.DetailsOfTissueAndSlidePreparation
Evaluation criteria	Describe the evaluation criteria used in the study to judge if a substance is positive.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.EvaluationCriteria
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion
Test results	Include the main test results in this block of fields. Multiply this block of fields as often as required, e.g. for recording different results for both sexes used. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the genotoxicity and toxicity results in the rich text field 'Any		ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs

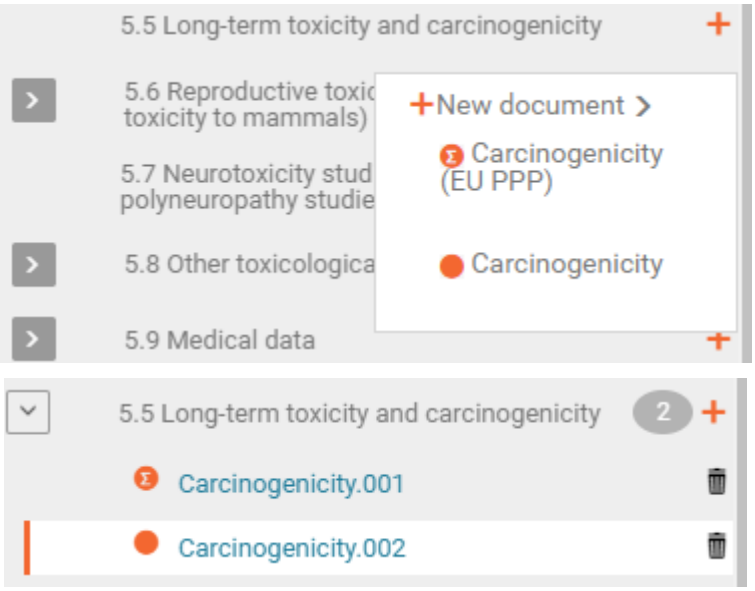
	other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.		
Key result	This read-only field displays the key results flagged in the corresponding results table(s), if any.	Check box	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.KeyResult
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Sex
Genotoxicity	Indicate if there was evidence of genotoxicity. If result is considered positive or ambiguous, include dose(s) in the supplementary remarks field or representative table, e.g. predefined table or an excerpt from the study report.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Genotoxicity
Toxicity	Indicate whether signs of toxicity were observed or not. If yes, briefly describe the in life animal observations and the effects by dose in the supplementary remarks field (e.g. 'significantly decreased body weight gain in the high dose group). If necessary include further details in field 'Additional information on results'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.Toxicity
Vehicle controls validity	Indicate whether test with vehicle control(s) (i.e. without test substance, with/without solvent) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.VehContrValid
Negative controls validity	Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.NegContrValid
Positive controls validity	Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid.	Open list with remarks	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.PosContrValid
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.TestRs.RemarksOnResults
Test results			
Additional informati	Briefly describe the results of results of range-finding study if any. For the definitive study, provide further details on results. Use freetext template and delete/add elements as	Text template	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndD

on on results	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table and refer to respective table no. (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). Note: Depending on the regulatory programme some form of a table may be mandatory.		iscussion.ResultsDetails
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.GeneticToxicityVivo.ApplicantSummaryAndConclusion

5.5 Long-term toxicity and carcinogenicity

The following documents are located under section 5.5 'Long-term toxicity and carcinogenicity'

- Carcinogenicity (EU PPP) – Endpoint summary
- Carcinogenicity – Endpoint study record



5.5 Carcinogenicity (EU PPP) – Endpoint Summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details for both rat and mice species:
- Long-term effects (target organ/critical effect)
- Relevant reference points (e.g. NOAELs) for long-term toxicity.
- Carcinogenicity (target organ, tumour type)
- Relevant reference points (e.g. NOAELs) for carcinogenicity

The document should contain the information needed to be reported according to the list of end points for long-term toxicity and carcinogenicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of	Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.AdministrativeDataSummary

	carcinogenicity studies and effects.		
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment
Long-term toxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral
Link to relevant study records		Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral.RelevantRecords
Study name / type	The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4	Endpoint reference list	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral.RelevantRecords.StudyNameType
Endpoint conclusion	Endpoint conclusion (Species version) – common block Multiple species can be reported, e.g.: two species, rat and mouse should be reported for pesticides. Endpoint conclusion: "Adverse effect observed" should be chosen if adverse		ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.LongTermToxOral.RelevantRecords.EndpointConclusion

	effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for repeated dose toxicity (e.g. 2-year study), "no study available (further information necessary)" should be chosen. Dose descriptor: The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. If the dose descriptor is expressed in ppm, it should first be converted to ng/kg, µg/ kg or mg/ kg. Study duration: Choose the duration of the selected robust study summary: i.e. chronic. Experimental exposure time per week (hours/week): In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and		

	the days per week the animals were exposed. Species: The species reported in the selected robust study summary should be chosen here. System: The systems in which adverse effects were observed should be specified here. Organ: The organ in which adverse effects were observed should be specified here. If adverse effects were observed in several organs, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor.		
Endpoint conclusion			
Carcinogenicity: via oral route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Multiple species can be reported, e.g.: two species, rat and mouse should be reported for		ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaOralRoute.LinkToRelevantStudyRecords.EndpointConclusion

	pesticides. Endpoint conclusion: "Adverse effect observed" should be chosen if the substance was found to be carcinogenic. "No adverse effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity "No study available (further information necessary)" should be chosen. Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects. Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies. Species: The species reported in the selected robust study summary should be chosen here. System: The systems in which cancer was observed should be specified here. Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several		

	organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.		
Endpoint conclusion			
Carcinogenicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute
Link to relevant study records	For relevant study record – common block The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score, duration of the study, whether or not the study is GLP.	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if the substance was found to be carcinogenic. "No adverse effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity "No study available (further information necessary)" should be chosen Dose descriptor: The	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaInhalationRoute.EndpointConclusion

	selection of the dose descriptor should only refer to carcinogenic effects. Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies. Species: The species reported in the selected robust study summary should be chosen here System: The system in which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor. Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor.		
Carcinogenicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSaf

			etyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block Endpoint conclusion: "Adverse effect observed" should be chosen if the substance was found to be carcinogenic. "No adverse effect observed" should be chosen if the substance was not found to be carcinogenic in the available study(ies). If "No study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for carcinogenicity "No study available (further information necessary)" should be chosen. Dose descriptor: The selection of the dose descriptor should only refer to carcinogenic effects. Study duration: Choose the duration of the selected robust study summary. Most of the in vivo carcinogenicity studies are chronic studies. Species: The species reported in the selected robust study summary should be chosen here. System: The system in	Header 3	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.CarcinogenicityViaDermalRoute.EndpointConclusion

	which cancer was observed should be specified here. If cancer was observed in several systems, the target system in which the adverse effects gives rise to highest concern should be selected, i.e. the system that is associated with the dose descriptor Organ: The organ in which cancer was observed should be specified here. If cancer was observed in several organs, the target organ in which the adverse effects gives rise to highest concern should be selected, i.e. the organ that is associated with the dose descriptor		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this textarea where relevant	Rich text area	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAHumanRelevanceFramework.MoAHumanRelevanceFramework
Additional information	Discussion(Header 1) – common block Provide additional informatoion related to the endpoint, for example: -Further description of the critical effects/target organ for long-term	Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.Discussion

	toxicity, such as direction of the critical effect: e.g. increased liver weight in rats. -Further description of the critical effects/target organ for carcinogenicity, such as tumour type: e.g. adenocarcinoma in rats		
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Carcinogenicity_EU_PPP.JustificationForClassificationOrNonClassification.JustifClassifCarc

5.5 Carcinogenicity – Endpoint Study record

Purpose:
The results of the long-term studies conducted and reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the identification of effects, following repeated exposure to the active substance, and in particular shall be sufficient to:
- identify adverse effects resulting from long-term exposure to the active substance,
- identify target organs, where relevant,
- establish the dose-response relationship,
- establish the reference point (e.g. NOAELs) and, if necessary, other appropriate reference points.

Correspondingly, the results of the carcinogenicity studies taken together with other relevant data and information on the active substance, shall be sufficient to permit the evaluation of hazards for humans, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify carcinogenic effects resulting from long-term exposure to the active substance; 3.4.2013 Official Journal of the European Union L 93/27 EN (b) to establish the species, sex, and organ specificity of tumours induced; (c) to establish the dose-response relationship; (d) where possible, to identify the maximum dose eliciting no carcinogenic effect; (e) where possible, to determine the mode of action and human relevance of any identified carcinogenic response.

ENDPOINT_STUDY_RECORD.Carcinogenicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.DataSource

Materials and methods	Material and methods – common block Applicable test guideline: - Method B.32 Carcinogenicity test (Annex to Regulation (EC) No 440/2008). - Method B.33 Combined chronic toxicity/carcinogenicity test (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 451: Carcinogenicity Studies. OECD Test Guideline 453: Combined Chronic Toxicity/Carcinogenicity Studies. - other	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other.	Open list	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation

Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.Remarks
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable.	Text area	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of	Indicate duration in days, weeks or months, e.g. '104 weeks' or '18 months'.	Multi-line	ENDPOINT_STUDY_RECORD.Carcinogenicity.

treatment / exposure		text	MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control	Indicate whether and what type of concurrent control	Multi	ENDPOINT_STUDY_RE

animals	groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	select open list with remarks	CORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including toxicokinetic data if available, a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all.	Text templ	ENDPOINT_STUDY_RECORD.Carcinogenicity.

pathology	Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	ate	MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.ResultsOfExaminations
Relevance of carcinogenic effects / potential	Discuss carcinogenic effects / potential, i.e. state if there was (not) a treatment related increase in tumour incidence as compared to controls and specify tumour type if applicable. Indicate if dosing was not considered adequate. Discuss weight of evidence with respect to relevance of tumours observed for human health. This should be in line with information entered under 'Target system / organ toxicity'. Discuss conclusions given in supporting documentation.	Text area	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.ResultsOfExaminations.RelevanceOfCarcinogenicEffectsPotential
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.EffectLevels

	related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Carcinogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Carcinogenicity.ApplicantSummaryAndConclusion

5.6 Reproductive toxicity (includes reproduction toxicity to mammals

The following documents are located under section 5.6 'Reproductive toxicity (includes reproduction toxicity to mammals'

- 5.6 Toxicity to reproduction (EU PPP) – Endpoint Summary
- 5.6. Toxicity to reproduction -– Endpoint study record
  - 5.6.1 Generational studies (includes reproduction toxicity to mammals) – Endpoint study record
  - 5.6.2 Developmental toxicity studies (includes reproduction toxicity to mammals) – Endpoint study records

Reproductive toxicity (includes reproduction toxicity to mammals) – Endpoint summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details:
Reproduction toxicity
- Reproduction target / critical effect for parental, reproductive and offspring
- Relevant parental reference point (e.g. NOAELs).
- Relevant reproductive reference point (e.g. NOAELs).
- Relevant offspring reference point (e.g. NOAELs).

Developmental toxicity (rats and rabbits)
- Developmental target / critical effect
- Relevant maternal reference point (e.g. NOAELs).
- Relevant developmental reference point (e.g. NOAELs).

The document should contain the information needed to be reported according to the list of end points for reproductive toxicity (SANCO/12592/2012-rev. 2, 22 March 2019).
Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP - v1.0 (Final)			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of reproductive toxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment
Toxic effect type	In this field, you should select whether there is a relationship between the exposure concentration and the magnitude of the toxic effect, i.e. dose-dependent, or whether the toxic effect is driven but not modulated by the exposure concentration, i.e. concentration-driven.	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicEffectType
Effects on reproductive toxicity / fertility		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.LinkToRelevantStudyRecords
Effect on fertility-reproductive toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.EndpointConclusion

	reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on "reproductive toxicity". The study duration of the selected robust study summary should be amongst: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443)". Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides). Experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed. The species should be reported in the relative		

	field.		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.BasisForEffectLevel
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.RemarksOnResult
Species	The species reported in the selected robust study summary should be chosen here.	Open list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaOralRoute.Species
Effect on fertility-parental toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute
Endpoint conclusion	Endpoint conclusion (Species version) –	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_E

	common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The dose descriptor should only refer for the specific effect on "parental toxicity". The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies or as "multigeneration" studies (e.g. for pesticides). Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides). The experimental exposure conditions should be reported in hours per week. This		U_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.EndpointConclusion

	can be done considering the hours per day and the days per week the animals were exposed. The species should be reported in the relative field, usually the rat.		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.BasisForEffectLevel
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnParentalToxViaOralRoute.RemarksOnResult
Effect on fertility-offspring toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute
Endpoint conclusion	Endpoint conclusion (Species version) –	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_E

	common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on "offspring toxicity". The duration of the selected robust study summary. Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies or as "multigeneration" studies (e.g. for pesticides). Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies or as "developmental" studies (e.g. for pesticides). The experimental exposure conditions should be added in hours per week. This		U_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.EndpointConclusion

	can be done considering the hours per day and the days per week the animals were exposed The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.BasisForEffectLevel
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityOffspringToxOralRoute.RemarksOnResult
Effect on fertility: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute

Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information. The duration of the selected robust study summary. Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies.	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaInhalationRoute.EndpointConclusion

	The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed The species reported in the selected robust study summary should be chosen in the relative field, usually the rat.		
Effect on fertility: via dermal route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaDermalRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.EffectOnFertilityViaDermalRoute.EndpointConclusion

	reported in the section "Description of key information". The duration of the selected robust study summary, should be: Two-generation studies (OECD 416) and extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies. The experimental exposure conditions should be added in hours per week. This can be done considering the hours per day and the days per week the animals were exposed The species reported in the selected robust study summary should be chosen in the relative field.		
Additional information		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation
	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnFertility.AdditionalInformation.AdditionalInfo

	study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.		
Effects on developmental toxicity		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity
Description of key information	Report Information to support the developmental toxicity.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.LinkToRelevantStudyRecords
Effect on developmental toxicity: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute

Developmental toxicity	According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The two species should be reported.		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse developmental effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse developmental effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for developmental toxicity, "no study available (further information necessary)" should be chosen. The selection of the dose descriptor should only refer for specific effect on maternal toxicity. The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.EndpointConclusion

	as "subacute" studies The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.BasisForEffectLevel
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaOralRoute.DevTox.RemarksOnResult
Developmental			

toxicity			
Effect on developmental toxicity - maternal: via oral route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal
Maternal toxicity	According to EU data requirements on pesticides at least two developmental toxicity studies should be available, one in rat and one in rabbits. The two species should be reported.		ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse developmental effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse developmental effects were observed at or below the limit dose level. If "no study available" is chosen, a justification needs to be provided. If the dossier contains a testing proposal for developmental toxicity, "no study available (further information necessary)" should be chosen. The selection of the dose descriptor should only refer for the	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.EndpointConclusion

	specific effect on developmental toxicity. The duration of the selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies. The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.		
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.BasisForEffectLevel
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and	Open list with remarks (2000)	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxViaOralRouteMaternal.MaternalToxicity.RemarksOnResult

	entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'.		
Maternal toxicity			
Effect on developmental toxicity: via inhalation route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information". The duration of the	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaInhalationRoute.EndpointConclusion

	selected robust study summary should be: Pre-natal developmental toxicity studies(OECD 414) is to be reported as "subacute" studies. The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed. The species reported in the selected robust study summary should be chosen in the relative field i.e. rat or rabbits.		
Effect on developmental toxicity: via dermal route		Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse reproductive effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse reproductive effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The selection of the dose descriptor should	Closed list	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.EffectOnDevelopmentalToxicityViaDermalRoute.EndpointConclusion

	only refer for the specific effect on reproduction. Other effects (e.g. maternal toxicity) and dose descriptors should be reported in the section "Description of key information". The duration of the selected robust study summary should be: Two-generation studies (OECD 416) or extended one-generation studies (OECD 443) are to be reported as "subchronic" studies. Pre-natal developmental toxicity studies (OECD 414) and screening studies for reproductive toxicity (OECD 421/422) are to be reported as "subacute" studies. The experimental exposure conditions should be reported in hours per week. This can be done considering the hours per day and the days per week the animals were exposed. The species reported in the selected robust study summary should be chosen in the relative field.		
Additional information	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.AdditionalInformation

	choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.		
	Provide any additional information related to the endpoint.	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.EffectsOnDevelopmentalToxicity.AdditionalInformation.AdditionalInfo
Toxicity to reproduction: other studies		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies
Description of key information	Report Information to support the toxicity on reproduction.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.DescriptionOfKeyInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.DescriptionOfKeyInformation.KeyInfo
Link to relevant study records	For relevant study record – common block If other studies relevant to toxicity to reproduction are available should be reported here. The specifics should be	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.LinkToRelevantStudyRecords

	reported in the section "Description of key information".		
Additional information	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.	Header 3	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.AdditionalInformation
		Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.ToxicityToReproductionOtherStudies.AdditionalInformation.AdditionalInfo
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/w	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework.MoAAnalysisHumanRelevanceFr

	eb/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this text area where relevant		amework
Additional information	Discussion(Header 1) – common block If available, for other routes than oral provide additional information related to the endpoint, for example: Reproduction target / critical effect, Relevant parental reference point (e.g. NOAELs), Relevant reproductive reference point (e.g. NOAELs), Relevant offspring reference point (e.g. NOAELs), If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.ToxicityToReproduction_EU_PPP.JustificationForClassificationOrNonClassification.JustificationForClassificationOrNonClassification

Reproductive toxicity – Endpoint study record

Purpose:
Possible effects on reproductive physiology and the development of progeny shall be investigated and reported concerning the following aspects:

- Impairment of male and female reproductive functions or capacity, for example from effects on oestrus cycle, sexual behaviour, any aspect of spermatogenesis or oogenesis, or hormonal activity or physiological response which would interfere with the capacity to fertilise, fertilisation itself or development of the fertilised ovum up to and including implantation.
- Harmful effects on the progeny, for example any effect interfering with normal development, both before and after birth. This includes morphological malformations such as anogenital distance, nipple retention, and functional disturbances (such as reproductive and neurological effects).

Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using this endpoint study record.

ENDPOINT_STUDY_RECORD.ToxicityReproduction			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g: Reproductive toxicity (one-/two generation studies): - Method B.35 Two-generation reproduction toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 416: Two-Generation Reproduction Toxicity. - OECD Test Guideline 443: Extended One-generation Reproduction Toxicity. - pre-natal developmental toxicity studies - Method B.31	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods

	Prenatal developmental toxicity study (Annex to Regulation (EC) No 440/2008). - OECD Test Guideline 414: Prenatal developmental toxicity study. - OECD Test Guideline 426: Developmental neurotoxicity study.		
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.LimitTest
Justification for study design	A justification of the study design should be provided if the relevant test guideline used allows some flexibility, particularly regarding - the selection of doses, - length of pre-mating exposure period, producing an F2 generation, - termination day for F2 generation, - including additional cohorts to assess developmental neurotoxicity and/or developmental immunotoxicity.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.JustificationForStudyDesign
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other'	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods

	and specify.		.AdministrationExposure .RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Mass median aerodynamic diameter (MMAD)	Specify the particle size distribution in terms of mass median aerodynamic diameter (MMAD). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Vehicle	Select the vehicle used. If not available from picklist, select 'other'. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.Vehicle

Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Details on mating procedure	Briefly describe the mating procedure. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnMatingProcedure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration of treatment or exposure (with unit) for each reproductive phase and generation,	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentEx

	e.g. (P) Males: [...] days/weeks before mating. (P) Females: [...] days/weeks before mating, [...] days/weeks during mating, [...] days/weeks during resulting pregnancies, [...] days/weeks through weaning of their F1 offspring. (F1) Males: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation. (F1) Females: [...] days/weeks at weaning, during growth into adulthood, mating and production of an F2 generation, until weaning of the F2 generation.		posure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations

	Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Indicate number of animals used per dose group, e.g. [#] (P) males caged with [#] (P) females; [#] (F1) males, [#] (F1) females. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproducti

	including a brief description on dose selection and animal assignment rationale if appropriate. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		on.MaterialsAndMethods .AdministrationExposure .DetailsOnStudyDesign
Positive control	Indicate if a positive control was used and if necessary indicate purity, Lot/batch No.	Multi-line text	ENDPOINT_STUDY_REC ORD.ToxicityReproducti on.MaterialsAndMethods .AdministrationExposure .PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_REC ORD.ToxicityReproducti on.MaterialsAndMethods .Examinations
Parental animals: Observations and examinations	Indicate which clinical examinations were performed in the parental animals and the time schedule for those examinations. State if any examination was not performed and with what parental generation as applicable. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate tables(s) if available and	Text template	ENDPOINT_STUDY_REC ORD.ToxicityReproducti on.MaterialsAndMethods .Examinations.ParentalA nimalsObservationsAndE xaminations

	tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If the study is a combined repeated dose toxicity / reproduction toxicity study or includes a developmental neurotoxicity part, include a note in the block 'Cross-reference' and describe these study parts separately in the respective data point entry form(s), i.e. 'Repeated dose toxicity (route x)' or 'Neurotoxicity'. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Oestrous cyclicity (parental animals)	Indicate whether and how [e.g., vaginal smear] and for how long [x cycles or x weeks] the oestrous cyclicity was determined. Indicate whether a screening for normal cycles (in a pre-treatment period) has been performed.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.EstrousCyclicityParentalAnimals
Sperm parameters (parental animals)	Indicate which sperm parameters were examined. State if any examination was not performed and with what parental generation as applicable. Also indicate	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.SpermParametersParentalAnimals

	the dose groups that were examined if not all.		
Litter observations	Indicate which litter observations were made. State if any examination was not performed and with what generation as applicable. Also indicate the dose groups that were examined if not all. In parentheses, include the time of observation (lactation day), e.g. (Day 0). As an alternative option, include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.LitterObservations
Postmortem examinations (parental animals)	Indicate when the surviving parental males/females were sacrificed and the postmortem examinations performed. Use freetext template and delete/add elements as appropriate. As an alternative option,	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsParentalAnimals

	include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Postmortem examinations (offspring)	Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined if not all. Use freetext template and delete/add elements as appropriate. As an alternative option or in addition, include a table and refer to respective table no. (use predefined or other appropriate table(s) if any and tailor it/them to your needs). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.PostmortemExaminationsOffspring
Statistics	List parameters that were analysed by which test methods. Indicate whether these are appropriate. Statistical analysis of e.g. anogenital distance (AGD) and nipple	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.Statistics

	retention should be based on individual pup data, taking litter effects into account. Where appropriate, the litter is the unit of analysis. Statistical analysis of pup body weight should be based on individual pup data, taking litter size into account. Due to the limited dimensions of some study (e.g. screening tests), statistical analyses in the form of tests for "significance" may be of limited value for many endpoints, especially reproductive endpoints. In these cases, some of the most widely used methods, especially parametric tests for measures of central tendency, are inappropriate. If statistical analyses are used then the method chosen should be appropriate for the distribution of the variable examined and be selected prior to the start of the study. Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.		
Reproductive indices	Describe which reproductive indices were calculated from breeding and parturition records of animals in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.ReproductiveIndices

Offspring viability indices	Describe which viability indices were calculated from lactation records of litters in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.Examinations.OffspringViabilityIndices
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion
Results: P0 (first parental generation)		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration
General toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinSigns

	incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservDermalIrritationIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s)	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy

	(predefined table) may be mandatory.		
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. The effects should be also considered in relation to organ weight.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservBodyweight

	toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservFoodConsum
Food efficiency	Indicate whether any	Closed list	ENDPOINT_STUDY_REC

	effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservFoodEfficiency
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionI

	related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		ncidenceAndSeverityObservWaterConsum
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservOphthalm

	information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHaematol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHaematol

	programme some form of a table(s) (predefined table) may be mandatory.		
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservClinChem
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Effects seen on hormone levels should be described. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservClinChem
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.Gener

	examined' or 'not specified' as applicable.		alToxicityP0.EndocrineFindings
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityEndocrine
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservUrin
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservUrin

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeurobehaviour
Description (incidence and severity)	Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeurobehaviour

	information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Immunological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ImmunologicalFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityImmunologicalFindings

	programme some form of a table(s) (predefined table) may be mandatory.		
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Include (both) body weight, organ weights and relative weights (related to bw). Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservOrganWeights
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsP

	not. Select 'not examined' or 'not specified' as applicable.		arentalGeneration.GeneralToxicityP0.ObservGrpathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservGrpathol
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservNeuropathol

	adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description (using scores) where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopathol

	accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Histopathological findings: neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.ObservHistopatholNeoplastic
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.GeneralToxicityP0.DescriptionIncidenceAndSeverityOtherEffects
Reproductive function / performance (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0
Reproductive function: oestrous cycle	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	treatment-related or not. Select 'not examined' or 'not specified' as applicable. Indicate if it is oestrous cycles pre-treatment effects or treatment related.		.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservEstrousParent
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservEstrousParent
Reproductive function: sperm measures	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservSpermParent
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservSpermParent
Reproductive performance	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.ObservReproPerformParent
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.ReproductiveFunctionPerformanceP0.DescriptionIncidenceAndSeverityObservReproPerformParent

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on results (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.DetailsOnResultsP0.DetailsOnResults
Effect levels (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.KeyResult
Dose descriptor	Select the relevant dose	Open list with remarks	ENDPOINT_STUDY_REC

	descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.Effect

	element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		LevelsP0.Efflevel.Based On
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.EffectLevelsP0.Efflevel.RemarksOnResults

	explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'		
Target system / organ toxicity (P0)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganTox

	the target organ(s) affected.		icity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsParentalGeneration.TargetSystemOrganToxicityP0.TargetSystemOrganToxicity.RelevantForHumans
Results: P1 (second parental generation)		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParent

			alGeneration
General toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservClinSigns
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralTo

	examined' or 'not specified' as applicable.		xicityP1.ObservDermalIrritationIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceMortality
Body weight and weight changes	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	treatment-related or not. Select 'not examined' or 'not specified' as applicable.		.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodConsum

	effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservFoodEfficiency

	accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservWaterConsum

	table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOphthalm
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHaematol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHaematol
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservClinChem
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservClinChem

	comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.EndocrineFindings
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityEndocrine

	of a table(s) (predefined table) may be mandatory.		
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservUrin
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservUrin
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeurobehaviour
Description (incidence and	Where relevant describe functional investigations	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproducti

severity)	in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		on.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeurobehaviour
Immunological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ImmunologicalFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncid

	related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		enceAndSeverityImmunologicalFindings
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservOrganWeights

	information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservGrpathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservGrpathol

	programme some form of a table(s) (predefined table) may be mandatory.		
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservNeuropathol
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHistopathol
Description	Describe the incidence	Text area	ENDPOINT_STUDY_REC

(incidence and severity)	and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHistopathol
Histopathological findings: neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.ObservHistopatholNeoplastic
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DescriptionIncidenceAndSeverityOtherEffects

	repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.GeneralToxicityP1.DetailsOnResults
Reproductive function / performance (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1
Reproductive function: oestrous cycle	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductiveFunctionEstrousCycle
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionEstrousCycle

	toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Reproductive function: sperm measures	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductiveFunctionSpermMeasures
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductiveFunctionSpermMeasures
Reproductive performance	Indicate whether any effects were observed and whether they were	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	treatment-related or not. Select 'not examined' or 'not specified' as applicable.		.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.ReproductivePerformance
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.ReproductiveFunctionPerformanceP1.DescriptionIncidenceAndSeverityReproductivePerformance
Details on results (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.DetailsOnResultsP1.DetailsOnResults
Effect levels (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

			.ResultsP1SecondParentalGeneration.EffectLevelsP1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Endpoint
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.BasedOn

	field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.EffectLevelsP1.Efflevel.RemarksOnResults
Target system / organ toxicity (P1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSyst

			emOrganToxicityP1
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParent

	This field provides context-related picklist values depending on the selection made in the preceding field 'System'.		alGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related. Please indicate if maternal toxicity is seen.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner (monotonic or non-monotonic).	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsP1SecondParentalGeneration.TargetSystemOrganToxicityP1.TargetSystemOrganToxicity.RelevantForHumans
Results: F1 generation		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring
General toxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservClinOffspring

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinOffspring
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DermalIrritationOffspringIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityDermalIrritationOffspringIfDermalStudy

	reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Mortality / viability	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservViabilityOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservViabilityOffspring

	mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is seen.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservBodyweightOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservBodyweightOffspring

	of a table(s) (predefined table) may be mandatory.		
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservFoodConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservFoodConsumOffspring
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservFoodEfficiencyOffspring
Description (incidence and	Describe the incidence and severity of effects	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproducti

severity)	by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		on.ResultsAndDiscussion .ResultsOfExaminations Offspring.GeneralToxicit yF1.DescriptionIncidenc eAndSeverityObservFoo dEfficiencyOffspring
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_REC ORD.ToxicityReproducti on.ResultsAndDiscussion .ResultsOfExaminations Offspring.GeneralToxicit yF1.ObservWaterConsu mOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_REC ORD.ToxicityReproducti on.ResultsAndDiscussion .ResultsOfExaminations Offspring.GeneralToxicit yF1.DescriptionIncidenc eAndSeverityObservWat erConsumOffspring

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOphthalmOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOphthalmOffspring

	presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservHaematolOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHaematolOffspring
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations

	not. Select 'not examined' or 'not specified' as applicable.		Offspring.GeneralToxicityF1.ObservClinChemOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservClinChemOffspring
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservUrinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservUrinOffspring

	adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Sexual maturation	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservMaturationOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservMaturationOffspring

	tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Anogenital distance (AGD)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.AnogenitalDistance
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityAnogenitalDistance

	of a table(s) (predefined table) may be mandatory.		
Nipple retention in male pups	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.NippleRetentionInMalePups
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityNippleRetentionInMalePups
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Please indicate if maternal toxicity is	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservOrganWeightsOffspring

	seen.		
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservGrpatholOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows,	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservGrpatholOffspring

	whether the effects are reversible or irreversible. Please indicate the scores of these malformations or number of pups where this is seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Histopathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.ObservHistopatholOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityObservHistopatholOffspring

	information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.GeneralToxicityF1.DescriptionIncidenceAndSeverityOtherEffectsOffspring

	programme some form of a table(s) (predefined table) may be mandatory.		
Developmental neurotoxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1
Behaviour (functional findings)	Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.BehaviourFunctionalFindings
Description	Describe the incidence	Text area	ENDPOINT_STUDY_REC

(incidence and severity)	and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalNeurotoxicityF1.DescriptionIncidenceAndSeverityBehaviourFunctionalFindings
Developmental immunotoxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1
Developmental immunotoxicity	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1.DevelopmentalImmunotoxicity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DevelopmentalImmunotoxicityF1.DescriptionIncidenceAndSeverityDevelopmentalImmu

	effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		notoxicity
Details on results (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.DetailsOnResultsF1.DetailsOnResults
Effect levels (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations

	hazard/risk assessment or classification purpose.		Offspring.EffectLevelsF1.Efflevel.KeyResult
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations Offspring.EffectLevelsF1.Efflevel.Endpoint
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations Offspring.EffectLevelsF1.Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations Offspring.EffectLevelsF1.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminations Offspring.EffectLevelsF1.Efflevel.BasedOn

	type is not known.		
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.EffectLevelsF1.Efflevel.RemarksOnResults
Target system / organ toxicity (F1)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystem

	specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		OrganToxicityF1.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the	Closed list	ENDPOINT_STUDY_REC

	effects in systems and/or organs are treatment related.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsOfExaminationsOffspring.TargetSystemOrganToxicityF1.TargetSystemOrganToxicity.RelevantForHumans
Results: F2 generation		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation
General toxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinOffspring

	adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DermalIritationOffspringIfDermalStudy
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityDermalIrritationOffspringIfDermalStudy

	tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Mortality / viability	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservViabilityOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservViabilityOffspring

	of a table(s) (predefined table) may be mandatory.		
Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservBodyweightOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservBodyweightOffspring
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodConsumOffspring
Description (incidence and	Describe the incidence and severity of effects	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproducti

severity)	by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		on.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodConsumOffspring
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservFoodEfficiencyOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservFoodEfficiencyOffspring

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservWaterConsumOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservWaterConsumOffspring

	presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOphthalmOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOphthalmOffspring
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.Ge

	not. Select 'not examined' or 'not specified' as applicable.		neralToxicityF2.ObservHaematolOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHaematolOffspring
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservClinChemOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservClinChemOffspring

	adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservUrinOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservUrinOffspring

	tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Sexual maturation	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservMaturationOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservMaturationOffspring

	mandatory.		
Anogenital distance (AGD)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.AnogenitalDistance
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityAnogenitalDistance
Nipple retention in male pups	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.NippleRetentionInMalePups
Description (incidence and	Describe the incidence and severity of effects	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproducti

severity)	by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		on.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityNippleRetentionInMalePups
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservOrganWeightsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservOrganWeightsOffspring

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservGrpatholOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservGrpatholOffspring

	presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Histopathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.ObservHistopatholOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityObservHistopatholOffspring
Other effects	Indicate whether any effects were observed and whether they were treatment-related or	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.Ge

	not. Select 'not examined' or 'not specified' as applicable.		neralToxicityF2.OtherEffectsOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.GeneralToxicityF2.DescriptionIncidenceAndSeverityOtherEffectsOffspring
Developmental neurotoxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOfF1Generation
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalNeurotoxicityOfF1Generation.BehaviourFunctionalFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		.ResultsF2Generation.DevelopmentalNeurotoxicityOfF1Generation.DescriptionIncidenceAndSeverityBehaviourFunctionalFindings
Developmental immunotoxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOfF1Generation
Developmental immunotoxicity	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOfF1Generation.DevelopmentalImmunotoxicity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DevelopmentalImmunotoxicityOfF1Generation.DescriptionIncidenceAndSeverityDevelopmentalImmunotoxicity

	and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on results (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2
	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.DetailsOnResultsF2.DetailsOnResults
Effect levels (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2
			ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion

	corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		.ResultsF2Generation.EffectLevelsF2.Efflevel.Endpoint
Generation	Select the generation (e.g. 'P') the effect level refers to.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.EffectLevel
Based on	Indicate whether the	Open list with remarks	ENDPOINT_STUDY_REC

	concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.		ORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.EffectLevelsF2.Efflevel.RemarksOnResults

	by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'		
Target system / organ toxicity (F2)		Header 3	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrgan

	severe toxic effects on the target organ(s) affected.		Toxicity.LowestEffectiveDoseConc
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ResultsF2Generation.TargetSystemOrganToxicityF2.TargetSystemOrganToxicity.RelevantForHumans
Overall reproductive toxicity		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity

	Record if reproductive toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the reproductive effects occurred in the absence or presence of other toxic effects, are treatment and dose-response related and of human relevance.		ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.KeyResult
Reproductive effects observed	Flag to indicate if reproductive toxicity was observed in the study.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.ReproductiveEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.TreatmentRelated
Relation to other toxic effects	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.RelationToOtherToxicEffects
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.Re

			productiveToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.ReproductiveToxicity.ReproductiveToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproduction.ApplicantSummaryAndConclusion

5.6.1 Generational studies (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:
Multigeneration studies (e.g. two-generation toxicity study and/or 1-extended one generation study) should be reported using the endpoint study record under 5.6-toxicity to reproduction.
Other reproductive toxicity studies not covered by the endpoint study record under 5.6-toxicity to reproduction should be reported by using this template.

ENDPOINT_STUDY_RECORD.ToxicityReproductionOther			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.DataSource
Materials and methods	Material and methods – common block Type of method: Indicate if study was in vivo or in vitro test. If in vitro test, describe study design in field 'Any other information on materials and methods incl. tables'. If a specific template for in vitro assays is provided include the data in that template instead.	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMet

			hods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Duration of test	Indicate the complete duration of the test.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DurationOfTest
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line	ENDPOINT_STUDY_RECORD.ToxicityReproductio

		text	nOther.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Depending on type of study specify either number of dams or number of males and females.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Give details on the study design. As an option you may include an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Statistics	List parameters that were analyzed by which test methods.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AdministrationExposure.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.EffectLevels

	Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Observed effects		Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.ObservedEffects
Any other information on results incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicityReproductionOther.ApplicantSummaryAndConclusion

5.6.2 Developmental toxicity studies (includes reproduction toxicity to mammals) – Endpoint study record

Purpose:
The developmental toxicity studies reported, taken together with other relevant data and information on the active substance, shall be sufficient to permit the assessment of effects on embryonic and foetal development, following repeated exposure to the active substance, and in particular shall be sufficient: (a) to identify direct and indirect effects on embryonic and foetal development resulting from exposure to the active substance; (b) to identify any maternal toxicity; (c) to establish the relationship between observed responses and dose in both dam and offspring; (d) to establish reference point (e.g. NOAELs) for maternal toxicity and pup development; (e) to provide additional information on adverse effects in pregnant as compared with non-pregnant females; (f) to provide additional information on any enhancement of general toxic effects of pregnant animals.

ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.AdministrativeData

Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block Select species as appropriate. If not available from picklist, select 'other' and specify "i.e. rat or rabbit".	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Type of inhalation exposure (if applicable)	If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield.	Open list with remarks	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.TypeOfInhalationExposureIfApplicable
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together	Decimal	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.Geome

deviation (GSD)	with the appropriate qualifier(s) if applicable.		tricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Details on	Briefly describe the mating procedure. Use freetext template and delete/add elements as	Text templ	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratog

mating procedure	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	ate	enicity.MaterialsAndMethods.AdministrationExposure.DetailsOnMatingProcedure
Duration of treatment / exposure	Indicate duration of administration / exposure in days of pregnancy counting from day 0 of pregnancy, i.e. 6-14 days pc, 6-17 days pc, 6-18 days pc or other.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	In the case of an inhalation or dermal study include the daily exposure duration, e.g. '4 hours per day'. Use of non-standard dosing regime should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Duration of test	Indicate the complete duration of the test.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DurationOfTest
Doses / concentrations	Enter any remarks related to dose / concentration values.		ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter numeric value.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter number of females per dose, e.g. '20' or specify according to dose if different numbers were used and explain why. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. Use data from range-finding study if available. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations
Maternal examinations	Indicate if and which examinations were performed in the dams and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.MaternalExaminations
Ovaries and uterine content	Indicate if ovaries and uterine contents were examined and the type of examinations. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.OvariesAndUterineContent
Blood sampling	Indicate if plasma or serum were examined and the type of examinations. Use freetext template to indicate the volume of whole blood examined.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.BloodSampling
Fetal examinations	Indicate if and which examinations were performed in the fetuses. Describe in detail, i.e. external, soft tissue and skeletal examinations, including assignment of fetuses and standard/non-standard methodologies used. Indicate how many per litter were used, i.e. all, half, a distinct number, or any other. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.FetalExaminations

Statistics	List parameters that were analyzed by which test methods. Indicate whether these are appropriate. Differentiate between parametric and non-parametric analysis. Note: General statistical assumptions need not be stated unless there are deviations from generally applied techniques. Animals excluded from analyses should be in table footnotes.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Statistics
Indices	Describe which indices were calculated from cesarean section records of animals in the study. Include formulas or descriptions as provided in the study report.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.Indices
Historical control data	Describe whether historical control data were provided to allow comparison with concurrent controls. State source of data and what data were included.	Multi-line text	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.Examinations.HistoricalControlData
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion
Results: maternal animals		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals
General toxicity (maternal animals)	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.GeneralToxicityMaternalAnimals
Maternal developmental toxicity		Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity
Number of abortions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.NumberOfAbortions
Description (inciden	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.

ce and severity)	were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityNumberOfAbortions
Pre- and post-implantation loss	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.PreAndPostImplantationLoss
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityPreAndPostImplantationLoss
Total litter losses by resorption	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.TotalLitterLossesByResorption
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityTotalLitterLossesByResorption

	mandatory.		
Early or late resorptions	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.EarlyOrLateResorptions
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityEarlyOrLateResorptions
Dead fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DeadFetuses
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityDeadFetuses
Changes in pregnancy duration	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ChangesInPregnancyDuration
Description (incidence and	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.Mater

severity)	adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		nalDevelopmentalToxicity.DescriptionIncidenceAndSeverityChangesInPregnancyDuration
Changes in number of pregnant	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ChangesInNumberOfPregnant
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityChangesInNumberOfPregnant
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.DescriptionIncidenceAndSeverityOtherEffects

Details on maternal toxic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalDevelopmentalToxicity.ResultsDetailsMaternal
Effect levels (maternal animals)	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.EffectLevelsMaternalAnimals
Maternal abnormalities		Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities
	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group. Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities.KeyResult
Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Developmental abnormalities in dams include number of pregnant / non-pregnant dams, number of dams with abortions, early deliveries, stillbirths, resorptions and/or dead fetuses, mean number of implantations, live fetuses (pups), resorptions (early and late), dead fetuses, abortions and stillbirths per litter (with implants), pre and post implantation loss: number and percent, number of corpora lutea,	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities.Abnormalities

	duration of pregnancy, gravid uterine weight.		
Localisation	Select from the multiple drop-down list the developmental endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multi select open list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsMaternalAnimals.MaternalAbnormalities.MaternalAbnormalities.DescriptionIncidenceAndSeverity
Results (fetuses)		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses
Fetal body weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalBodyWeightChanges
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverity
Reduction in number of live	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ReductionInNu

offspring			mberOfLiveOffspring
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityReductionInNumberOfLiveOffspring
Changes in sex ratio	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInSexRatio
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInSexRatio
Changes in litter size and weights	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInLitterSizeAndWeights
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInLitterSizeAndWeights

	presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Anogenital distance of all rodent fetuses	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.AnogenitalDistanceOfAllRodentFetuses
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInAnogenitalDistance
Changes in postnatal survival	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ChangesInPostnatalSurvival
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityChangesInPostnatalSurvival
External malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ExternalMalformations
Descript	Describe the incidence and severity of effects by	Text	ENDPOINT_STUDY_RECORD.

ion (incidence and severity)	dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	area	DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityExternalMalformations
Skeletal malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.SkeletalMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeveritySkeletalMalformations
Visceral malformations	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.VisceralMalformations
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityVisceralMalformations

	mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.DescriptionIncidenceAndSeverityOtherEffects
Details on embryotoxic / teratogenic effects	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.ResultsDetailsDevelop
Effect levels (fetuses)	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.EffectLevelsFetuses
Fetal abnormalities		Header 3	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities
	Record if any abnormalities were observed in the study and where they are located. Describe the incidence and severity of effects by dose group.		ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.

	Copy this block of fields for referring to different developmental endpoints where the indicated effect is located if the type of effects is different.		ResultsFetuses.FetalAbnormalities.FetalAbnormalities
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.KeyResult
Abnormalities	Indicate whether any abnormalities were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. Fetal abnormalities include mean number and percent of live offspring; sex ratio; mean fetal/pup body weight by sex and with sexes combined; external, soft tissue and skeletal malformations and other relevant alterations; number and percent of fetuses and litters with malformations (including runts) and/or variations as well as description and incidences of malformations and main variations (and/or retardations).	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Abnormalities
Localisation	Select from the multiple drop-down list the fetal endpoint(s) where the indicated effect is located. Multiple items can be selected if they are all covered by the effects description given in the preceding field. Otherwise copy this block of fields and create additional lines as needed.	Multiselect open list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.Localisation
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.ResultsFetuses.FetalAbnormalities.FetalAbnormalities.DescriptionIncidenceAndSeverity
Overall developmental toxicity		Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity
	Record whether developmental toxicity was observed in the study. If yes, indicate the lowest effective dose / concentration, whether the developmental effects occurred in the absence or presence of maternal toxicity, are treatment and		ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity

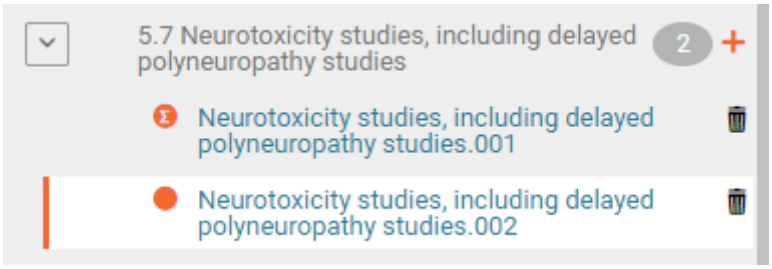
	dose-response related and of human relevance.		
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.KeyResult
Developmental effects observed	Flag to indicate if developmental toxicity was observed in the study.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DevelopmentalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.LowestEffectiveDoseConc
Treatment related	Flag to indicate if the reproductive effects are treatment related.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.TreatmentRelated
Relation to maternal toxicity	Flag to indicate if the reproductive effects occur in the absence of other toxic effects or are or are not a secondary non-specific consequence of other toxic effects.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.RelationToMaternalToxicity
Dose response relationship	Flag to indicate if the reproductive effects are in a dose-response manner.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the reproductive effects on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.DevelopmentalToxicity.DevelopmentalToxicity.RelevantForHumans
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables

Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DevelopmentalToxicityTeratogenicity.ApplicantSummaryAndConclusion

5.7 Neurotoxicity studies, including delayed polyneuropathy studies

The following documents are located under section 5.7 'Neurotoxicity studies, including delayed polyneuropathy studies'

- 5.7 Neurotoxicity – Endpoint Summary
- 5.7 Neurotoxicity – Endpoint Study record



5.7 Neurotoxicity – Endpoint Summary

Purpose:
The document should contain the information needed to be reported according to the list of end points for neurotoxicity
(SANCO/12592/2012-rev. 2, 22 March 2019). Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)
In case that there are not specific neurotoxicity studies available, a statement on whether neurotoxicity have been properly addressed in general toxicity studies and whether there is a neurotoxic potential should be included.
Please noted the developmental neurotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

ENDPOINT_SUMMARY.Neurotoxicity - v.6.2 (Final) [August 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment
Effect on neurotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaOralRoute.EndpointConclusion

	needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary in the relative field The species reported in the selected robust study summary should be reported in the relative field.		
Effect on neurotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaInhalationRoute.End

	observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary in the relative field The species reported in the selected robust study summary should be reported in the relative field.		pointConclusion
Effect on neurotoxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.LinkToRelevantStudyRecords

Endpoint conclusion	Endpoint conclusion (Species version) – common block Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to neurotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary in the relative field	Header 3	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnNeurotoxicityViaDermalRoute.EndpointConclusion
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guida	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework.MoAAnalysisHumanRelevanceFramework

	nce-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this textarea where relevant		
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: - Acute neurotoxicity (mention data if available, or 'study not required' if data are not required), and dose descriptor (e.g. NOAEL) - Repeated neurotoxicity (mention data if available, or 'study not required' if data are not required), and dose descritptor (e.g. NOAEL) - Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity) (mention study results.), and dose descritptor (e.g. NOAEL) If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.Neurotoxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Neurotoxicity.JustificationForClassificationOrNonClassification.JustifClassifRepTox

5.7 Neurotoxicity – Endpoint study record

Purpose:
Such studies shall be performed for active substances with structures that are similar or related to those capable of inducing neurotoxicity, and for active substances which induce specific indications of potential neurotoxicity, neurological signs or neuropathological lesions in toxicity studies at dose levels not associated with marked general toxicity. Performance of such studies shall also be considered for substances with a neurotoxic mode of pesticidal action. Neurotoxicity studies in rodents shall provide sufficient data to evaluate the potential neurotoxicity of the active substance (neurobehavioural and neuropathological effects) after single and repeated exposure.

ENDPOINT_STUDY_RECORD.Neurotoxicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.DataSource
Materials and methods	Material and methods – common block Applicable test guideline, e.g. "OECD 424 Method B.43".	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods
Test guideline			
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of	Range with	ENDPOINT_STUDY_RECORD.Neurotoxicity.M

aerodynamic diameter (MMAD)	particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	open list (Decimal)	aterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable.	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	- For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose or test, e.g. '10 in each dose group of FOB'. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). For a developmental neurotoxicity study it should be noted: The method of animal assignment should have	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	minimized potential problems related to litter effects, i.e., by using one pup/sex/litter (or one measure/litter, e.g., mean body weight for each litter). When allocating animals to FOB and motor activity testing, the same individual animals should have been evaluated at all scheduled time points. For the selection of animals and testing paradigms for cognitive (learning and memory) assessment, it is important to ensure that tasks were selected and/or animals allocated so that comparable assessments of learning were made at both times, i.e., shortly after PND 21 and around PND 60. Indicate whether the same or different animals were used for assessments at the weanling and adult ages. In general, the use of separate animals at the two time points is preferred, because for many tasks, initial learning (PND 21) may confound later (PND 60) assessment of learning. If the same animals were used at both times, different tasks would likely have been necessary. The selection of the test for assessing learning should have been adequately justified regardless of whether the same or a different task was used.		
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. For a developmental neurotoxicity study it should be noted: Dose selection rationale should be discussed, including information from the prenatal developmental or two-generation reproduction studies, if applicable. Any pilot study data (including biomarker data, such as cholinesterase activity) or pharmacokinetic data (e.g., milk or blood levels of test substance, or data that established time of peak effect) should be described in detail. If these data were submitted in a separate study report, the methods and results (including detailed tables of analytical results) should be presented in a separate record (include a reference in the block 'Cross-	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

	reference'); alternatively, they could be appended to this record.		
Examinations		Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. When tabulating parameters examined, refer to respective table no. If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency
Specific biochemical examinations	If specific biochemical determinations were made, provide details on the sampling, the tissues tested (e.g. plasma, whole blood, RBCs, brain (whole brain or regions)) and methodology. When tabulating parameters examined, refer to respective table no. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SpecificBiochemicalExaminations
Neurobehavioural examinations performed and frequency	Provide details on the neurobehavioural examinations performed and frequency. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s).	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.NeurobehaviouralExaminationsPerformedAndFrequency
Sacrifice and (histo)pathology	Indicate details on gross pathological and histopathological examinations. Also indicate those dose groups which were examined. Use freetext template and delete/add elements as appropriate (e.g. delete items on NTE activity if not applicable). Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl.	Text template	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.SacrificeAndHistoPathology

	tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). Specific guidance for acute or subchronic neurotoxicity: Indicate when and how were animals sacrificed, how many were perfused, what parameters were measured (e.g. brain weight, length and width), what were the procedures for perfusion, what tissues were evaluated, what type of staining was used, how were sections prepared (thickness, embedding media, number of sections). How many animals from each sex and treatment group were evaluated? Specific guidance for developmental neurotoxicity studies: see freetext template. Tables are optional, particularly for postmortem examinations of the offspring and the specific morphometric measures taken.		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.OtherExaminations
Positive control	Briefly describe the positive control data cited, and its acceptability for use with the current study. For positive control data to be acceptable, it must demonstrate the sensitivity of the test method to detect changes in the measured parameters. These data do not have to be from studies using prenatal exposures. However, the laboratory must demonstrate competence in evaluation of effects in neonatal animals perinatally exposed to chemicals and establish test norms for the appropriate age group. For observational measures, the data should demonstrate the ability to detect major neurotoxic endpoints, including limb weakness, paralysis, tremor, and autonomic signs; motor activity positive control data should demonstrate the ability to detect both increases and decreases in motor activity; pathology positive control data should demonstrate the ability to detect central and peripheral nervous system pathology (separate groups may be used to demonstrate each type of pathology, for example, acrylamide for peripheral nervous system pathology and trimethyl tin for central nervous system pathology). The methods should be completely described, and must be the same as those used in the study being evaluated (for example, the same equipment should be used, motor activity sessions should be of the same duration, the observation arena should be the same, the same sections should be evaluated for neuropathology, using the same types of stains, etc.), and preferably the same personnel should have conducted the testing. The data	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.PositiveControl

	presentation should be complete enough to evaluate the sensitivity of the method, including individual data and measures of variability. Statistical evaluations used to demonstrate sensitivity should also be the same as those used in the study being evaluated. The number of animals per test group should not be greater than that used in the study under evaluation. Positive control data should also demonstrate inter-observer reliability for the FOB (i.e., the same results should be seen regardless of who is doing the observations). The positive control data should have been collected within a reasonable time frame before the current study, e.g., the last few years. New data should also be collected when observational personnel or other critical laboratory elements change.		
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels
			ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.KeyResult
Dose descriptor	Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Endpoint

	or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.		
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration type is not known.	Open list with remarks	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.BasedOn
Sex	Select from drop-down list.	Closed list	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.EffectLevels.Efflevel.RemarksOnResults
Target system / organ	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.Tar

toxicity			getSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Neurotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Neurotoxicity.ApplicantSummaryAndConclusion

5.8 Other toxicological studies

The following documents are located under section 5.8 'Other toxicological studies

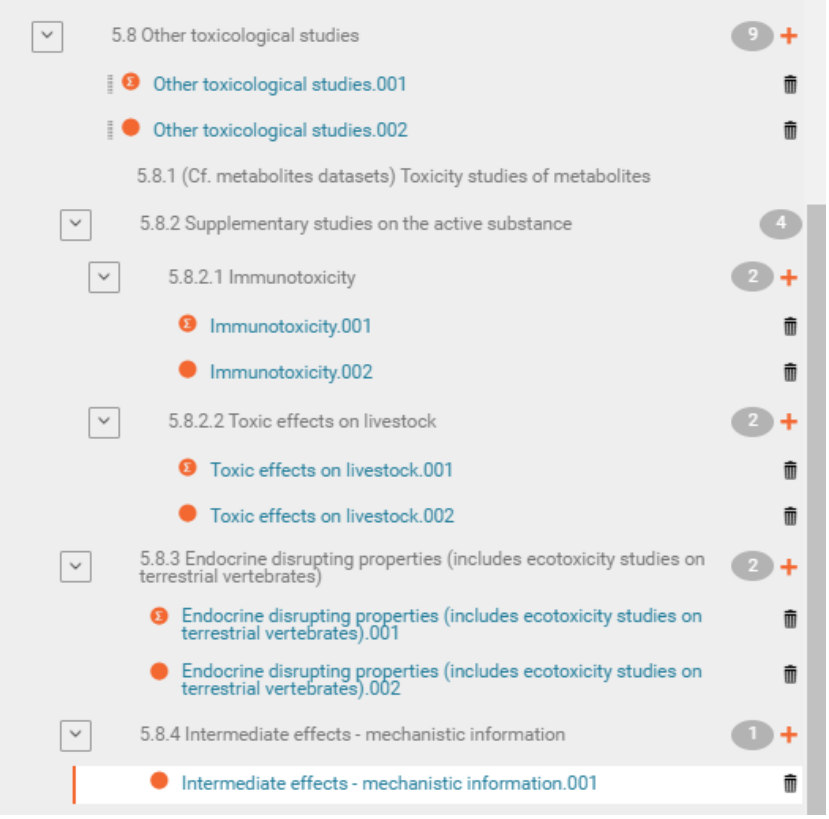
5.8 Other toxicological studies

- Endpoint Summary
- Endpoint study record
- 5.8.1 (Cf. metabolites datasets) Toxicity studies of metabolites – Endpoint study record
- 5.8.2 Supplementary studies on the active substance
    - 5.8.2.1 Immunotoxicity
        - Endpoint Summary
        - Endpoint study record
    - 5.8.2.2 Toxic effects on livestock
        - Endpoint Summary
        - Endpoint study record
- 5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates)
    - Endpoint Summary
    - Endpoint study record
    - 5.8.4 Intermediate effects - mechanistic information - Flexible record

Please noted that under IUCLID each metabolite should have their own dataset.

In terms of relevant metabolites for groundwater there is an specific document under section 7.6.

In case of metabolites to be included in the residue definition, their inclusion can be reported under "Proposed residue definition" document under 6.7.1.



5.8 Other toxicological studies – Endpoint Summary

Purpose:
Provide summary information of the most relevant study(-ies) from which the key value for chemical assessment is extrapolated. Provide only the most relevant details (according to Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

- Supplementary studies on the active substance

Provide an overall overview conclusion on the toxicological profile of metabolites found as residues in crops and/or livestock and/or in groundwater.

ENDPOINT_SUMMARY.AdditionalToxicologicalInformation			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of additional toxicological studies and effects.	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint, for example: - Provide a overview summary table with conclusion on the toxicological profile of metabolites (i.e. genotoxicity and general toxicity) found as residues in crops and/or livestock and/or in groundwater. See "IUCLID templates for PPP Risk Assessment - Template 5.4 - Template summary table on the assessment of the toxicological profile of metabolites" [http://doi.org/10.5281/zenodo.4557353] - Supplementary studies on the active substance (State which	Header 1	ENDPOINT_SUMMARY.AdditionalToxicologicalInformation.Discussion

	study was performed and in what species and the outcome, if applicable also the NOAEL and LOAEL.) If there is no additional information to be reported this field may be left empty.		

5.8 Other toxicological studies – Endpoint study record

Purpose:
Under IUCLID if a metabolite is entered in the Metabolites Information document a dataset is created and the study should be reported in this dataset if the test material is the metabolite.
This endpoint study record should be used for those studies where not specific IUCLID document can be used.
As example, comparative in vitro metabolism studies should be currently reported by using this template.

ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods
Type of study / information	Indicate the type of information provided in this record and include any relevant information in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' and/or 'Overall remarks' as appropriate. Note: Include only information that does not fit into any of the	Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TypeOfStudyInformation

	specific chapters. Use chapter 'Specific investigations: other studies' for studies on behavioural effects, biochemical or cellular interactions, chemobiokinetics general studies, cytotoxicity, endocrine system modulation, hematoxicity, hepatotoxicity, mechanistic studies, methaemoglobinaemia, nephrotoxicity, phototoxicity, respiratory irritation, splenic toxicity, or toxicogenomics.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalToxicologicalInformation.ApplicantSummaryAndConclusion

5.8.2.1 Immunotoxicity – Endpoint Summary

Purpose:
Summary information of to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated. Provide only the most relevant details, which could be: species, outcome also reference points (e.g. NOAEL)., if applicable.
In case that there are not specific immunotoxicity studies available, a statement on whether immunotoxicity has been properly addressed in general toxicity studies and whether there is a immunotoxicity potential should be included.

Please note the developmental immunotoxicity studies should be reported under 5.6 by using the template reproductive toxicity.

(Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

ENDPOINT_SUMMARY.Immunotoxicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of the immunotoxicity studies and effects.	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.AdministrativeDataSummary
		Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyInformation.KeyInformation
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment
Effect on immunotoxicity: via oral route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaOralRoute.EndpointConclusion

	observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the relative field .		
Effect on immunotoxicity: via inhalation route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute.LinkToRelevantStudyRecords
Results		Read-only	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunot

			oxicityViaInhalationRoute.LinkToRelevantStudyRecords.Results
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the relative field .	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaInhalationRoute.EndpointConclusion
Effect on immunotoxicity: via dermal route		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunot

			oxicityViaDermalRoute
Link to relevant study records	For relevant study record – common block	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaDermalRoute.LinkToRelevantStudyRecords
Endpoint conclusion	Endpoint conclusion (Species version) – common block "Adverse effect observed" should be chosen if adverse effects were observed at or below the limit dose level. "No adverse effect observed" should be chosen if no adverse effects were observed at or below the limit dose level. If "No study available" is chosen, a justification needs to be provided. The primary dose descriptor in this endpoint is the NOAEL. In some studies also the BMDL (benchmark dose level). The LOAEL should be used only if NOAEL is not available. The selection of the dose descriptor should only refer to immunotoxic effects. Other effects and dose descriptors should be reported in the section "Description of key information". Define the duration of the selected robust study summary. The species reported in the selected robust study summary should be reported in the	Header 3	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.EffectOnImmunotoxicityViaDermalRoute.EndpointConclusion

	relative field .		
Mode of Action Analysis / Human Relevance Framework		Header 2	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework
	This section is for incorporation of the WHO/IPCS Template Mode of Action Analysis / Human relevance framework at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The template is also available in HTML format that can be easily uploaded in this textarea where relevant	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.KeyValueForChemicalSafetyAssessment.MoAAnalysisHumanRelevanceFramework.MoAAnalysisHumanRelevanceFramework
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.Immunotoxicity.Discussion
Justification for classification or non-classification		Header 1	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification
	The available information should be compared against the classification criteria and the reasons for fulfilling or not fulfilling the classification criteria should be presented.	Rich text area	ENDPOINT_SUMMARY.Immunotoxicity.JustificationForClassificationOrNonClassification.JustifClassifRepTox

5.8.2.1 Immunotoxicity – Endpoint study record

Purpose:
Supplementary studies shall be carried out on the immunotoxicological potential where they are necessary to further clarify observed effects taking into account the results of the available toxicological and metabolism studies and the most important exposure routes.

ENDPOINT_STUDY_RECORD.Immunotoxicity			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.AdministrativeData
Data	Data source (Literature Reference) – common block	Head	ENDPOINT_STUDY_RECOR

source		er 1	D.Immunotoxicity.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.TestAnimals
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Vehicle	Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.Vehicle
Mass median aerodynamic diameter (MMAD)	For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.MassMedianAerodynamicDiameter
Geometric standard deviation (GSD)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Decimal	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.GeometricStandardDeviation
Remarks on MMAD	Enter any remarks related to the mass median aerodynamic diameter.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.RemarksOnMMAD
Details on exposure	Select freetext template for the respective type of study and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure

Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '28 days' or '18 months'.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L		ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations

	drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Note: Specific tables may be required.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection, animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign

Examinations		Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations
Observations and clinical examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. haematology) are reported in another study summary (e.g. repeated dose toxicity), include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.ObservationsAndClinicalExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SacrificeAndPathology
Cell viabilities	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.CellViabilities
Humoral immunity examinations	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. Example of brief description of protocol: 'Spleen IgM antibody response to a T-dependent antigen, sheep erythrocytes (sRBC) - Day 4 response: Animals were	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.HumoralImmunityExaminations

	exposed to the test substance or positive control for 28 days, then injected intravenously to sheep erythrocytes on day 25. On day 29 (peak day of IgM response), the animals were sacrificed, spleens were removed and weighed, then spleen cells were prepared on day 30. The primary response to sheep erythrocytes was measured using a modified hemolytic plaque assay (Jerne, N.K., et al., Plaque forming cells: Methodology and Theory. Transpl. Rev. 18:130-191, 1974). Cell counts were performed and the number of cells/spleen, AFC/spleen and AFC/106 spleen cells were determined.' Example of brief description of protocol for Enzyme-Linked Immunosorbent Assay (ELISA): 'The effects of test substance on antibody response to antigen were determined by an ELISA using methods described by Temple et al. (1995). Test animals were dosed with test material for ... days. Animals were exposed to sheep erythrocytes on day...IgM titers in serum were determined ... days after immunization.'		
Specific cell-mediated immunity	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Describe cell harvest and culture and proliferation measurement ((3H) thymidine) incorporation, etc.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.SpecificCellMediatedImmunity
Non-specific cell-mediated immunity	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Example of brief description of protocol: 'Following ... days of exposure to test material or positive control, the effects of test substance on spontaneous cytotoxic activity were determined by incubating splenocytes from treated and control animals with 51Cr-labeled YAC-1 lymphoma cells (target cell). Following a 4-hour incubation period, the amount of radiolabel released from target cells was determined (measure of NK cytolysis).'	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.NonSpecificCellMediatedImmunity
Other functional activity assays	Indicate if and which examinations were performed and give details on the method and test protocol, the dose groups and number of animals examined. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.OtherFunctionalActivityAssays

	Example of brief description of protocol: 'On day 30, a single cell suspension was prepared from each spleen and incubated in flat bottom microtiter plates (RPMI media supplemented with 10% fetal bovine serum and 5x10-5 2-mercaptoethanol). The spleen cells were cultured in either non-treated or anti-CD3-treated wells (100 µL of 1 µg/mL anti-CD3) and incubated at 4°C overnight. Prior to harvest on day 3, the cells were pulsed with 3H-thymidine for 18-24 hours.' Example of brief description of protocol for enumeration total B cells, total T cells and T cell subpopulations: 'Following ... days of dosing, single cell preparations from each spleen were seeded at 1x106 cells/well into a 96-well microtiter plate. Phenotypic analysis of total B cell, T cell, and T cell subpopulations were conducted using monoclonal antibody conjugates to fluorescein isothiocyanate (FITC) or phycoerythrin (PE). The specific monoclonal antibodies used were: OX19 conjugated to PE to enumerate total T-cells (CD5+), OX38 conjugated to FITC to enumerate CD4+ cells (T helper cells) and OX8 conjugated to FITC to enumerate CD8+ cells (T suppressor/cytotoxic cells). For both the CD4+ and CD8+ cells, a double label with OX19 was used. OX33 conjugated to FITC was used to enumerate CD45+ (B lymphocytes). Following the initial staining with antibody and washing with staining buffer, the DNA specific fluorescent stain propidium iodide (PI) was added to each well as a viability stain. Following a 5 minute incubation with PI, the cells were washed once with staining buffer and then enumerated on a Coulter Epics XL-MCL Flow Cytometer. At least 5,000 cells were counted for each sample.'		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.OtherExaminations
Positive control	Briefly describe the positive control data cited, and its acceptability for use with the current study. Criteria for acceptability include the positive demonstration of sensitivity of the test methods to detect changes in the measured parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.PositiveControl
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.Examinations.Statistics
Any other information on	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMeth

materials and methods incl. tables			odsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations
Specific immunotoxic examinations		Header 3	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations
Cell viabilities	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.CellViabilities
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityCellViabilities
Humoral immunity examinations	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.HumoralImmunityExaminations
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityHumoralImmunityExaminations

	data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Specific cell-mediated immunity	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.SpecificCellMediatedImmunity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeveritySpecificCellMediatedImmunity
Non-specific cell-mediated immunity	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.NonSpecificCellMediatedImmunity
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityNonSpecificCellMediatedImmunity
Other functional activity assays	Indicate whether any effects were observed and whether they were treatment-related or not, adverse or not and irreversible or reversible. Select 'not examined' or 'not specified' as applicable.	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFunction

			alActivityAssays
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFunctionalActivityAssays
Other findings	Report results related to pathogenicity, infectiveness or clearance in studies with micro-organisms	Closed list	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.OtherFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.ResultsOfExaminations.SpecificImmunotoxicExaminations.DescriptionIncidenceAndSeverityOtherFindings
Effect levels	Effect levels (OHT 67-69, 72-74) – common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.EffectLevels
Target system / organ toxicity	Target system (OHT RepDoseTox etc.) - Target system BLOCK -OHT 67-69- 72- 73- 76- 77- common block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.TargetSystemOrganToxicity
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.Immunotoxicity.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall	Overall remarks, attachments – common block	Head	ENDPOINT_STUDY_RECOR

remarks, attachments		er 1	D.Immunotoxicity.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.Immunotoxicity.ApplicantSummaryAndConclusion

5.8.2.2 Toxic effects on livestock – Endpoint summary

Purpose:
Summary information of to the most relevant study(ies) providing data to establish maximum residue levels for food of animal origin. In case studies on toxic effects on livestock are available (currently not a data requirement under EU pesticide legislation) should be summarised by using this template.
It is not mandatory to fill this template in case there are not data available.

ENDPOINT_SUMMARY.ToxicEffectsLivestockPets			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of the relevant study and effects	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ToxicEffectsLivestockPets.Discussion

5.8.2.2 Toxic effects on livestock – Endpoint study record

Purpose:
Provide data in order to determine the residue in products of animal origin which will result from residues in feedingstuffs or fodder crops.

ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 503 study on metabolism.	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods

Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.TestAnimals
Route of exposure	Indicate to which route of exposure the information or description of experimenta study refers to.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.RouteOfExposure
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. If no vehicle was used, select 'unchanged (no vehicle)'. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on exposure	Select freetext template for the respective route of administration and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. Further route-dependent information to be included: - For oral studies: State whether the analytical data indicated that the variance between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii)	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	Concentration analysis. It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study. - For inhalation studies: State whether the analytical data indicated that the variance between nominal and actual concentrations was acceptable. - For dermal studies: State whether the analytical data indicated that the variance between nominal and actual concentrations of the test substance in the vehicle was acceptable.		
Duration of treatment / exposure	Indicate duration in days, weeks or months, e.g. '5 days' or '10 weeks'.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'once' or 'daily injections' or '2 doses per day, 7 days per week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Post exposure period	Indicate observation period (in days, weeks, months) after last exposure to the test material.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.PostExposurePeriod
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentra			

tions			
No. of animals per sex per dose	Enter value or specify if different number of animals were used per sex and/or dose level.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Further details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign
Examinations		Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.Examinations.SacrificeAndPathology

	Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion
Clinical signs and mortality	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservClinSigns
Body weight and weight gain	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservFoodConsum
Water consumpti	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to	Closed list	ENDPOINT_STUDY_RECORD.ToxicEffectsLives

on and compound intake (if drinking water study)	this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable. Water consumption may not be specifically requested under the respective test guideline, unless the substance was administered in the drinking water.	with remarks (2000)	tock.ResultsAndDiscussion.ObservWaterConsum
Haematology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservHaematol
Clinical chemistry	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservClinChem
Urinalysis	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservUrin
Gross pathology and organ weights	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservGrpathol
Histopathology	Indicate whether any treatment-related effects were observed. In the supplementary remarks field related to this list field, describe the effects by dose (if 'yes') or provide any further explanation (if 'no effects'), e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Closed list with remarks (2000)	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ObservHistopathol
Details on results	Describe the effects by dose level for each of the previous fields answered 'yes'. If answered 'no effects', you may provide any further explanations, e.g. stating that effects were observed, but considered negligible and not of biological or statistical significance (to be explained why). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.ResultsDetails

	Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables' and refer to respective table no., e.g. 'see Table 1' (use predefined table if any). Narrative accompanying such tabular data should address the toxicological significance of the results and not repeat what is presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) may be mandatory.		
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ToxicEffectsLivestock.ApplicantSummaryAndConclusion

Links to support material:
Guidelines for residue data under Directive 91/414/EEC and Regulation EC 396/2005 (Appendix G-livestock feeding studies):
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_app-g.pdf

5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates) – Flexible summary

Purpose:
To report the assessment of the endocrine disrupting (ED) properties (for both human health and the environment) according to the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

Endpoint Study Records of individual mammalian toxicology ED studies should be included under 5.8.3 and 5.8.4 whereas Endpoint Study Records of individual ecotoxicology ED studies are presented under 8.2.3. Please add under this section cross references to the respective Endpoint Study Records are presented.

Besides presenting the conclusions of the weight of evidence assessment, it is also requested to make a proposal for a further testing strategy where this is necessary to conclude the ED assessment (e.g. in case the data package is insufficient) and timeline for the execution of the additional study/ies proposed in the strategy. The conclusions of the weight of evidence assessment should be complemented by the inclusion of the substantiating line of evidence and of the mode of action (MoA) analysis.

In the ECHA/EFSA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, particular instructions on how to present the assessment are provided. The applicant is kindly requested to present the assessment in line with the Guidance document. Furthermore, the Excel file, completed in line with the template for reporting the available information relevant for ED assessment (Appendix E.1 to the Guidance) should be submitted as attachment.

FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest			
Name	**Instructions**	**Type**	**Field Path**
Administrative data		Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.AdministrativeDataSummary.DataProtection
ED assessment		Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment
Assessment of ED for humans (T-modality)		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality
Assessment of the lines of evidence		Header	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.E

		3	dAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence
Have T-mediated parameters been sufficiently investigated ?	Provide an assessment for the following information by specifying if the T-mediated adversity in humans has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.SufficientInvestigationT
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation). Example: WoE for T-mediated adversity • Thyroid histological changes (follicular dilatation, FC hyperplasia and FC adenoma) observed in two species (mouse and rat) in the **carcinogenesis studies** (study ID x and y) and considered adverse (intermediate and high doses). • The two carcinogenesis studies were conducted at the **MTD**. • Based on survival, body weight, food consumption, clinical chemistry and clinical signs • The proliferative effect was confirmed by an increase in cell proliferation observed in a short study (up to 28 days) and lower dose (time & dose concordance). • Additional target organ toxicity was observed in the adrenal, kidney (only mouse) and liver at the same doses (**relevant for consideration on potential non-endocrine MOA**) • For the liver, changes were mainly characterized by panlobular hypertrophy, hepatocellular necrosis, fatty change and hepatocellular neoplasm. Considered adverse and observed in multiple studies also of shorter duration (l**ikely lead toxic effect**)	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation). Example: WoE for T-mediated endocrine activity • TPO in vitro investigation negative • Decrease in THs in the mouse was observed in studies of shorter duration (14 and 28 days) and at lower doses (35 and 350 mg/kg/day).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity

<table>
<tr><td></td><td>Decrease in THs in the rat was observed is a study of shorter duration (14 days) and dose tested of 700 mg/kg bw per day.
Increase at week 16 only in TSH (measured in rat and mouse) were observed in mouse.</td><td></td><td></td></tr>
<tr><td>WoE for adversity and endocrine activity</td><td>Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.</td><td>Text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity</td></tr>
<tr><td>Has endocrine activity been sufficiently investigated ?</td><td>Provide an assessment for the following information by specifying if the T-mediated endocrine activity in humans has been sufficiently investigated (or not) and the rationale.</td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated</td></tr>
<tr><td>Selection of relevant scenario</td><td>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.
For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Selection of relevant scenario
<table><tr><th>Adversity based on T-mediated parameters</th><th>Positive mechanistic OECD CF level 2/3 Test</th><th>Scenario</th><th>Next step of the assessment</th></tr><tr><td>No (sufficiently investigated)</td><td>Yes/No</td><td>1a</td><td>Conclude: ED criteria not met because there is not “T-mediated” adversity</td></tr><tr><td>Yes (sufficiently</td><td>Yes/No</td><td>1b</td><td>Perform MoA analysis</td></tr></table></td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario</td></tr>
</table>

	investigated)					
	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)		
	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no **T-mediated endocrine activity** observed		
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	The fields in the MoA analysis fields should be completed only for scenarios 1b, 2a(i) and 2b. In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis." Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be in the field 'Conclusion on MoA Analysis'.					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.				Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.PostulatedMoa

<table>
<tr><td>Event type</td><td>Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.EventType</td></tr>
<tr><td>Event description</td><td>Description of the event e.g. TSH; increased or Nuclear receptor activation (liver).</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.EventDescription</td></tr>
<tr><td>Supporting evidence</td><td>Supporting evidence a the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.SupportingEvidence</td></tr>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.PostulatedMoa.RelevantRecords</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.
Example Dose: and temporal-concordance between key events of the postulated MoA
<table>
<tr><th></th><th>MIE CAR-PXR activation</th><th>KE1 Phase I /Phase II catabolic activation</th><th>KE2 ↓serum concentration of T4</th><th>KE 3 ↑ in TSH</th><th>KE4 ↑ in follicular cells proliferation</th><th>AO Thyroid hyperplasia/adenoma</th></tr>
<tr><td>In vitro 3-10 µM</td><td>96 hours +++</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>35 mg/kg bw per day mouse</td><td>7-28 days +++</td><td>7-28 days +++</td><td>7-28 days ++</td><td>7-28 days ++</td><td>7-28 days ++</td><td></td></tr>
</table></td><td>Rich text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.EmpiricalSupport</td></tr>
</table>

	460 (mouse)/ 318 (rat) mg/kg bw per day						104 weeks +		
Conclusion on MoA analysis	The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well. When more than one MoA is postulated, include a conclusion for each MoA postulated. Example: Summary of the MoA analysis							Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.MoaAnalysis.ConclusionOnMoa

	MIE to KE1	**KE1 to KE2**	**KE2 to KE3**	**KE3 to KE4**	**KE4 to KE5**	**KE5 to AO**
Biological plausibility for the KER	Strong, well documented	Strong, well documented	String, well documented	Strong well documented	Strong, well documented	Strong well documented
Empirical support for the KER	Moderate, /strong, some evidence is indirect	Moderate, evidence is indirect, THs clearance was not measured	Moderate, only in one species and occasionally controversial	Strong, dose and time related	Strong dose and time related	Strong, dose and time related
Essentiality of the KE	Strong	Na	Na	Na	Na	Na

	Consistency	Some KEs are consistently observed in different studies and species The pattern of effect is consistent across studies and species and in line with the postulated MOA		
	Analogy	The same MOA has been seen in the same species with multiple substances and this is well documented		
	Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.		
Uncertainty analysis			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors			FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.		Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion		Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansTmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis				
Assessment of ED for humans (EAS-modality)			Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality
Assessment of the lines of evidence			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence

Have EAS-mediated parameters been sufficiently investigated ?	Provide an assessment for the following information by specifying if the EAS-mediated adversity in humans has been sufficiently investigated (or not) and the rationale	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.SufficientInvestigationEas
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation). Example: WoE for EAS-mediated adversity • The most relevant studies for adversity are 2 two-years rat studies • Leydig cells adenoma observed in 2 two-year rat studies. Dose-dependent increase observed below MTD. • Dose-dependent decrease of testis weight observed in 1 two-year rat study. Effect observed below MTD. • The two carcinogenesis studies were conducted at the **MTD.** (Based on survival, body weight, food consumption, clinical chemistry and clinical signs). • Additional target organ toxicity was observed in the liver.	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation). Example: WoE for EAS-mediated endocrine activity • Several *in vitro* assays providing evidence indicative of anti-androgenic activity. • Decreased serum testosterone and increased testicular testosterone in 90-days rat study in male. • Increased LH levels (rat 2-weeks) in males. • Decreased weight of several male reproductive organs from 3 Hershberger studies.	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed	Text	FLEXIBLE_SUMMARY.EndocrineDisruptingProp

<table>
<tr><td>and endocrine activity</td><td>to then select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.</td><td>area</td><td>ertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity</td></tr>
<tr><td>Has endocrine activity been sufficiently investigated?</td><td>Provide an assessment for the following information by specifying if the EAS-mediated endocrine activity in humans has been sufficiently investigated (or not) and the rationale.</td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated</td></tr>
<tr><td>Selection of relevant scenario</td><td>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.
For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Selection of relevant scenario

Example: Selection of relevant scenario

<table>
<tr><th>Adversity based on EAS-mediated parameters</th><th>Positive mechanistic OECD CF level 2/3 Test</th><th>Scenario</th><th>Next step of the assessment</th></tr>
<tr><td>No (sufficiently investigated)</td><td>Yes/No</td><td>1a</td><td>Conclude: ED criteria not met because there is not "EAS-mediated" adversity</td></tr>
<tr><td>Yes (sufficiently investigated)</td><td>Yes/No</td><td>1b</td><td>Perform MoA analysis</td></tr>
<tr><td>No (not sufficiently investigated)</td><td>Yes</td><td>2a (i)</td><td>Perform MoA analysis (additional information may be needed for the analysis)</td></tr>
<tr><td>No (not sufficiently investigated)</td><td>No (sufficiently investigated)</td><td>2a (ii)</td><td>Conclude: ED criteria not met because no EAS-mediated endocrine activity</td></tr>
</table>
</td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario</td></tr>
</table>

				observed		
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
	In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis." Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.					
MoA analysis	The following fields should be completed only for scenarios 1b, 2a(i) and 2b. In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis." Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.				Multi-line te	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.

<table>
<tr><td></td><td></td><td>xt</td><td>PostulatedMoa</td></tr>
<tr><td>Event type</td><td>Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.EventType</td></tr>
<tr><td>Event description</td><td>Description of the event e.g. LH; increased or Leydig cells hyperplasia</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.EventDescription</td></tr>
<tr><td>Supporting evidence</td><td>Supporting evidence a the Lowest Observable Adverse Effect Level e.g. One-generation study (64.6 mg/kg/day in dam).</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.SupportingEvidence</td></tr>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.PostulatedMoa.RelevantRecords</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.

Example: Dose- and temporal-concordance between key events of the postulated MoA
<table>
<tr><th></th><th>MIE</th><th>KE1
↓ serum testosterone</th><th>KE2
↑ LH levels</th><th>KE3
↑ testicular testosterone</th><th>KE4
Leydig cells hyperplasia</th><th>AO
Leydig cells tumors</th></tr>
<tr><td>6.25 mg/kg bw per day (rat)</td><td></td><td></td><td></td><td></td><td>104 weeks
++</td><td>104 weeks
++</td></tr>
</table></td><td>Rich text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.EmpiricalSupport</td></tr>
</table>

	10 mg/kg bw per day (rat)					117 weeks ++	117 weeks ++		
	23 mg/kg bw per day (rat)					24-52 weeks +			
	31.26 mg/kg bw per day (rat)					26 weeks +	26 weeks +		
	100 mg/kg bw per day (rat)		13 weeks ++		13 weeks ++				
	200 mg/kg bw per day (rat)			2 weeks ++					
Conclusion on MoA analysis	The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well. When more than one MoA is postulated, include a conclusion for each MoA postulated. Example: Summary of the MoA analysis							Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.MoaAnalysis.ConclusionOnMoa

		MIE to KE1 Androgen receptor to decreased testosterone	**KE1 to KE2** Decreased testosterone to increased LH	**KE2 to KE3/4** Increased LH to Leydig cell hyperplasia	**KE4 to AO** Leydig tumors		
	Biological plausibility	STRONG: well documented that anti-androgenic activity leads to ↓ testosterone	STRONG: ↓ testosterone induces negative feedback to hypothalamus to ↑ LH production	STRONG: LH induces Leydig cells to produce Testosterone. This over time can lead to hyperplasia	STRONG: It is known that a continuum exists between epithelial cell hyperplasia and tumors		
	Empirical support	WEAK: Dose and time concordance were compromised by the dose selection and study design (selected parameters, hormones, and length of the study)			STRONG: dose and temporal concordance observed in several rat studies		
	Essentiality	No data					
	Consistency	Particularly Leyding cells hyperplasia and tumors have been observed in several studies. Also AR anti-androgenic activity supported by several *in vitro* assays					
	Analogy	Similar effects are known to occur with multiple chemicals acting on the same MIE, including therapeutic drugs.					
	Specificity	Although a clear experimental understanding of early KEs is lacking, the sequence of KEs from the MIE to the AO is considered specific					
Uncertainty						He	FLEXIBLE_SUMMARY.E

analysis		ader 3	ndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors		FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.	Textarea	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion	Textarea	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForHumansEasmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Assessment of ED for non-target organisms (T-modality)		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality
Assessment of the lines of evidence		Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence
Have T-mediated parameters been sufficiently investigated ?	Provide an assessment for the following information by specifying if the T-mediated adversity in non-target organisms has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.SufficientInvestigationT
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceAdv

<table>
<tr><td></td><td></td><td></td><td>erseEffects</td></tr>
<tr><td>Lines of evidence for endocrine activity</td><td>List the relevant lines of evidence for endocrine activity (also using a tabular representation).</td><td>Rich text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity</td></tr>
<tr><td>WoE for adversity and endocrine activity</td><td>Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to the select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.</td><td>Text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity</td></tr>
<tr><td>Has endocrine activity been sufficiently investigated ?</td><td>Provide an assessment for the following information by specifying if the T-mediated endocrine activity in non-target organisms has been sufficiently investigated (or not) and the rationale..</td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated</td></tr>
<tr><td>Selection of relevant scenario</td><td>In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659.
For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied.

Under the conditions as specified above, the selection of scenario 2(iii) is not applicable.

Example: Selection of relevant scenario
<table>
<tr><td>Adversity based on T-mediated parameters</td><td>Positive mechanistic OECD CF level 2/3 Test</td><td>Scenario</td><td>Next step of the assessment</td></tr>
<tr><td>No (sufficiently investigated)</td><td>Yes/No</td><td>1a</td><td>Conclude: ED criteria not met because there is not “T-mediated” adversity</td></tr>
<tr><td>Yes (sufficiently investigated)</td><td>Yes/No</td><td>1b</td><td>Perform MoA analysis</td></tr>
</table></td><td>Closed list with remarks</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario</td></tr>
</table>

	No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)		
	No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no **T-mediated endocrine activity** observed		
	No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario		
	Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis		
MoA analysis	The following fields should be completed only for scenarios 1b, 2a(i) and 2b. In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis." Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity. Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.				Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here.					FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated. .				Multi-line	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmod

<table>
<tr><td></td><td></td><td>text</td><td>ality.MoaAnalysis.PostulatedMoa.PostulatedMoa</td></tr>
<tr><td>Event type</td><td>Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.EventType</td></tr>
<tr><td>Event description</td><td>Description of the event e.g. Change in Thyroid histopathology</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.EventDescription</td></tr>
<tr><td>Supporting evidence</td><td>Supporting evidence at the Lowest Observable Adverse Effect Level e.g. Amphibian metamorphosis assay (AMA), 5 mg/l</td><td>Multi-line text</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.SupportingEvidence</td></tr>
<tr><td>Link to relevant study records</td><td>Link to the reference entity for the supporting evidence.</td><td>Literature reference list</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.PostulatedMoa.RelevantRecords</td></tr>
<tr><td>Postulated MoA</td><td></td><td></td><td></td></tr>
<tr><td>Empirical support</td><td>When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document.

Example: Dose- and temporal-concordance between key events of the postulated MoA
<table>
<tr><th></th><th>MIE

TPO inhibition</th><th>KE1

change in thyroid histopayhology</th><th></th><th></th><th></th><th>AO

Delayed development /time to metamorphosis</th></tr>
<tr><td>In vitro</td><td>+++</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>AMA</td><td></td><td>7-21 days</td><td>21 day</td><td></td><td></td><td></td></tr>
</table></td><td>Rich text area</td><td>FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.EmpiricalSupport</td></tr>
</table>

			++	s +						
	LAGDA		16 weeks +++ (interim sacrifice)				16 weeks+++ (interim sacrifice)			

Conclusion on MoA analysis

The conclusion of the MoA analysis should be presented in a tabular form.
In this section, when relevant, comparative MoA analysis can be reported as well.

When more than one MoA is postulated, include a conclusion for each MoA postulated.

Example: Summary of the MoA analysis

	MIE to KE1	**KE1 to A0**
Biological plausibility for the KER	Strong, well documented	Strong, well documented
Empirical support for the KER	Moderate, /strong, some evidence is indirect	Moderate, evidence is indirect, THs clearance was not measured
Essentiality of the KE	Strong	Na
Consistency	Some KEs are consistently observed in different studies and species The pattern of effect is consistent across studies and species and in line with the postulated MOA	
Analogy	The same MOA has been seen in the same species with multiple substances and this is well documented	

Rich text area

FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.MoaAnalysis.ConclusionOnMoa

	Specificity	This MOA is not very specific and can occur as a consequence of activation of different MIE. However, the upstream KEs are specific of a liver mediated MIE. As such, this MOA is specific.		
Uncertainty analysis			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider uncertainty associated with assessment inputs e.g. missing studies and uncertainty associated with methodology e.g. excluded factors.			FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis
Identified uncertainties	Describe each uncertainty related to the both MoA analysis and assessment of the lines of evidence.		Textarea	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion		Textarea	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsTmodality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis				
Assessment of ED for non-target organisms (EAS-modality)			Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality
Assessment of the lines of evidence			Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence
Have EAS-mediated parameters been sufficiently investigated ?	Provide an assessment for the following information by specifying if the EAS-mediated adversity in non-target organisms has been sufficiently investigated (or not) and the rationale		Closed list with re	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.SufficientIn

		marks	vestigationEas
Lines of evidence for adverse effects	List the relevant lines of evidence for adversity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceAdverseEffects
Lines of evidence for endocrine activity	List the relevant lines of evidence for endocrine activity (also using a tabular representation).	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.EvidenceEndocrineActivity
WoE for adversity and endocrine activity	Based on the lines of evidence presented above, the overall WoE for adversity and endocrine activity should be reported. This is needed to the select the relevant scenario and to decide if it is possible to conclude without performing a MoA analysis.	Text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.WoeAdversityEndocrineActivity
Has endocrine activity been sufficiently investigated ?	Provide an assessment for the following information by specifying if the EAS-mediated endocrine activity in non-target organisms has been sufficiently investigated (or not) and the rationale.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.HasEndocrineActivityBeenSufficientlyInvestigated
Selection of relevant scenario	In case of pesticides, for applications submitted for the renewal of approval of active substances after 10 November 2018, the regulatory dossier should already contain the ED assessment in line with the new scientific criteria, and therefore there is no possibility to apply a clock stop to request additional data in accordance with the provisions of Regulation (EU) 2018/1659. For new active substances an additional clock stop in accordance with the provisions Regulation (EU) 2018/1659 cannot be applied. Under the conditions as specified above, the selection of scenario 2(iii) is not applicable. Example: Selection of relevant scenario	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.AssessmentLinesOfEvidence.SelectionOfRelevantScenario

Adversity based on T-mediated parameters	**Positive mechanistic OECD CF level 2/3 Test**	**Scenario**	**Next step of the assessment**
No (sufficiently investigated)	Yes/No	1a	Conclude: ED criteria not met because there is not "**T-mediated**" adversity
Yes (sufficiently investigated)	Yes/No	1b	Perform MoA analysis
No (not sufficiently investigated)	Yes	2a (i)	Perform MoA analysis (additional information may be needed for the analysis)
No (not sufficiently investigated)	No (sufficiently investigated)	2a (ii)	Conclude: ED criteria not met because no **T-mediated endocrine activity** observed
No (not sufficiently investigated)	No (not sufficiently investigated)	2a (iii)	Generate missing level 2 and 3 information. Alternatively, generate missing "EATS-mediated" parameters. Depending on the outcome move to corresponding scenario
Yes (not sufficiently investigated)	Yes/No	2b	Perform MoA analysis

MoA analysis	The following fields should be completed only for scenarios 1b, 2a(i) and 2b. In some cases, a detailed MoA analysis is not needed as explained in Section 3.5.2 of the ECHA-EFSA Guidance to identify EDs: "In the case of adversity based on "EATS-mediated" parameters, the underlying knowledge (i.e. by coherence analysis (Susser, 1991)) of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis." Where the information available is sufficient to establish a biological plausible link between endocrine activity and T-mediated adversity.	Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis

	Therefore, in such case, the assessment can be finalised and the conclusion described in the field 'Conclusion on MoA Analysis'.		
Postulated MoA	Based on the assessed lines of evidence described above, postulate the MoA. In case it is concluded that the available information is not sufficient to postulate the MoA, this conclusion should be reflected here. A tabular representation can also be reported here. If the postulated MoA is a non-EATS MoA, please indicate it after the name of the postulated MoA.		FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa
Name of postulated MoA	Name of the postulated mode of action, this element must be completed if more than one mode of action is postulated. Group the events and supporting evidence for each mode of action postulated.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.PostulatedMoa
Event type	Indicate the event type e.g. MIE, KE1, KE2, KEn, …, AO.	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.EventType
Event description	Description of the event e.g. decrease in VTG level	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.EventDescription
Supporting evidence	Supporting evidence a the Lowest Observable Adverse Effect Level e.g. FSTRA (Fish Short-term reproduction Assay) (0.5 mg/l)	Multi-line text	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.SupportingEvidence
Link to relevant study records	Link to the reference entity for the supporting evidence.	Literature reference list	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.PostulatedMoa.RelevantRecords
Postulated MoA			
Empirical support	When relevant, empirical support should be reported in a tabular format. Reproduce table from guidance document. Example: Dose- and temporal-concordance between key events of	Rich text ar	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasMo

	the postulated MoA **MIE** | **KE1** ↓ estradiol level | **KE2** ↓ VTG level | **KE3** change on gonad histopathology | **AO**↓ Fecundity | Aromatase inhibition *in vitro (AC50=29.6µM)* | | | | | | Aromatase inhibition *in vitro (AC50=29.6µM)* 0.5 µg/l Fathead minnow | | ++ (3 weeks) | ++ (3 weeks) | | ++ (3 weeks) | 0.5 µg/l Fathead minnow 0.558 µg/l Fathead minnow | | | + (36 weeks) | + (36 weeks) | + (36 weeks) | 0.558 µg/l Fathead minnow 1 µg/l Fathead minnow | | | + 3 weeks) | | + (3 weeks) | 1 µg/l Fathead minnow	ea	dality.MoaAnalysis.EmpiricalSupport
Conclusion on MoA analysis	The conclusion of the MoA analysis should be presented in a tabular form. In this section, when relevant, comparative MoA analysis can be reported as well. When more than one MoA is postulated, include a conclusion for each MoA postulated. Example Summary of the MoA analysis **MIE to KE1** | **KE1 to KE2** | **KE2 to KE3** Increased LH to | **KE to AO** **Biological plausibility** | STRONG: The link between aromatase | MODERATE – The role of E2 as major regulator | MODERATE – Based on the available knowledg | STRONG - the link between changes in female	Rich text area	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.MoaAnalysis.ConclusionOnMoa

		inhibition and decrease in estradiol level (E2) is supported by the available knowledge (AOP 25, Villeneuve 2016)	of VTG production is well known. Therefore, it can be assumed that a decrease in estradiol level will also lead to a decrease in VTG in plasma.	e it is not clear whether a decrease in VTG can lead to the observed histopathology changes in ovary. However, specific gonad histopathology is categorised as 'EAS-mediated' by the OECD GD 150. In addition, the link between VTG level and yolk formation is also supported by the biological knowledge.	gonad histopathology and decreased fecundity is supported by the biological knowledge.		
	Empirical support	MODERATE – There is little direct support for dose-response concordance of these key events in vivo. However, using in vitro systems concentra	STRONG – Although the decrease in estradiol and VTG levels were observed at the same concentrations, this can be scientifically explained	MODERATE – histopathology changes were measured only in longer term study and only observed at the highest tested concentration. The	STRONG – fecundity was observed at the same concentration as histopathology changes and above.		

		tions that reduce aromatase activity tend to elicit reductions in estradiol production.	by a number of factors (e.g. dose spacing in the test system; higher variation in VTG concentration in plasma than in circulating steroids)	VTG decrease was observed at the same concentration. However, this can be due to the dose spacing and tested concentrations			
	Essentiality	MODERATE- No data are available to support the assessment of essentiality. However, the available knowledge and validated AOP (25) supports the essentiality of key events.					
	Consistency	The KEs have been observed consistently in three different studies with different duration. The pattern of effects is consistent between the studies; there are no conflicting observations. Consistency across species cannot be assessed because there are only studies on one species.					
	Analogy	Aromatase inhibition is well established for compounds belonging to the same chemical class.					
	Specificity	Liver histopathology changes observed in one study at the highest tested concentration where other effects were also observed. However, the positive indication of endocrine activity from various studies and cell lines allowed to exclude a non-ED MOA.					
Uncertainty analysis						Header 3	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis
Uncertainty analysis	List all points of uncertainty, consider undcertainty associated with assessment inputs e.g. missing studies and those associated with methodology e.g. excluded factors						FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis
Identified	Describe each uncertainty related to the both MoA analysis and					Te	FLEXIBLE_SUMMARY.E

uncertainties	assessment of the lines of evidence.	xtarea	ndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis.IdentifiedUncertainties
Justification	Characterise the overall impact of the source of uncertainty on the assessment conclusion	Textarea	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.EdAssessment.EdForNonTargetOrganismsEasModality.UncertaintyAnalysis.UncertaintyAnalysis.Justification
Uncertainty analysis			
Overall conclusion ED assessment	Report under this section whether the ED criteria are met according to Regulation EU 2018/605.	Header 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment
Overall conclusion ED assessment for humans		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentHumans
Does the substance meet the ED criteria for humans?	Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for humans? Provide the reasoning behind the conclusion. .	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentHumans.CriteriaForHumansMet
Overall conclusion ED assessment for non-target organisms		Header 2	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms
If ED criteria are met for humans, is the adverse effect identified relevant for wild mammals' population?	When replying this question, explain the relevance at population level of the adverse effect(s) observed in the dataset for concluding on the ED criteria for_humans. Provide the reasoning behind the conclusion.	Closed list with remarks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.AdverseEffectRelevantForMammals
Does the substance	Is there a biologically plausible link between endocrine activity and	Clos	FLEXIBLE_SUMMARY.EndocrineDisruptingProp

meet the ED criteria for wild mammals?	observed adverse effect(s) that are relevant for wild animals? Provide the reasoning behind the conclusion.	ed list wi th re m ar ks	ertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.EdCriteriaMammalsMet
Does the substance meet the ED criteria for non-target organisms other than wild mammals?	Is there a biologically plausible link between endocrine activity and observed adverse effect(s) that are relevant for non-target organisms other than wild mammals? Provide the reasoning behind the conclusion.	Cl os ed list wi th re m ar ks	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.OverallConclusionEdAssessment.OverallConclusionEdAssessmentNonTargetOrganisms.ImpactOnOtherOrganisms
Additional information	Discussion(Header 1) – common block Provide any additional information to support this assessment of endocrine disrupting properties Upload the Excel file, in the format for reporting the available information specified in the guidance (this excel file with be published). Appendix E.1 to the Guidance (https://doi.org/10.2903/j.efsa.2018.5311	He ad er 1	FLEXIBLE_SUMMARY.EndocrineDisruptingPropertiesAssessmentPest.Discussion

Link to support material:

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018.
Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp.
https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN

EFSA Scientific Committee (2017) Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971

OECD Series on Testing and Assessment: No 150: Guidance document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. ENV/JM/MONO(2012)22, 524 pp

EFSA Scientific Committee; Scientific Opinion on the hazard assessment of endocrine disruptors: scientific criteria for identification of endocrine disruptors and appropriateness of existing test methods for assessing effects mediated by these substances on human health and the environment. EFSA Journal 2013;11(3):3132

Workshop report on OECD countries activities regarding testing, assessment and management of endocrine disrupters. Series on testing and assessment No 118. 18 January 2010.

OECD Series on Testing and Assessment: No 148: Guidance document on the androgenised female stickleback screen

Guidance on Uncertainty Analysis in Scientific Assessments, 10.2903/j.efsa.2018.5123

5.8.3 Endocrine disrupting properties (includes ecotoxicity studies on terrestrial vertebrates) – Endpoint study record

Purpose:
If there is evidence that the active substance may have endocrine disrupting properties, additional information or specific studies shall be required: — to elucidate the mode/mechanism of action, — to provide sufficient evidence for relevant adverse effects. Studies required shall be designed on an individual basis and taking into account Union or internationally agreed guidelines, in the light of the particular parameters to be investigated and the objectives to be achieved.

ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening [September 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD 229, OECD 230, OECD 231, OECD 234.	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods
Test type		Text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestType
Limit test	Indicate if the experiment was a limit test.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.LimitTest
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestMaterials
Test animals	Test animals (OHT: Repeated dose toxicity) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals
State	Select as appropriate.	Closed list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.TestAnimals.State
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Administrati

			onExposure
Route of administration	Select as appropriate. If not available from picklist, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.RouteOfAdministration
Details on route of administration	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of the oral route and method of administration.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnRouteOfAdministration
Vehicle	Select the vehicle used. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field. Note that some of the vehicles provided in this list are used for specific routes of administration only.	Open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.Vehicle
Details on oral exposure	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. The use of an aqueous solution/suspension should be considered first and the most common approach is to use a solution/suspension in oil (e.g. corn, peanut, sesame or olive oil). However, as these oils have different caloric and fat content, thus the vehicle might affect total metabolizable energy (ME) intake.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnOralExposure
Analytical verification of doses or concentrations	Indicate whether the doses or concentrations were analytically verified.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.AnalyticalVerificationOfDosesOrConcentrations
Details on analytical verification of doses or concentrations	For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis. State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable. If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'. It may be appropriate to include a cross-reference to	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnAnalyticalVerificationOfDosesOrConcentrations

	another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.		
Duration of treatment / exposure	Indicate duration in days, e.g. '7 days'.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DurationOfTreatmentExposure
Frequency of treatment	Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.FrequencyOfTreatment
Doses / concentrations	Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required.		ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Dose / conc.	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.DoseConc
Remarks	Enter any remarks related to dose / concentration values.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DosesConcentrations.Remarks
Doses / concentrations			
No. of animals per sex per dose	Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable. For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '...	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerSexPerDose

	see Table 1'). Note: Specific tables may be required.		
Control animals	Indicate whether and what type of concurrent control groups were used. If not available from picklist, select 'other' and specify. Copy field if more than one type of control was used.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.ControlAnimals
Details on study design	Include any details on the study design including a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.DetailsOnStudyDesign
Positive control	Uterotrophic Bioassay: Indicate data from the Baseline Positive Control Test and periodic positive control data (reference oestrogen: 17α-ethinyl estradiol). Hershberger Bioassay: Indicate that a reference androgen agonist (Testosterone Propionate) or a reference androgen antagonist (Flutamide) have been used.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AdministrationExposure.PositiveControl
Examinations		Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations
Observations and examinations performed and frequency	Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary. Use freetext template and delete/add elements as	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.ObservationsAndExaminationsPerformedAndFrequency

	appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.		
Sacrifice and pathology	Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1'). Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.SacrificeAndPathology
Other examinations	Describe any other examinations.	Text area	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.OtherExaminations
Statistics	List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale.	Multi-line text	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.Examinations.Statistics
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion
Endocrine disrupting potential	Indicate the endocrine disrupting potential derived from the test results. If positive or ambiguous, include dose(s) / concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '…see Table 1')	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.EndocrineDisruptingPotential
Maximum tolerated dose level	Indicate whether the maximum tolerated dose has been exceeded or not with respect to the endocrine disrupting potential specified in the previous field. This is in particular relevant if the no positive potential has been found.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.MaximumToleratedDoseLevelExceede

exceeded			d
Results of examinations	Results of examinations (OHT: Repeated dose toxicity: oral) – common block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.ResultsOfExaminations
Effect levels	Effect levels (OHT 67-69, 72-74) – common block Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify. Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'.	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.EffectLevels
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EndocrineDisrupterMammalianScreening.ApplicantSummaryAndConclusion

5.8.4 Intermediate effects - mechanistic information - Flexible summary

Purpose:
This OECD Harmonised Template (OHT) aims to collect non-apical observations obtained from methods such as in vitro testing or from other classes of methods (e.g. ex vivo or in silico methods) providing mechanistic information, i.e. effects on molecular, subcellular, cell, tissue or organ level that can be relevant to the hazard assessment (e.g. through Defined Approaches, Integrated Approaches on Testing and Assessment, as part of weight of evidence and are underpinned by Adverse Outcome Pathways).
In the area of pesticides this OHT can be used for example to:
1) report level 1 and level 2 data and studies of the conceptual framework for testing and assessment of endocrine disrupters submitted for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.
2) Mechanistic information relevant for understanding the mode of action of tumour formation if applicable.

Reporting apical vs mechanistic knowledge
using OECD Harmonised Templates

In the context of chemical hazard and risk assessment, two classes of knowledge are relevant:

Apical Knowledge	**Mechanistic** Knowledge
Knowledge about traditional, **directly measured whole-organism outcomes** of exposure in ***in vivo*** tests, generally death, reproductive failure, tumour formation, skin/eye irritation, skin/respiratory sensitisation or developmental dysfunction.	Knowledge about the **sequence of events** leading from the exposure to an effective dose of a chemical to the production of a specific biological response in the target organ, in most cases measured in **non-in-vivo** tests.
*"One **in-vivo** test tells us **whether** an adverse outcome has been observed or not."*	*"A series of tests, **mainly non-animal**, tells us **why** an adverse outcome is likely to manifest itself or not."*

OECD Harmonised Templates allow reporting both kinds of knowledge, if available, and they can complement each other.

*Report **apical knowledge** …* ⇓⇓⇓	*Report **mechanistic knowledge** …*	
For effects on biotic systems, use: OHTs **41** to **57** For health effects, use:	*In a regulatory context: If Mechanistic Knowledge was generated according to an OECD Test Guideline for which an (apical) endpoint OHT[14] was created* ⇓⇓⇓	*In all other cases* ⇓⇓⇓

[14] Example: future endocrine disruptor related TG methods

OHTs **58** to **84** & **86**	Use the **suitable** endpoint OHT, and there, use the mechanism-oriented fields, if available, else use appropriate other fields.	Use OHT **201**

If **OHT 201** is used, it is possible to depict (part of) an AOP by reporting individual observed Intermediate Effects as manifestations of an AOP Key Event:

FLEXIBLE_RECORD.IntermediateEffects			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	FLEXIBLE_RECORD.IntermediateEffects.AdministrativeData
Reason / purpose for cross-reference	Select the appropriate reason of the cross-reference, i.e.: - adverse outcome pathway (AOP) (in case the mechanistic information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field - assessment report (for referring to a record that contains an assessment report as attachment) - defined approach for combining with results from another in vitro method - reference to other assay used for mechanistic information derivation (for optional indication in a study summarising if reference is made to the outcome of another assay) - reference to same	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.AdministrativeData.CrossReference.ReasonPurpose

	study (e.g. if different test systems/in vitro models were used and the results recorded in different records, or different test materials were assessed in the same study, using common reference and control items) - reference to other study (e.g. if another study provides mechanistic information or key event relevant for the same Adverse Outcome Pathway or if another study is considered relevant in the interpretation of the test results) - other: (to be specified)		
Study objective(s) / purpose / aim	Specify the objective, purpose and/or aim of the study explaining clearly why the study was performed and what (regulatory) question is answered. For example: - determination of skin sensitising properties of the test chemical by measurement of CD54 and CD86 expression in THP-1 cells after exposure to the CV75 concentration. - gather information on mode of action. - derive a point of departure.	Text area	FLEXIBLE_RECORD.IntermediateEffects.AdministrativeData.StudyObjectives
Data source	Data source (Literature Reference) – common block	Header 1	FLEXIBLE_RECORD.IntermediateEffects.DataSource
Effect identification	The effect has to be identified by providing a 'Process', 'Object' and	Header 1	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification

	'Action'. As a minimum, the 'Process' and 'Action' or the 'Object' and 'Action' must be identified. More than one combination can be provided (e.g. Cell Activation, CD54 molecule, increased & Cell Activation, CD86 molecule, increased). If both Process and Object are provided they have to be concordant with the chosen Action (e.g. both process and object are increased or decreased). See Yves et. al (2017) https://www.liebertpub.com/doi/10.1089/aivt.2017.0017 and the website https://aopwiki.org/ for the concept and its implementation in practice, respectively. If no suitable terms are available in picklist for Process and Object, please select 'Other' and introduce a new ontology- based term. Please consult the Ontology Lookup Service (OLS) to retrieve the terms that best describe the mechanisms you are reporting. OLS is a repository of the latest versions of biomedical ontologies and it is available at https://www.ebi.ac.uk/ols/index (Jupp S. et al. (2015) A new Ontology Lookup Service at EMBL-EBI. In: Malone, J. et al. (eds.) Proceedings of SWAT4LS International Conference 2015).		

	For each effect identified with a process, object and action (P/O/A), the results can be reported in the reporting section. Please use the following P/O/A for existing OECD test guidelines and methods. TG442C, DPRA and ADRA: protein binding / - / increase TG442D, Keratinosens: keratinocyte activation / aldo-keto reductase family 1 member C2 (AKR1C2) / increase TG442D, Lusens: keratinocyte activation / NAD(P)H dehydrogenase [quinone] 1 (NQ01) / increase TG442E, h-CLAT: cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase and cell activation / CD86 molecule / increase TG442E, U-SENS: cell activation / CD54 molecule (intercellular adhesion molecule 1) / increase TG442E, IL8 LUC: cell activation / interleukin 8 (IL8) / increase TG455, ERTA STTA, VM7Luc and ERα CALUX: nuclear receptor activity / estrogen receptor alpha / increase, agonism and nuclear receptor activity / estrogen receptor alpha / decrease,		

	antagonism TG456, H295R Steroidogenesis Assay: steroid hormone biosynthetic process / estradiol / alteration and steroid hormone biosynthetic process / testosterone / alteration TG458, ARTA STTA, AR-CALUX and 22Rv1/MMTV GR-KO: nuclear receptor activity / androgen receptor / increase, agonism and nuclear receptor activity / androgen receptor / decrease, antagonism TG493, hrER binding FW assay and CERI assay: Nuclear receptor binding / estrogen receptor alpha / binder–non binder		
P/O/A details			FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Details
Process	Process represents the dynamics of the underlying biological system (e.g., receptor binding) (Ives et al, 2017). The Process is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017). Select the process that best describes the mechanistic information observed or select 'other' to specify the Process and provide a term. Please consult the Ontology Lookup	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Details.Process

	Service (OLS) which is available at https://www.ebi.ac.uk/ols/index to choose a Process term. If possible please select as Process one term belonging to the following ontology Gene Ontology (GO). For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field. Cytotoxicity data should only be reported as a process (e.g. cell death) when it is the scope of the study to determine cytotoxicity. In cases where cytotoxicity is measured for supporting information e.g. for dose selection/elimination, it should not be considered as a process. Such data are reported as 'Other observations'.		
Object	Object represents the subject of the (biological) effect observed, for example, a specific biological receptor that is activated or inhibited The Object is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017, doi:10.1089/aivt.2017.0017). It is optional to record both Process and Object. If both Process	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Details.Object

	and Object are recorded they have to be concordant with the chosen Action. Select the object that best describes the subject of the effect observed or select 'other' to specify the Object and provide a term. Please consult the Ontology Lookup Service (OLS) which is available at https://www.ebi.ac.uk/ols/index to choose a Process term. If possible please select as Object one term belonging to the following ontologies protein Ontology (PR) or Chemical Entities of Biological Interest (ChEBI). For most terms there will be several options. It is therefore important to also copy the preferred ontology identifier into the remarks field. More than one object can be provided e.g. when changes of more than one biomarker is measured.		
Action	Action represents the type of effect observed e.g. "decrease" in the case where a receptor is inhibited to indicate a decrease in the signalling by that receptor. Action is also used to annotate Key events in the Adverse Outcome Pathway Wiki (https://aopwiki.org/) as described in Ives et al, 2017,	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Details.EffectAction

	doi:10.1089/aivt.2017.0017). Action is used together with the field Process and/or Object. The Action field is always required to describe the effect observed and it can form the following syntaxes "Process, Action" e.g. "gene expression, increase" or "Process, Object, Action" e.g. receptor activity, estrogen receptor, increase. Select the Action that best describes the effect observed or select 'other' to specify the action and provide a term		
P/O/A details			
Details on effect identification	Enter any relevant details concerning the Effect Identification. E.g. in case of selection of more than one triplet for "Process, Object, Action" or when a meaningful term was not found.	Text area	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.EffectDetails
Context	This repeatable block of fields allows for indicating in which target system (on organ level) the observed effect(s) play a role. This may be used in the AOP / MOA building as appropriate. Copy this block of fields for referring to different target systems if applicable. For a given system, multiple organs can be selected.		FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Context
System	Select the specific system where the observed effect(s) play	Open list	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Context.Syst

	a role. More than one 'Context' item can be created.		em
Organ	Select from the multiple drop-down list the target organ(s) addressed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Context.Organ
Remarks	Include any remarks as appropriate.	Text area	FLEXIBLE_RECORD.IntermediateEffects.EffectIdentification.Context.Remarks
Context			
Materials and methods		Header 1	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods
Method used	Indicate if the study was conducted according to a test guideline. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate 'equivalent or similar to guideline' in the 'Qualifier' field preceding the field 'Method used'.	Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed
Qualifier	Select appropriate qualifier, i.e.: - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if a guideline was not available or an available guideline was not used. If so, fill in field	Closed list	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.Qualifier

	'Principle of the method').		
Method used	The method names are only visible when 'according to guideline' is selected. In the remarks field, you can enter the specific test guideline (if applicable) and version number, In case 'equivalent or similar to guideline' was selected, provide any remarks as applicable, particularly: - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.MethodUsed
Deviations	In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of	Closed list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.Deviations

	the section MATERIALS AND METHODS.		
Principle of the method	For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template. The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application. The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.PrincipleOfTheMethod
GLP compliance	Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was	Closed list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.GLPCompliance

	followed.		
Other quality systems, standards or guidance followed	Indicate whether the study was conducted following a laboratory-specific quality system or standard such as the OECD guidance on Good In Vitro Method Practice (OECD GIVIMP). Other quality systems, not listed, may be added under 'other'. When selecting OECD GIVIMP, the submitter ensures that the following elements (if applicable) are documented and/or reported: The purpose of the study. Test and control items: The chemical name, CAS-number lot/batch number of the test and control items. The purity, stability homogeneity, solubility and solvent/vehicle of the test and control item was stated or is traceable according to information given regarding manufacturer and lot/batch number. In case of mixtures, the composition of different constituents. In case of nanomaterials, clear identification of the tested nanomaterial (e.g. particle size, shape, particle size distribution, surface area, coating). Test System: The in vitro test system (e.g. tissue or organ fragment / organ	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.OtherQualityFollowed

	explant/ dissociated cells / primary cells culture/ continuous or finite cell line/ stem cells/ complex culture system/ re-differentiated cells/ sub-cellular fractions like cytosol and microsomes/ proteins) was described, justified and characterised to confirm/authenticate the identity. The source or supplier of the test system. Metabolic competence of the test system was described. The number of passages of the test system used,. The test system mass, volume, or dimensions. The type of media used. The use of serum or animal free chemically-defined alternatives. The use of growth factors was described. The use of antibiotics. The incubation temperature, humidity and CO2. All measures taken to avoid or screen for contamination by mycoplasma, bacteria, fungi and virus were described. Apparatus, materials and reagents: The apparatus was described. The limit of detection or limit of quantitation of the apparatus. The materials and reagents. The culture dimensions (mm2 or ml). The use of animal-derived materials or reagents (e.g. Trypsin, antibodies, collagen, Matrigel etc.).		

	The use of fully animal-free materials and reagents. Test item treatment: The test item concentrations/dose levels. Biological fluid characterisation was described (quantification of proteins and cells/tissue present). Binding to biological fluid and culture material. Test system number, density, dimension, quantity used during treatment. The duration of treatment. The number of replicates per concentration/dose. The number of times the experiment was repeated (independent biological runs). Data collection and analysis: The experimental design and layout (e.g. plate layout) and relevant acceptance criteria. The time points for data collection. The effect of the test item on cytotoxicity was measured. Other observations that may impact the results (e.g. autofluorescence, absorbance by the test system). Details on calculation of results. All results were clearly presented, including negative and failed runs. The statistical methods and software used. A clear description on how to interpret read outs, evaluation/data interpretation criteria and criteria for decision-		

	making was given. Funding and competing interests: The funding sources for the study. Any competing interests were disclosed or it was explicitly stated that the authors did not have any competing interests. Information on the overall availability of the IPR protected components, including whether they are commercially available or require a Material Transfer Agreement or other licensing agreements. (See OECD Guiding principles on good practices for the availability/distribution of protected elements in OECD test guidelines).		
Attached background material			FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.AttachedBackgroundMaterial
Attached document	Attach any document that provides information on the method used, such as the SOP, protocol, QMRF or a scientific publication. Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Single file attachment	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.AttachedBackgroundMaterial.AttachedDocuments
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.MethodUsed.AttachedBackgroundMaterial.Remarks

Attached background material			
Test material	Test Material – common block	Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestMaterials
Test system		Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem
Type of test system	A test system is any biological, chemical or physical system or a combination thereof used in a study (OECD (2018), Guidance Document on Good In Vitro Method Practices (GIVIMP), OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris). Examples of physical chemical based test systems: serum protein, peptide, enzyme. Select complex biological test system for example in case of: 3D model, induced pluripotent stem cells, organ on a chip, co-cultures, etc. Select 'other:' in case you don't find a suitable option, for example when your test system is a test kit or a lower in vivo organism.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem.TestSystemType
Test system identity	The test systems listed are those from existing test guidelines. Select the test system used or select other and provide the test system identity. Furthermore, provide information on: - Source / supplier - Catalogue / batch	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem.TestSystemIdentity

	number - Species and strain (as relevant) of the origin of the test system. In case a co-culture of cell lines is used, or S9 mix or microsomes are used in combination with a cell line, the user is asked select 'other' and to provide the identity of all components under 'remarks'. In the later fields for 'details on the test system' and 'metabolic competence' the test system can be further described.		
Genetic modification of the test system	When applicable, provide the following information on the genetic modification: - Gene inserted - Gene species (e.g. human, rat, mouse) - Additional information on modification	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem.GeneticModOfSystem
Details of the test system	Freetext template: TEST SYSTEM DESCRIPTION Provide a short description of the test system, including (species, organ, tissue or cell type (e.g. human monocytoc leukemia cell line or human cryopreserved pooled liver tissue homogenate 9000 g fraction (S9): For cell lines: - Number of passages used, if applicable: - Cell cycle length, doubling time or proliferation index: - Measures taken for avoiding or screening for contamination by mycoplasma, bacteria,	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem.TestSystemDetails

	fungi and virus - Periodically checked for karyotype stability: [yes/no] - Differentiation performed [yes/no], describe: MEDIA USED and incubation conditions - Type and composition of media, including use of serum and antibiotics: - Incubation conditions such as CO2 concentration, humidity level, temperature, if applicable:		
Metabolic competence of the test system	Select the option that fits best and describe the knowledge about the metabolic competence (i.e. Phase I and/or II biotransformation capacity) of the test system under remarks. For example, when the test system used is cryopreserved human pooled liver tissue homogenate 9000 g fraction (S9) procured from a commercial supplier, select "metabolic activity, specify" and specify: contains phase I and II metabolic enzymes present in the microsomal (e.g. cytochrome P450s, Flavin-containing monooxygenase, uridine 5'-diphospho-glucuronosyltransferases, carboxylesterases) and cytosolic (e.g. sulfotransferases, glutathione S-transferases,	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestSystem.MetabolicCompetence

	methyltransferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase) fractions.		
Detection method		Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.DetectionMethod
Detection method used	Indicate the readout used. Select a detection method type from the picklist and provide the type of instrument (e.g. HPLC, Spectrophotometer, Flow cytometer) or chose 'other: and specify the type or equipment used / analysis performed.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.DetectionMethod.DetectionMethodUsed
Details on detection method	Quantitative analytical methods: 'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. "parent compound", "parent and transformation products" or "transformation product: .....") in matrices. Use free text template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report. Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.DetectionMethod.DetailsOnDetectionMethod

	"data collection method" and "enforcement method" see help text for field "Instrument / detector". Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Freetext template: Option 1: Semi or non-quantitative detection methods SEMI OR NON-QUANTITATIVE DETECTION METHODS Instrument type and model: Option 2 Option 2: Quantitative analytical methods QUANTITATIVE ANALYTICAL METHODS Instrument type and model: COMPOUND (ANALYTE): ... - Method ID: - Extraction solvent/technique: - Cleanup strategies: - Derivatisation (if any): - Instrument/detector (if further details): - Standardisation method: - Stability of standard solution: - Retention times: - Detection limit (Limit of Quantification) - Other: INTERFERING SUBSTANCE(S): STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS: PROBLEMS /		

	PRECAUTIONS: - Special problems encountered: - Precautions to be taken during: - analysis of samples: - handling of samples: - storage of samples: TOTAL TIME FOR COMPLETION:		
Test design		Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign
Test material preparation		Header 3	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.TestMaterialPreparation
Concentration selection of the test material	For data interpretation it is important to know on what basis the highest concentration tested was selected. Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment. Example for TG442E (h-CLAT) Highest concentration to be used is either of the following concentrations: - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.ConcentrationSelection

	for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium. - Maximum 1000 µg/mL for non-cytotoxic test chemicals that dissolve in DMSO and subsequently in medium. Any free text explanation can be given in the adjacent text field to justify the dose level selected.		
Vehicle / solvent	If a vehicle or solvent was used, select the relevant item or use 'other:' and specify. You can give further relevant information in the supplementary remarks field, e.g. lot/batch no., purity, concentration, etc. In case a solvent is used that is different from those recommended in the in vitro method Standard Operating Procedure or test guideline, a justification for the choice must be provided.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.Vehicle
Dilution steps / dose intervals	Indicate if the test material was further diluted before exposure of the test system. In case of dose range, provide the amount of concentrations and dilution factor. Example description: The test material was first diluted in 70% ethanol and subsequently diluted 500-fold in cell culture	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.TestMaterialPreparation.DilutionStepsDoseIntervals

	medium. Another 2-fold dilution was executed in the well to obtain a total of 1000-fold dilution and a final solvent concentration of 0.07%. Freetext template: DILUTION STEPS PERFORMED Provide the following information (where available): - Dilution steps from 'stock solution' in the vehicle/solvent including the final % of vehicle/solvent in the exposure medium - Dose intervals in case of dose range - Number of concentrations prepared		
Control and reference items		Header 3	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems
Controls / reference items used	Indicate whether controls / reference substances were used. If 'yes' is selected, the details can be entered in the repeatable block 'Controls / reference substances'.	Closed list	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceItemsUsed
Controls / reference items	Indicate whether solvent/vehicle controls, negative controls, true negative controls (i.e. negative reference substances) and/or positive controls (i.e. positive reference substances) were tested concurrently. Repeat this block of fields as necessary. In case of a robust study summary or as requested by the regulatory programme, also provide information		FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances

	in the supplementary remarks field, e.g. to the identity, supplier, lot and purity of the control substance(s) and the concentration / amount applied.		
Type of controls used	Select the type of control used to demonstrate the proper performance of the test system and therefore the validity of the experiments. More than one control/reference item can be provided. See (GIVIMP, OECD guidance document 286 in the series on testing and assessment). Solvent / vehicle controls consist of solvent or vehicle alone, without test item (test material), and otherwise treated in the same way as the treatment groups. Negative / untreated controls consist of culture medium without solvent / vehicle or test item, and otherwise treated in the same way as the treatment groups. True negative controls include items (e.g. chemicals) with known lack of activity. Positive controls include items with known activity. Reference items are substances with known activity, used as basis for comparison with the	Open list	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.TypeOfControls

	test item (test material).		
Description of reference and control items used	Select the reference or control item used or provide the name and identifier (e.g. CAS number), and in the remarks field the purity and concentration (range) used. If 'other:' is selected, provide the name and identity (CAS number) in the additional text field. For each selection (including the 'other:'), provide purity (%) and concentration (range or single concentration) in the field 'Remarks'	Open list with remarks (2000)	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.ControlOrReferenceItemsUsed
Remarks	Additional information, such as solvents used.	Text area	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ControlAndReferenceItems.ControlsReferenceSubstances.Remarks
Controls / reference items			
Experimental conditions		Header 3	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ExperimentalConditions
Number of replicates	Provide the number of replicates per concentration and the number of independent experiments performed. For each experiment, valid or invalid, results should be reported. NUMBER OF REPLICATIONS: - Number of replicates per concentration (single, duplicate, triplicate) - Number of independent	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ExperimentalConditions.NumberOfReplicates

	experiments		
Experimental conditions	Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD Programme, Pesticides NAFTA or EU REACH) thereof. Concentration of biological test systems is usually expressed as cell density (amount of cells/cm2 or cells/ml seeded) or confluence (%). Concentration of physical chemical test systems is usually expressed in mg/ml or molarity. Incubation conditions are e.g. temperature, CO2, concentration, humidity level, etc. A vessel can e.g. be a test tube or cell culture plates with 24, 96 or 384 wells. Freetext template: METHOD OF TREATMENT/ EXPOSURE:	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ExperimentalConditions.ExperimentalConditions

	- Concentration of the test system (e.g. cell density or number of cells used) - Description how the test material was added to the test system (e.g. in medium, in suspension) TREATMENT AND HARVEST SCHEDULE: - Pre-incubation period, if applicable - Exposure duration / duration of treatment - Frequency of administration, e.g. single, repeated or continuous - Harvest time after the end of treatment (sampling/recovery times) - Incubation conditions - Vessel type used for exposure - OTHER:		
Additional analysis: e.g. cytotoxicity assay or other	This picklist was established on basis of GIVIMP annex I (OECD, 2018). Select the viability assay used to measure cytotoxicity: Select 'other cytotoxicity assay' in case another type of cytotoxicity assay was used. Select 'other type of analysis' in case another or another type of analysis was performed that is important for the	Closed list with remarks (2000)	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.ExperimentalConditions.AdditionalAnalysis

	interpretation of results (e.g. pH, autofluorescence, etc.). In the remarks field any additional information can be provided.		
Data analysis		Header 3	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.DataAnalysis
Acceptance criteria for the test material results	Acceptance criteria: Criteria for when results can be accepted, i.e. a set of well-defined parameters describing aspects of the method such as range for positive and negative controls (GIVIMP, OECD, 2018). For cell-based methods, the acceptance criteria should include the level of cytotoxicity or other type of interference that is accepted / not accepted. Any free text explanation can be given to specify which criteria exist for acceptance of results, e.g. related to reference and control substances or vehicle/solvent control, cytotoxicity or other interference, capturing of full dose-response, minimum/maximum response to be observed or outliers. Freetext template: Provide a description or list of the study acceptance criteria:	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.DataAnalysis.AcceptanceCriteria

Data calculation and statistics	Provide the method used to calculate the results from raw data to the parameters calculated, such as normalisation, use of calibration curve, subtraction of control values, calculation of averages, Standard deviations etc. List the statistical methods used to derive the parameters to be reported. Include a statement on the appropriateness of the statistical analysis used. Parameters, their explanation and values should be provided in the "Test results" section. Example of data calculation and statistical analysis performed: Relative Light Units raw data were copied to commercially available software Graphpad Prism for hill curve fitting (variable slope, four parameters). Subsequently, the EC50 value and its CV were calculated. Specify if outlier analysis is performed and what (statistical) method was used to exclude values. Calculations performed - Statistical methods used - Where relevant,	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.DataAnalysis.DataCalculationAndStatistics

	provide the method used to exclude outliers.		
Evaluation / data interpretation criteria	Describe the evaluation criteria used in the study to judge if the test material is positive, negative or equivocal. For example: When there is more than 10% binding to the androgen receptor (as expressed in relative light units) for more than two concentrations, the result is 'positive'. h-CLAT: When the RFI of CD86 is equal to or greater than 150% in at least one tested concentration (with cell viability ≥ 50%), the result for the test material is positive. The EC150 value is calculated where possible. DPRA: The mean of cystein and lysine depletion is: Less than 6.38%: minimal reactivity. Between 6.38% and 22.62%: low reactivity Between 22.62% and 42.47%: moderate reactivity. More than 42.47%: high reactivity. Consider also precipitation and co-elution.	Text template	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.TestDesign.DataAnalysis.EvaluationDataInterpretationCriteria

	Evaluation / data interpretation criteria: - Results will be expressed as:		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Here you may for example provide details on specific material or reagents used. In case of TG442E, h-CLAT you could provide the information on the type of antibodies used, as these are essential components of the method	Header 2	FLEXIBLE_RECORD.IntermediateEffects.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion
Test results		Header 2	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults
Test results	Report the parameters obtained and effective concentration(s) for the type of effect specified in the 'Test results' fields. Copy this field block for entering more than one experiment if necessary, e.g. for a test guideline or if different concentration ranges were tested. One experiment may include more than one replicate for each tested concentration. An independent experiment is usually carried out with independently prepared controls, test system, reagents used for analysis and on a different time.		FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults

	Set this flag if a key observation should be identified for the conclusion section.		
Details of the effect identification	Select the relevant item of effect identification details indicated under 'Details'.	Link to repeatable entry	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.DetailsOfTheEffectIdentification
Key result	Set this flag if a key observation should be identified for the conclusion section.	Check box	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.KeyObservation
Concentration selection of the test material	For data interpretation it is important to know on what basis the highest concentration tested was selected. Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment. Example for TG442E (h-CLAT) Highest concentration to be used is either of the following concentrations: - 1.2-fold the CV75 concentration of the test chemical, i.e. the concentration where 25% of the cells is dead. - Maximum 5000 µg/mL for non-cytotoxic test chemicals that dissolve or stably disperse in the solvent saline and subsequently in medium.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationSelection

	- Maximum 1000 µg/mL for non-cytotoxic test chemicals that dissolve in DMSO and subsequently in medium. Any free text explanation can be given in the adjacent text field to justify the dose level selected.		
Concentration range tested	Indicate the lowest and highest concentration tested. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ConcentrationRangeTested
Number of replicates and outliers	Specify the number of replicates per concentration and if any values were excluded after outlier analysis. - Number of replicates: - Information on outlier removal: - Impact of outlier removal on the results:	Text template	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.NumberOfReplicatesAndOutliers
Parameter and result			FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult
Parameter	This picklist displays either the parameters specific to the selected method, or general parameters in case another method is used. Provide the relevant parameters, representative of the	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult.Parameter

	effect measured, that are calculated for your method. Existing test guidelines and OHTs for in vitro methods (e.g. OHT 66-1) may provide additional suggestions for other type of parameters. For guideline methods, all relevant parameters are listed. In case of a non-guideline method, the listed parameters are from existing OECD test guidelines, where the use of the parameters is explained. E.g. CV75 is the test chemical concentration that results in 75% cell viability. The PC value is obtained by interpolation in case a full dose response is not obtained for the test material. Provide in the remarks field, other information that provides explanation of the parameter. E.g. when % depletion is selected, provide information on what is depleted (e.g. cysteine, lysine, etc.). Explanation of some parameters: EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at the limit (e.g. 1.5, 150 or 200) prescribed by the method used.		

	No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment. Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed. PC10, 50, 80 represents the concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated.. CL, in vitro, INT is in vitro intrinsic (metabolic) clearance.		
Result for the parameter	Provide the result for the selected parameter and select the appropriate unit.	Unit measure with Open List (Decimal)	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ParameterAndResult.ParameterResult
Parameter and result			
Other observations			FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation
Observation	Indicate other observations that are important for results interpretation such as information on cytotoxic	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Observation

	concentrations, precipitation observed at specific concentrations, other parameters measured. Specify the observation and respective test concentration(s). Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. '… see Table 1'). Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.		
Concentration	Provide the result for other observations and select the appropriate unit.	Range with open list (Decimal)	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.OtherObservation.Concentration
Other observations			
Results for the test material	The options in the picklist are derived from existing in vitro OECD test guidelines. Indicate the result of the test conducted. In the remarks field additional information can be added. For example when selecting binder additional information could be 'competitive', 'non competitive', 'specific' or 'non-specific'. Example of results from TG442C, DPRA: - Minimal reactivity - Low reactivity - Moderate reactivity - High reactivity	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.ResultsForTheTestMaterial
Acceptance of results	Select the element for which acceptance	Multi select open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.Results

	criteria exist and indicate in the remarks field if the results are valid or invalid. In case results are invalid, please describe in the next field 'Remarks on results' why the result is invalid (e.g. precipitation observed, toxicity of the test material, co-elution with the peptide, etc.), and what is the impact of invalid data on the results.		AndDiscussion.TestResults.TestResults.AcceptanceOfResults
Remarks on results	This field can be used for: - explaining expert judgement, in case it was applied; - providing a justification; - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - providing information in case a result may be over-estimated or under-estimated; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; - explaining the impact on the results in case one or more acceptance criteria were not met;	Text area	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.RemarksOnResults

	- any additional information.		
Attached material			FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial
Type of attachment	Choose the type of document from the picklist or select 'other:' For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here or in the overall results section. Upload file(s) containing data or results by clicking the 'Select files' button. As appropriate, enter any additional information, e.g. language. The file name and the filename extension is displayed after uploading the document.	Multi select open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.AttachmentType
Attachment	Attach the document indicated in the field "Type of attachment".	Single file attachment	FLEXIBLE_RECORD.IntermediateEffects.ResultsAndDiscussion.TestResults.TestResults.AttachedMaterial.Attachment
Attached material			
Test results			
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	FLEXIBLE_RECORD.IntermediateEffects.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion
Overall results and conclusion	Provide the overall result for the test material, on basis of one or more experiments and all observations reported in this template. Convey a clear statement on the	Text template	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.OverallResults

	mechanistic information obtained. Add the effect concentration in the next fields. Example from h-CLAT: The RFI of CD86 is greater than 150% at 2 tested concentrations (with cell viability ≥ 50%) in 2 of 2 experiments. Therefore the test material is activating dendritic cells and is a possible skin sensitizer.		
Type of result	Indicate if the results are qualitative when the result is yes/no or positive/negative or quantitative when dose-response information is obtained and an effect level (concentration) can be determined.	Closed list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.TypeOfResult
Effect concentration	Where available, provide the effect concentration taking into account results from more than one experiment. Explanation of some parameters: EC 1.5, 150 and 200 represents the concentration where the test material triggers the effect at the limit (e.g. 1.5, 150 or 200) prescribed by the method used. No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.	Open list with remarks	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.EffectConcentrationChoice

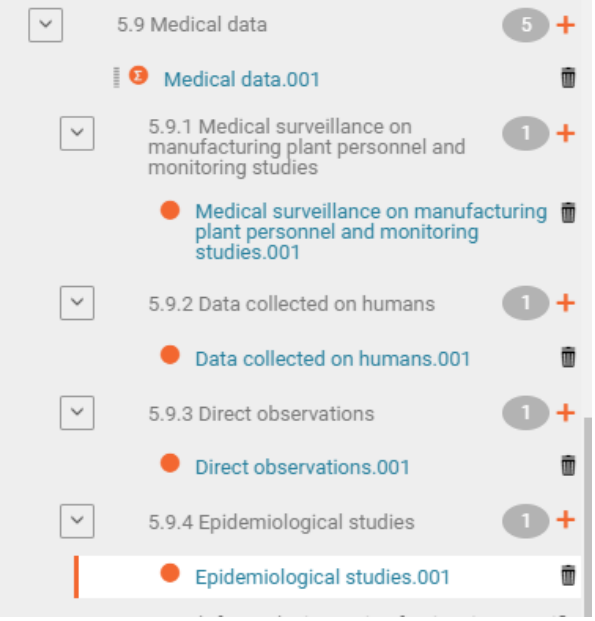
	Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed. PC10, 50, 80 represents the concentration of a test material where the response is 10, 50 or 80% of the response induced by the reference chemical. PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated.		
Concentration	Provide the effect concentration and select the appropriate unit.	Range with open list (Decimal)	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.InterpretationOfResultsObservations.Concentration
Executive summary	If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective free text template if available from the drop-down list or copy it from the corresponding document. You may also provide information on other existing data or studies that confirm the results obtained.	Header 2	FLEXIBLE_RECORD.IntermediateEffects.ApplicantSSummaryAndConclusion.ExecutiveSummary

	Consult the programme-specific guidance (e.g. EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009; OECD HPVC, Pesticides NAFTA or EU REACH) thereof.		

5.9 Medical data

The following documents are located under section 5.9 'Medical data'

- 5.9 Medical data – Endpoint summary
  - 5.9.1 Medical surveillance on manufacturing plant personnel and monitoring studies – Endpoint study record
  - 5.9.2 Data collected on humans – Endpoint study record
  - 5.9.3 Direct observations – Endpoint study record
  - 5.9.4 Epidiomiological studies – Endpoint study record



5.9 Medical data – Endpoint summary

Purpose:
Where available and without prejudice to Article 10 of Council Directive 98/24/EC (1), practical data and information relevant to the recognition of the symptoms of poisoning and on the effectiveness of first aid and therapeutic measures shall be submitted. Such data and information shall include reports of any studies investigating antidote pharmacology or safety pharmacology. Where relevant, the effectiveness of potential antagonists to poisoning shall be investigated and reported.
Data and information relevant to the effects of human exposure, where available, shall be used to confirm the validity of extrapolations made and conclusions reached with respect to target organs, dose-response relationships, and the reversibility of adverse effects. Such data may be generated following accidental, occupational exposure or incidents of intentional self-poisoning, and shall be reported if available.
The document should contain the information needed to be reported according to the list of end points for medical data SANCO/12483/2014– rev. 3 (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-list-endpoints_rev-3.pdf?)
Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide brief description of relevant studies and effects e.g. Limited; new active substance,-no detrimental effects on health in manufacturing personnel. For example: - Limited; new active substance, - no detrimental effects on health in manufacturing personnel	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ExposureRelatedObservationsHumans.Discussion

5.9.1 Medical surveillance on manufacturing plant personnel and monitoring studies– Endpoint study record

Purpose:
Reports of occupational health surveillance programs and of monitoring studies shall be submitted, supported with detailed information on the design of the programme, the number of exposed persons included in the programme, the nature of their exposure to the active substance, and their exposure to other potentially hazardous agents. Such reports shall, where feasible, include data relevant to the mechanism of action of the active substance. These reports shall, where available, include data from persons exposed in manufacturing plants, or during or after application of the active substance (for example from monitoring studies in operators, workers, residents, bystanders or victims of accidents). Available information on adverse health effects including allergenic responses in workers and others exposed to the active substance, shall be provided, and include where relevant details of any incident. The information provided shall, where available, include details of frequency, level and duration of exposure, symptoms observed and other relevant clinical information.

ENDPOINT_STUDY_RECORD.HealthSurveillanceData			
Name	**Instructions**	**Type**	**Filed Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods
Study type	Indicate the appropriate study type. Optionally, include details in the supplementary remarks field. Definitions: - Biological effect monitoring: involves the measurement of a biological change that is non-adverse and reversible (in contrast to medical monitoring), e.g. liver toxicity biomarkers (i.e. activity of aminotransferase and other enzymes). - Biological exposure monitoring: measurement of biomarkers to assess the exposure from	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.StudyType

	dietary, environmental or occupational sources. Biomarkers of exposure include either the measurement of levels of chemical agents and their metabolites in body fluids, tissue, cells or excreta, or the measurement of biological responses such as cytogenetic and reversible physiological changes in the exposed individuals. - Health record from industry: a review of medical records and occupational exposure.- Health record, other: any other review of medical history and records (e.g. exposed non-occupational). - Medical monitoring: aims to measure early signs and symptoms of adverse effects for preventive reasons. - Medical screening: method for detecting disease or body dysfunction before an individual would normally seek medical care. Aim: early diagnosis and treatment. - Other: any other type of study or information, e.g. self-reported symptoms.		
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.EndpointAddressed

	NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.		
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Include detailed information on the design of the health surveillance programme and exposure to the substance in question and to other chemicals. Include or attach tables as appropriate.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.Method.DetailsOnStudyDesign
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillance

			Data.ResultsAndDiscussion
Results	Describe the results of the health surveillance study. In addition, include or attach tables and/or an excerpt from the study report.	Text area	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.HealthSurveillanceData.ApplicantSummaryAndConclusion

5.9.2 Data collected on humans – Endpoint study record

Purpose:
Where available, reports from studies with humans, such as tests on toxicokinetics and metabolism, or tests on skin irritation or skin sensitisation, shall be submitted. In general, the reference values shall be based on animal studies, but if appropriate scientifically valid and ethically generated human data are available and show that humans are more sensitive and lead to lower regulatory limit values, these data shall take precedence over animal data.

ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods
Type of study / information	Briefly indicate the type of information (which does not fit into any of the specific chapter.)	Multi-line text	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TypeOfStudyInformation
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the	Multi	ENDPOINT_STUDY_RECORD.ExposureRelatedObserva

	endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	select open list	tionsOther.MaterialsAndMethods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.TestMaterials
Method		Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Describe the study design including any relevant information from a study report, publication or other source. Include or attach tables or excerpts from study report as appropriate.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnStudyDesign
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE	Text template	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.Method.DetailsOnExposure

	GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion
Results	Provide exposure data as available and describe any relevant outcome of the study. If appropriate present the data in tabular form and/or attach excerpt(s) from the study report.	Text area	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.Results
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ExposureRelatedObservationsOther.ApplicantSummaryAndConclusion

5.9.3 Direct observations – Endpoint study record

Purpose:
Available reports from the open literature, relating to clinical cases and poisoning incidents, where they are from refereed journals or official reports, shall be submitted together with reports of any follow-up studies undertaken. Such reports shall, where available, contain complete descriptions of the nature, level and duration of exposure, as well as the clinical symptoms observed, first aid and therapeutic measures applied and measurements and observations made. L 93/32 Official Journal of the European Union 3.4.2013 EN (1) OJ L 131, 5.5.1998, p. 11. Where supported with the necessary level of detail, such documentation shall be used to confirm the validity of extrapolations from animal data to man and to identify unexpected adverse effects which are specific to humans.

ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.AdministrativeDat

			a
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods
Study type	Select type of medical data.	Open list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.StudyType
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.TestMaterials
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.TypeOfPopulation
Subjects	Describe the subject(s) examined based on the freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.Subjects
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.EthicalApproval
Route of exposure	Indicate the route of exposure. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.RouteOfExposure
Reason of exposure	Indicate the reason of exposure.	Open list	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.ReasonOfExposure
Exposure	Indicate whether the exposure was measured or	Closed	ENDPOINT_STUDY_RECO

assessment	estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	list with remarks	RD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Describe type and incidence of exposure including quantitative data if available, i.e. state if single or multiple exposure, duration, exposure concentrations (if inhalation), amount of substance ingested, dermal contact etc. Include methods of analysis if data available. If exposure was estimated, describe how this was done, if available.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.DetailsOnExposure
Examinations	Indicate type of examinations performed and at what time after start of exposure. Use freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.Examinations
Medical treatment	Indicate if and what medical treatment exposed / intoxicated persons received.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.Method.MedicalTreatment
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscussion
Clinical signs	Describe any relevant signs and symptoms observed.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscussion.ClinicalSigns
Results of examinations	Describe the results of examinations based on freetext template (delete/add elements as appropriate). As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscussion.RsExaminations
Effectivity of medical treatment	Indicate whether and during what time intoxicated persons responded to medical treatment.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscussion.EffectivityMedicalTreatment
Outcome of incidence	Describe the clinical manifestation of signs and symptoms, partial or total recovery after what time etc. If reported, give data on any follow-up examinations.	Text area	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscussion.Outcome
Any other information on	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ResultsAndDiscus

results incl. tables			sion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.DirectObservationsClinicalCases.ApplicantSummaryAndConclusion

5.9.4 Epidemiological studies – Endpoint study record

Purpose:

Provide data of relevant epidemiological studies, if available.

ENDPOINT_STUDY_RECORD.EpidemiologicalData			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.DataSource
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods
Study type	Select appropriate study type.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.StudyType
Endpoint addressed	If the study recorded gives useful information on one or several of the classic endpoints, select the endpoint(s) addressed from the picklist. Multiple selection is possible. If not listed, select 'other' and specify. NOTE: The list of endpoints provided is a generic list. Some endpoints may not be applicable for the type of study summarised in this record.	Multi select open list	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.EndpointAddressed
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.TestMaterials
Method		Hea	ENDPOINT_STUDY_R

		der 2	ECORD.EpidemiologicalData.MaterialsAndMethods.Method
Type of population	Indicate whether subjects of the general population and/or from an occupational environment were investigated. If two independent studies are reported by the same report, use two separate records.	Multi select open list	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.TypeOfPopulation
Ethical approval	Where ethical approval is required, indicate whether and what kind of consent was received from the persons studied. Include details in the supplementary remarks field. If 'not applicable' or 'no' is selected, give reasoning as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.EthicalApproval
Details on study design	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. Explanations: - HYPOTHESIS TESTED: If study type is cohort or case control study, state the hypothesis(es) tested in this study. - STUDY PERIOD: Give dates during which the data were collected (from ... to ...) - SETTING: Indicate the setting where this study took place, e.g., occupational, residential, hospital-based, clinical practice, environmental (e.g., fenceline of waste sites, air monitoring); its geographic location(s); and any other pertinent information. - STUDY POPULATION: Include details on the study population using the predefined items and inserting additional ones if required. Alternatively include or a attach a table and refer to respective Table no. - COMPARISON POPULATION: Indicate one of the predefined types; delete those being not applicable. Provide details, e.g., note the parameters that were 'matched' (i.e., smoking, age, sex, etc.). - HEALTH EFFECTS STUDIED: Describe as appropriate. Note whether the diagnosis of the effects was made blind to exposure status. Alternatively include or a attach a table and refer to respective Table no.	Text template	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.DetailsOnStudyDesign
Exposure assessment	Indicate whether the exposure was measured or estimated. For robust study summaries or as requested by the regulatory programme, provide further details in the following freetext field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.ExposureAssessment
Details on exposure	Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from	Text	ENDPOINT_STUDY_RECORD.Epidemiologic

	the study report. Explanations: - TYPE OF EXPOSURE: Characterise type of exposure including information on manufacturing / processing / use as applicable. If available, describe special exposure situations / workplaces. - TYPE OF EXPOSURE MEASUREMENT: Indicate relevant predefined type(s); delete those being not applicable. - EXPOSURE LEVELS: Give exposure level(s) reported (with units) or insert/attach table, for several exposure conditions and levels. - EXPOSURE PERIOD: Describe when subjects were exposed and duration of exposure, i.e., hours, hours per day, days, days per week, weeks, months, years, person years, other. - POSTEXPOSURE PERIOD: State period of time elapsed between last exposure/first examination or time study was conducted. - DESCRIPTION / DELINEATION OF EXPOSURE GROUPS / CATEGORIES: If several exposure groups (e.g. different concentrations or durations) are analysed, identify the exposure groups or categories, number of subjects within each group, sex, other categorical descriptions, etc.	tem plat e	alData.MaterialsAndMethods.Method.DetailsOnExposure
Statistical methods	Describe all statistical methods used and the data to which they were applied (include sample size and power calculations, if available).	Mul ti-line text	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.Method.StatisticalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Hea der 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Hea der 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion
Results	Provide exposure data as available. Give numbers of cases for each effect/disease/parameter under consideration, include measures of disease frequency (SMRs, ORs, PMRs, RR, prevalence, incidence, adjusted and/or crude rates), correlations, distributions etc., statistical data (significance, confidence intervals). If appropriate present the data in tabular form. Upload predefined table in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').	Tex t tem plat e	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.Results
Confounding factors	Indicate any (possible) confounding factor(s), e.g. multi chemical exposure or smoking, and discuss their influence on the observed causal association.	Tex t are	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDis

		a	cussion.ConfoundingFactors
Strengths and weaknesses	Explain findings and discuss any other factors, i.e. bias, validity issues, reliability issues (including the adequacy of the exposure estimation or measurements), representativeness concerns, unique nature of study, influence of past exposures, latency, turnover rates in occupation studies.	Text area	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.StrengthsWeaknesses
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.EpidemiologicalData.ApplicantSummaryAndConclusion

Section 6: Residues in or on treated products, food and feed

General note on instructions for section 6: please follow the instructions of the common blocks by clicking on the reference link, **unless specific instructions are provided.**

6. Residues in or on treated products, food and feed - Endpoint summary

Purpose:
Provide an overall conclusion on the residues information submitted in Section 6 and to address any points where a suitable sub-section could not be identified. This summary can also be useful for specific MRL purposes of application, such as "include an active substance in Annex IV".

ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary

		Confidentiality	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Description of key information	Please report here an overall narrative summary of the residue section. Indicate whether all data requirements were fulfilled in all sub-sections of Section 6. Should it not be the case, please indicate the main deviations/missing data/substantive arguments that support the overall conclusions of the residue section. For MRL applications, this rich text field should be used by the applicant to report, in accordance with article 7 1b of Regulation 396/2005, a presentation of the application dossier including: (i) a summary of the application; (ii) the main substantive arguments. In this rich text field, you may also address any points where a suitable sub-section could not be identified. For example, this can be useful for specific purposes for MRL application (e.g. include an active substance in IV") or for any other specific cases for which the standard endpoint summaries may not be fully suitable. However, there is no need to repeat tables and summaries that are duly	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation

	reported in the respective endpoint summaries of the detailed sections. For example, residue trials data selected to derive and propose a MRL shall be reported in Section 6.3.		
		Rich text area	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion
		Rich text area	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	You can attach here any useful document that support the above statement. However, do not repeat the attachments that are already reported in the respective endpoint summaries of the detailed sections. For example, the MRL OECD calculator.xls shall be reported in Sections 6.3 and 6.7.2, but not here.		
Attached (sanitised) documents for publication	Same as above with sanitized version for the document(s).	Attachments list	ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs.Discussion.AttachedSanitisedDocsForPu

			blication

6.1 Storage stability of residues – Endpoint summary

Purpose:
Provide a summary overview of the demonstrated freezer storage stability period per compound per matrix and to conclude whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application.

ENDPOINT_SUMMARY.StabilityResiduesCommodities			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommodities.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.StabilityResiduesCommodities.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommodities.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study (or studies) from which the key value(s) for the storage stability of residues is/are derived.	Endpoint reference list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.StabilityResiduesCommodities.LinkToRelevantStudyRecord.Results
Description of key information	Please make a statement as to whether the storage stability of residues in matrices of plant and animal origin was sufficiently elucidated in the context of the present application (according to the relevant data requirements and OECD test guidelines 506) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed	Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation

	parameters on the available key studies used for risk assessment should be reported in the detailed blocks below (one repeatable block for "storage stability - plant" and one repeatable block for "storage stability - animal"). If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it in each study row below (field remarks).		
		Rich text area	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.KeyInformation
Storage stability - plant	Repeat this block to create one row per key result (e.g. one row for each combination stability matrix/compound(s) covered with the most critical storage stability conditions.		ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant
Category	Select the matrix to which the key results apply (e.g. commodities with "high water content"). Category defined according to OECD TG 506.	Open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Category
Commodity	Indicate the commodity(ies) tested in the study (multi-selection is possible).	Multi select open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Commodity
Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, report it in different rows. If the	Text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.CompoundSCovered

	sum of parent and metabolites was tested for stability, specify it in this field.		
Substance(s)	Link (cross reference) to the substance(s) indicated in the above field.	Entity reference list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.SubstanceS
Temperature (°C)	Indicate the temperature tested in the study (e.g. -18°C).	Decimal	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Temperature
Tested period (lenght of the study)	Enter the entire period (as number) for which stability of the compounds was tested. The preferred reporting unit is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If the period is lower than one month, report in full days. Example: If the study investigated storage stability for 24 months but residues are only stable for 12 months, please report 24 months in the present field.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.TestedPeriod
Demonstrated stability period	Enter the entire period (as number) for which stability of the compounds was tested. The preferred reporting unit is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If the period is lower than one month, report in full days. Example: If the study investigated storage	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.DemonstratedStability

	stability for 24 months but residues are only stable for 12 months, please report 24 months in the present field.		
Remarks	Add here any relevant information on the preparation of the samples and/or on any specific storage conditions for which stability has been shown. Examples for additional comments: - Mode of fortification, e.g. whole commodity or homogenised; - Analysis of fortified samples or samples from metabolism studies with incurred residues; For specific cases, e.g. stability of sum of compounds sharing common moiety, use the same field to explain.	Multi-line text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityPlant.Remarks
Storage stability - plant			
Storage stability - animal	Repeat this block to create one row per key result (e.g. one row for each combination animal commodity(ies)/compound(s) covered with the most critical storage stability conditions. Fields and instruction are the same as for storage stability in plant matrices.		ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal
Category		Open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.Category
Commodity	Commodity(ies) covered by the stability study(ies).	Multi select open list with remarks	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.Commodity

Compound(s) covered	Indicate which compound(s) were tested for storage stability. If parent and metabolites were tested independently, report it in different rows. If the sum of parent and metabolites was tested for stability, specify it in this field.	Text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.CompoundSCovered
Substance(s)		Entity reference list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.SubstanceS
Temperature (°C)		Decimal	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.Temperature
Tested period (lenght of the study)		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.TestedPeriod
Demonstrated stability period	Enter the period (as number) for which stability of the compounds was demonstrated. The preferred reporting format for storage stability is months (m). Enter data using one decimal point, e.g. 244 days would be 3.8 months using an average of 30.4 days per month. If stability is lower than one month, report in full days.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.DemonstratedStability
Remarks		Multi-line text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.KeyInformation.StorageStabilityAnimal.Remarks
Storage stability - animal			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.StabilityResiduesCommod

			ities.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		
Attached (sanitised) documents for publication	Add any additional document that supports the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY.StabilityResiduesCommodities.Discussion.AttachedSanitisedDocsForPublication

6.1 Storage stability of residues – Endpoint study record

Purpose:
The aim of these studies is to demonstrate the time period for which stability has been shown in representative commodities from crops, by extrapolation to processed fractions derived from crops, and products of animal origin.

ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataProtec

			tion
Endpoint	Select from picklist the relevant endpoint (here 'stability of residues in stored commodities').	Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.Admin

			istrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.StabilityOfResidues

			InStoredCommod.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than		Text template	ENDPOINT_STUDY_RECORD.StabilityOfResidues

guideline			InStoredCommod.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.GLPComplianceStatement
Test material		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Indicate if labelled or non-labelled test material was used. Generally, stability studies are carried out with non-labelled test material. In this case, please indicate "No" in this field. In the rare cases where the commodities used for stability study were obtained from metabolism studies using radiolabelled material, please indicate "Yes" in this field.	Open list with remarks	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.Materi

			alsAndMethods.StudyDesign
Bulk raw agricultural commodity (RAC)	Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term RAC means the same as "primary food commodity" or "primary feed commodity". Indicate here the raw agricultural commodity name or the nearest name equivalent to the commodity description being used in the study. If not available, select 'other:' and specify commodity(ies) on which storage stability test was performed. Please note that the codes and names of raw agricultural commodities currently contained in the picklist are extracted from the Codex Classification of Foods and Animal Feeds, issued by the Joint FAO/WHO Food Standards Programme. This will be improved in the next IUCLID release to match the classification used in the EU PPP Regulation. Meanwhile, please select the nearest name equivalent to the commodity description	Multi select open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.Commodity

	being used in the study.		
Details on stored commodities	Provide detailed description of commodities / matrices stored (whether raw or processed).	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.DetailsOnStoredCommodities
Storage conditions	Specify the main storage conditions such as freezer type (e.g. deep-frozen room), freezer temperature (e.g. -18°C), length of storage (e.g. 24 months), commodity form (e.g. extract, macerate, homogenized) and detailed conditions (e.g. dark or potential control condition including any special storage conditions, e.g. stabilizer added, humidity control, acid or base, lighting, container types/size, sample sizes/weight(s), etc. Use "insert existing templates" and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.StudyDesign.StorageConditions
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample collection	Include details on sampling time (age of raw commodity in days at each sampling time), number of samples/replicates. Use "insert existing templates" and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	Studies may be either performed on samples from treated crops or animals with incurred	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.Samplin

	residues or by fortification experiments. In the latter case, aliquots of prepared control samples shall be spiked with a known amount of chemical before storage under normal storage conditions. Include details on the sample handling and preparation. The following information should be addressed: Handling and shipping of commodities, any preparation done prior to extraction (e.g. homogenised samples). It should be clear whether samples contain incurred residues or if samples were spiked/fortified with the active substance/metabolites; whether samples were homogenised or not. Use "insert existing templates" and delete/add elements as appropriate. E.g. *RAC* samples were homogenized and fortified with *test material* at about *X* mg/kg.		gAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Details on analytical methodology	Provide details on the analytical method, i.e. describe methods fully or reference them if previously submitted. It may be sensible to outline the analytical methodology in Section 'Analytical methods'. If the method is already reported in the Section 'Analytical methods', reference to the corresponding endpoint	Text template	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	study record (UUID) is sufficient.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion
Residue levels	Option 1: Possibility to use the repeatable block to specify the residue level of each analyte determined for a given commodity at each sample date. Copy this block of fields for recording the results of multiple samplings. Option 2: If more convenient, you may skip this block and directly report the detailed results in the field below "Any other information on the results including tables". In such a case, simply copy/paste free text and Table(s), according to		ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels

	the recommended templates for this type of study.		
Test commodity		Open list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.TestCommodity
Other details on test commodity		Multi-line text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.OtherDetailsOnTestCommodity
Date of sample		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.DateOfSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.AnalysisDate

Method ID		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MethodID
Residue level		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevel
Mean residue level		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevel
Residue level (% of nominal spiking level)		Range (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ResidueLevelOfNominalSpikingLevel
Mean residue level (% of nominal spiking level)		Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanResidueLevelOfNominalSpikingLevel
Procedural recovery control (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.ProceduralRecoveryControl
Mean procedural recovery control (%)		Decimal	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.ResidueLevels.AnalyteMeasured.MeanProceduralRecoveryControl
Analyte measured			
Residue levels			
Storage stability of residues (Sample Integrity)	Briefly describe the conditions, which residues of [parent and/or metabolites]	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.Storage

	appeared to be [stable or [decreased or increased] by [percentage]]. Example: The residue of [parent and/or metabolites] decreased slowly with time. After [x months] of storage it amounted to [XX]% of the initial value and after [y months] of storage it amounted to [YY]% of the initial value Please make one statement per commodity. (Optional) Provide graph of residue stability in matrix as applicable as percent recovery over time, in an attachment (in the block below).		Stability
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on the results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each analyte determined for a given commodity at each sample date, please report the detailed results here, in	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation

	one or several table(s). Please use the recommended formats available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.1]. Repeat the tables as much as necessary. NB: According to OECD 506 guidance correction for day zero recovery and/or procedural recovery is not recommended. Other formats can be used provided that all information requested in OECD TG 506 is reported and that they are readable by the system.		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background			

material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document. Example: Samples of [ground or whole crop/matrix] were fortified with [analytes] at a level of [fortification level] and put into storage at [temperature]. At intervals of [xx, yy, and zz] months, stored samples and freshly fortified samples were analyzed for residues of [list analytes]. At each storage interval, [analytes] were	Rich text area	ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod.ApplicantSummaryAndConclusion.ExecutiveSummary

	determined using Method [Method ID], a [describe method]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg (ppm), thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices]. Under these conditions, residues of [active ingredient and metabolites (if applicable)] were stable {or [decreased or increased] by [percentage]} in [crop/matrix] for [duration of time].		

6.2 Metabolism, distribution and expression of residues

6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint summary

Purpose:
provide a summary of the key metabolism studies on residues in primary and rotational crops and used to conclude whether the nature of residues in plant (primary and rotational crops) was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

ENDPOINT_SUMMARY.MetabolismPlants			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MetabolismPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation
	Please make a statement whether the nature of residues in plant (primary and	Rich text area	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.KeyInformation

	rotational crops) was sufficiently elucidated in the context of the present application and highlight data gap(s) and the non-standard uncertainty(ies) (according to the relevant data requirements OECD TG 501 and OECD TG 502), if any. If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. For rotational crop studies, please make a statement here whether the study parameters cover the maximum soil concentration expected for the active substance (and its soil metabolites), considering the use and use pattern under assessment. Respective detailed parameters on the available key studies used for risk assessment should be reported in the repeatable block below.		
Primary crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of end points summary table. There is no need to report the detailed results of the studies but please be accurate on the study key parameters.		ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.PrimaryCrops
Link to relevant studies	Provide here the link to the relevant study(ies)	Endpoint reference list	ENDPOINT_SUMMARY.MetabolismPlants.KeyInf

	corresponding to the created row.		ormation.PrimaryCrops. RelevantStudies
Crop groups	Picklist (based representative crop groups defined in Annex 1 of OECD TG 501): Indicate the metabolism crop group covered by the study(ies) reported in this row (e.g. root crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.	Closed list	ENDPOINT_SUMMARY. MetabolismPlants.KeyInf ormation.PrimaryCrops. CropGroups
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the study. Multi-selection is possible (E.g. wheat grain + wheat straw).	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInf ormation.PrimaryCrops. Commodity
Treatment type	Indicate the type of treatment (e.g. foliar) tested in the study. If different types of treatments were tested in the same study, please create a separate row for each of the treatment type.	Multi select open list with remarks	ENDPOINT_SUMMARY. MetabolismPlants.KeyInf ormation.PrimaryCrops. TreatmentType
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If different application rates were tested in the same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInf ormation.PrimaryCrops. ApplicationRate
DAT	DAT (days after treatment): Indicate the time (in days) between treatment and sampling. Possibility to report a series of figures (e.g. 1; 3; 7; 14) and to specify the sampled commodities (e.g. 1	Multi-line text	ENDPOINT_SUMMARY. MetabolismPlants.KeyInf ormation.PrimaryCrops. Dat

	(fruit); 3 (leaves)…).		
Primary crops			
Rotational crops	Repeat this block to create one row per key metabolism study. This table should mimic the current list of end points summary table. There is no need to report the detailed results of the studies but please be accurate on the study key parameters.		ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops
Link to relevant studies	Provide here the link to the relevant study(ies) corresponding to the created row.	Endpoint reference list	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.RelevantStudies
Crop groups	Picklist (based on representative crop groups defined in OECD TG 502): Indicate the metabolism crop group covered by the study(ies) reported in this row (e.g. root/tuber crops). If the group is not in the picklist, please use "other" specify the group in the opening cells.	Open list	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.CropGroups
Commodity	Indicate the commodity(ies) for which nature of residues was investigated in the study. Multi-selection is possible (E.g. wheat grain + wheat straw).	Multi select open list with remarks	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.Commodity
PBI	PBI (Plant back interval): Indicate the time (in days) between treatment (application of active substance on previous crops or on bare soil) and planting. There is the possibility to report a series of figures (e.g. 30, 120 or 365 days).	Multi-line text	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.Pbi
Application rate	Indicate the application rate (with the unit) tested in the study (e.g. 1 kg a.s./ha). If	Multi-line text	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.ApplicationRate

	different application rates were tested in the same study, there is the possibility to report both in the same cells (e.g. 1 kg a.s./ha; 2 kg a.s./ha) or to create separate rows as more appropriate.		
Remarks	Indicate if the application was made on "bare soil" or on "growing crops". If application is done on growing crops, please specify the growth stage at application (BBCH scale) to be able to calculate the foliar interception accordingly.	Multi-line text	ENDPOINT_SUMMARY.MetabolismPlants.KeyInformation.RotationalCrops.Remarks
Rotational crops			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MetabolismPlants.Discussion
	This section can be used to add any additional useful text. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.MetabolismPlants.Discussion.Discussion
Attached background material			ENDPOINT_SUMMARY.MetabolismPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MetabolismPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.MetabolismPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports the above key information (e.g. calculation tables, graphs). The depicted metabolic pathways can be uploaded here.		

Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs) after sanitisation. The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase, provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.	Attachments list	ENDPOINT_SUMMARY.MetabolismPlants.Discussion.AttachedSanitisedDocsForPublication

6.2.1 Metabolism of residues in plants and in rotational crops – Endpoint study record

Purpose:
The results of the studies of metabolism in crops are used to elucidate the degradation pathway of the active substance and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.
Studies of metabolism in crops fulfil several major purposes:
1) Provide an estimate of the total residues in the various commodities after crop treatment, which allows determination of the distribution of residues within the crop, e.g., whether the pesticide is absorbed through roots or foliage or whether translocation occurs;
2) Identify the components of the terminal residue in the various commodities, thus indicating the components to be analysed for in residue quantification studies (i.e., the residue definition(s) for both risk assessment and enforcement).
3) Elucidate the metabolic pathway of the active ingredient in treated crops.

ENDPOINT_STUDY_RECORD.MetabolismInCrops			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData

		Confidentiality	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist (for metabolism studies in primary crops, please use the option "metabolism of residues in crops")	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.PurposeFlag
Robust study summary		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.RobustStudy
Used for classification		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.UsedForClassification
Used for SDS		Checkbox	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.DataWaivingJustification
Justification for		Text templ	ENDPOINT_STUDY_RECORD.MetabolismInCrops.Administ

type of information		ate	rativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource
Reference	Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'. If you entered the study in the MSS composer, the XML-files created with the MSS-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not	Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.Reference

	directly reported in the present study record. In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in this LITERATURE OBJECT. If you did not enter yourself the study in the MSS composer because the XML-files linked to this study record already exist (and are available to the Regulatory Authorities), the attachment of the XML-files is not mandatory. In such a case, please report the corresponding individual file number in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding file(s) in the database.		
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block MATERIALS AND METHODS This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods
Background information		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.BackgroundInformation
Product type	The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.ProductType
Test guideline	Mandatory field. Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline

	equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Add one block of fields for each guideline when more than one guideline is followed (e.g. US EPA in addition to OECD guideline).		
Qualifier	Mandatory field. Select appropriate qualifier, i.e. - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'). - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline').	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.Qualifier
Guideline	Mandatory field. Select the applicable test guideline, e.g. 'OECD TG 501' (for primary crops) or 'OECD TG 502' (for rotational crops). If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'. If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields. Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.	Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.Guideline
Version / remarks	Mandatory field. In this text field, you can enter any remarks as applicable, particularly: - To include any other title of the test guideline draft used, a subtitle, another version or update	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.VersionRemarks

	number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section.		
Deviations	Mandatory field. In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline	Mandatory field. If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined free text template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate. For a non-guideline experimental study, a high-level free text template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the free text template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate. Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate.	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.MethodNoGuideline
GLP compliance	Mandatory field. Indicate whether the study was conducted following Good Laboratory Practice or not. In case	Closed list with remar	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.GLPComplianceStatement

	'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.	ks	
Test material	Test Material – common block This part of the metabolism study should be reported via the "MSS composer". However, test material information and specific details on test material used for the study shall be entered here to link the present study record to the test materials created in this dataset.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Mandatory field. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.Radiolabelling
Radiolabelled test material	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
Radiolabel no.	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiolabelNo
SMILES notation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radioche	Field not mandatory.	Rang	ENDPOINT_STUDY_RECORD

mical purity (%)	To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	e (Decimal)	.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiochemicalPurity
Specific activity as received	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityAsReceived
Specific activity of dose	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityOfDose
Remarks	Field not mandatory. Use this field to enter any remarks.	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.Remarks
Radiolabelled test material			
Crop information		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation
Test crops	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops
Test crop no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.TestCropNo
Type of rotational crop		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.TypeOfRotationalCrop
Crop		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.Crop
Crop code		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.CropCode

Crop variety		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.Variety
Scientific name		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.ScientificName
Crop group		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.CropGroup
Growth stage at application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.GrowthStageAtApplication
Growth stage at harvest		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.GrowthStageAtHarvest
Harvested commodities		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.HarvestedCommodities
Harvested procedure		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.TestCrops.HarvestedProcedure
Test crops			
Other details on test crops	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndCropInformation.DetailsOnTestCrops
Test site and soil properties		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties
Test site type	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.TestSiteType
Soil	Field not mandatory.		ENDPOINT_STUDY_RECORD

properties	To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties
Soil type no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.SoilTypeNo
Soil type		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.SoilType
pH		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.PH
Organic matter (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.OrganicMatter
Sand (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.Sand
Silt (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.Silt
Clay (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.Clay
Moisture holding capacity		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.MoistureHoldingCapacity
CEC (meg/100 g)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoilProperties.SoilProperties.CECMeg100G
Soil properties			
Other details on test site	Field not mandatory. To be reported via the MSS composer (please	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.TestSiteAndSoi

	make sure that this information is available in the XML-file attached to this record).		lProperties.DetailsOnTestSite
Environmental conditions		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions
Temperature	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Temperature
Rainfall	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Rainfall
Lighting	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.Lighting
Potential for photodegradation of substance	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.EnvironmentalConditions.PotentialForPhotodegradationOfSubstance
Application		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application
Use pattern information	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.UsePatternInformation
Method of application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.UsePatternInformation.MethodOfApplication
Rate(s) of application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.UsePatternInformation.RateSOfApplication
Number of applications		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.UsePatternInformation.NumberOfApplications
Timing of applications		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.Us

			ePatternInformation.TimingOfApplications
PHI / PBI		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.UsePatternInformation.PHIPBI
Use pattern information			
Other details on application	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.DetailsOnApplication
Further details on study design	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.Application.FurtherDetailsOnStudyDesign
Sampling and analysis of crop plants		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis
Details on sampling	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSamplingAndAnalyticalMethods
Details on extraction and analysis	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnExtractionAndAnalysis
Details on identification and characterisation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnIdentificationAndCharacterisation
Flowchart of extraction and fractionation schemes	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes
Description		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes.Description

Illustration (picture/ graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes.IllustrationPictureGraph
Flowchart of extraction and fractionation schemes			
Sampling and analysis of soil		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil
Details on sampling of soil	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil.DetailsOnSamplingOfSoil
Details on analytical methodology for soil residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues
Appendix: Treatment groups		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups
Treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups
Test no.		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.TestNo
Number		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.Number
PHI / PBI		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.PHIPBI

Method of application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.MethodOfApplication
Rate(s) of application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.RateSOfApplication
Number of applications		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.NumberOfApplications
Timing of applications		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.TimingOfApplications
Matrix (RAC or extract)		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.MatrixRACOrExtract
Experimental descriptor		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.ExperimentalDescriptor
Remarks		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.Remarks
Reference (citation)		Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.ReferenceCitation
Radiolabel no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.RadiolabelNo
Test crop no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroups.TestCropNo
Soil type no.		Link to repea	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AppendixTreat

		table entry	mentGroups.TreatmentGroups.SoilTypeNo
Treatment groups			
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Field not mandatory. In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion	This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed results of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out the fields of the present section. However, the fields marked as "mandatory" shall be fulfilled to ensure a minimum structured data and to make best use of the report generator.	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction efficiency of radioactive residues using enforcement method	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Type of method		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsA

			ndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.TypeOfMethod
Recovered equivalents (mg/kg)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.RecoveredEquivalentsMgKg
Overall extraction efficiency (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.OverallExtractionEfficiency
Defined residue (mg/kg)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.DefinedResidueMgKg
Defined residue extraction efficiency (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.DefinedResidueExtractionEfficiency
Extraction efficiency of radioactive residues using enforcement method	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Quantitation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.Quantitation
TRR results	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiv

			eResidues.TRRResults.RadiolabelNo
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices
Matrix		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.Matrix
Timing and application		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.TimingAndApplication
Preharvest interval (PHI)		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.PreharvestIntervalPHI
Plant-back interval (PBI)		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.PlantBackIntervalPBI
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.TRRPpm
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.RemarksOnResult
TRRs in matrices			
TRR results			
Other details on	Field not mandatory. To be reported via the MSS composer (please	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsA

total radioactive residues (TRRs)	make sure that this information is available in the XML-file attached to this record).		ndDiscussion.TotalRadioactiveResidues.TotalRadioactiveResidues
Extraction, characterisation, and distribution of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues
Distribution of parent and metabolites	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.RadiolabelNo
Metabolite fraction		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.MetaboliteFraction
Identity of parent or metabolite		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.IdentityOfParentOrMetabolite
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices
Matrix		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.Matrix

TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.TRRPpm
Remarks on result		Multi select open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.RemarksOnResult
TRRs in matrices			
Distribution of parent and metabolites			
Other details on distribution of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfResidues
Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Matrix (RAC or extract)		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.MatrixRACOrExtract

Plant-back interval (PBI)		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.PlantBackIntervalPBI
Storage temperature		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.StorageTemperature
Actual study duration		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.ActualStudyDuration
Interval / Limit of demonstrated storage stability		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.IntervalLimitOfDemonstratedStorageStability
Summary of storage conditions			
Storage stability of residues (Sample Integrity)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability
Summary of radioactive residues in crops		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops
Characterisation and identification of radioactive residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.Radi

			olabelNo
Metabolite fraction		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.MetaboliteFraction
Identity of parent or metabolite		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.IdentityOfParentOrMetabolite
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices
Matrix		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.Matrix
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.TRRPpm
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.RemarksOnResult
TRRs in matrices			

Characterisation and identification of radioactive residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Other details on characterisation and identification of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.CharacterisationAndIdentificationOfResidues
Summary of radioactive residues in soil		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil
Radioactive residues in soil	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.RadiolabelNo
Metabolite fraction		Open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.MetaboliteFraction
Identity of parent or metabolite		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.IdentityOfParentOrMetabolite
TRRs in soil samples			ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.TRRsInSoilSamples
Soil sample		Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.Radi

			oactiveResiduesInSoil.TRRsInSoilSamples.SoilSample
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.TRRsInSoilSamples.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.TRRsInSoilSamples.TRRPpm
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInSoil.RadioactiveResiduesInSoil.TRRsInSoilSamples.RemarksOnResult
TRRs in soil samples			
Radioactive residues in soil			
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway
Identification of compounds from metabolism study	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy
Identity of compound		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy.IdentityOfCompound
Identification of compounds from metabolism study			
Metabolic pathway	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetab

	XML-file attached to this record).		olicPathway.MetabolicPathway
Metabolic map (picture/ graph)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicMapPictureGraph
Appendix: Metabolites and their parents in treatment groups		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups
Metabolites in treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups
ID no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.IDNo
Identity of compound		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.IdentityOfCompound
Parent compound(s)		Entity reference list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.ParentCompoundS
Treatment group (Test no.)		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.TreatmentGroupTestNo
Expertise		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.Expertise

Type of expertise		Multi select open list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.TypeOfExpertise
Metabolites in treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Any other information on results incl. tables	Field not mandatory. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments
Overall remarks	Field not mandatory. In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. If you entered in the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste this report in this field. Additional text can be added to complement the basic report generated by the MSS-composer.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).		ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document	Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g.	Single file	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallR

	language. The file name is displayed after uploading the document.	attachment	emarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/ graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInCrops.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ApplicantSummaryAndConclusion
Conclusions	Mandatory field. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Mandatory field. Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInCrops.ApplicantSummaryAndConclusion.ExecutiveSummary

Links to support material:

Please find specific instructions on who to structure the results of metabolism studies plants and livestock under the following link:

https://www.efsa.europa.eu/en/applications/pesticides/tools

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint summary

Purpose:
provide a summary of the key parameters of metabolism studies on livestock for individual groups of animals used to conclude whether the nature of residues in livestock/fish was sufficiently elucidated. Please briefly summarize the parameters of the key metabolism studies.

For studies performed on livestock, the recommendation is to use of the MSS-composer and to upload of the xml-files created with the MSS-composer.

ENDPOINT_SUMMARY.MetabolismInLivestock			
Name	Instructions	IUCLID6 DataType	IUCLID6 Path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MetabolismInLivestock.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in commodities of animal origin are derived.	Endpoint reference list	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.MetabolismInLivestock.LinkToRelevantStudyRecord.Results
Description of key information	Please make a statement whether the nature of residues in commodities of animal origin was sufficiently investigated in the context of the present dossier (according to the relevant data requirements and OECD TG 503) and highlight data gap(s) and the non-standard uncertainty(ies), if any. If studies reported in	Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.KeyInformation

	this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. Respective detailed parameters on the available key studies used for risk assessment should be reported in a table format. Please use the recommended format, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.2.2].		
		Rich text area	ENDPOINT_SUMMARY.MetabolismInLivestock.KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion
	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for differentiating results when several studies were identified to be relevant for the	Rich text area	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.Discussion

	assessment. If there is no additional information to be reported this field may be left empty.		
Attached background material			ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty	Text	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material	Add any additional document that supports the above key information (e.g. calculation tables, graphs). The depicted metabolic pathways can be uploaded here.		
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). The overview of metabolism studies [cf. residue Template 6.2 (http://doi.org/10.5281/zenodo.4621089)] can be uploaded here by the applicant, although not mandatory. The uploaded file should not contain confidential material. Please note that the overview of the metabolism studies (excel file) will be generated later by the EMS/RMS during the risk assessment phase,	Attachments list	ENDPOINT_SUMMARY.MetabolismInLivestock.Discussion.AttachedSanitisedDocsForPublication

	provided that all MSS-composer xml-files of the metabolism studies are available to the RMS/EMS.		

6.2.2 Metabolism of residues in livestock (incl. fish) – Endpoint study record

Purpose:
The results of the studies of metabolism in livestock are used to elucidate the degradation pathway of the active ingredient and require the identification of the metabolism and/or degradation products when a pesticide is applied to a crop directly or indirectly.

Studies of metabolism in livestock fulfil several major purposes:
1) provide an estimate of total terminal residues in edible animal products;
2) identify the major components of the total terminal residue in edible animal products;
3) indicate the distribution of residues between relevant edible animal products;
4) provide evidence whether or not a residue should be classified as fat soluble;
5) quantify the total residue in certain animal products (milk or eggs) and excreta;
6) quantify the major components of the residue and to show the efficiency of extraction procedures for these components'
7) characterise and quantify conjugated and bound residues;
8) indicate the components to be analysed for in residue quantification studies (livestock feeding studies);
9) generate data from which a decision on the need for feeding studies on food producing animals can be made

ENDPOINT_STUDY_RECORD.MetabolismInLivestock			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.DataProtection
Endpoint		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.

			RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.

			CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource
Reference	Indicate the bibliographic reference of the study report or publication the study summary is based on. Select item from 'Literature Reference' database or create 'New Reference'. If you entered in the study in the MSS composer, the XML-files created with the MSS-composer should be attached in the LITERATURE object, to which reference is made here. These XML-files shall contain all the data fields on material and methods and on results and discussions that were not directly reported in the present study record. In the field "attached documents", please use the function "select files" and attach here each XML-file associated to study referred to in	Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.Reference

	this LITERATURE OBJECT. If you did not enter yourself the study in the MSS composer because the XML-files linked to this study record already exist (and are available to the Regulatory Authorities), the attachment of the XML-files is not mandatory. In such a case, please report the corresponding individual file number in the field "other study identifier(s)" to help the Regulatory Authority identifying the corresponding file(s) in the database.		
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block This part of the metabolism study should mainly be reported in a separate tool which is the "MSS composer". Therefore, all detailed parameters concerning the materials and methods of the metabolism studies should be contained in the XML-file created with the "MSS-composer" and there is no need to fill out all the fields in the present section. However, the fields marked as "mandatory" shall be	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods

	fulfilled to ensure a minimum structured data and to make best use of the report generator		
Background information	Mandatory field.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.ProductType
Type of study	Mandatory field.	Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TypeOfStudy
Test guideline	Mandatory field.		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.MethodNoGuideline
GLP compliance	Mandatory field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethod

			s.GLPComplianceStatement
Test material	Test Material – common block This part of the metabolism study should be reported via the "MSS composer". However, test material information and specific details on test material used for the study shall be entered here to link the present study record to the test materials created in this dataset.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Mandatory field. Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.Radiolabelling
Radiolabelled test material	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial
Radiolabel no.	Field not mandatory. To be reported via the	Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivest

	MSS composer (please make sure that this information is available in the XML-file attached to this record).		ock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiolabelNo
SMILES notation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SMILESNotation
Radiochemical purity (%)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.RadiochemicalPurity
Specific activity as received	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityAsReceived
Specific activity of dose	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.SpecificActivityOfDose
Remarks	Field not mandatory. Use this field to enter any remarks	Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestMaterials.RadiolabelledTestMaterial.Remarks
Radiolabelled test material			
Test animals		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals
General test animal information	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation

	to this record).		
Animal information no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.AnimalInformationNo
Species		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.Species
Scientific name		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.ScientificName
Age		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.Age
Weight at study initiation (kg)		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.WeightAtStudyInitiationKg
Health status / condition of animals		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.HealthStatusConditionOfAnimals
Health status		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.HealthStatus
Description of housing / holding area		Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.GeneralTestAnimalInformation.DescriptionOfHousingHoldingArea
General test animal			

information			
Other details on housing conditions and test animals	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals
Test animal dietary regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime
Dietary regime no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.DietaryRegimeNo
Composition of diet		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.CompositionOfDiet
Feed consumption		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.FeedConsumption
Water		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.Water
Acclimation period		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.AcclimationPeriod
Predosing		Closed list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.TestAnimalDietaryRegime.Predosing
Test animal dietary regime			

Other details on dietary regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure
Test animal dosing regime	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime
Dosing regime no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.DosingRegimeNo
Treatment type		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.RouteOfAdministration
Treatment level		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.TreatmentLevel
Vehicle		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.Vehicle
Parameters		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.Parameters
Dosage rate		Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethod

			s.AdministrationExposure.TestAnimalDosingRegime.Dosing
Timing / duration		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.TimingDuration
Timing from final dose to sacrifice		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.TestAnimalDosingRegime.TimingFromFinalDoseToSacrifice
Test animal dosing regime			
Other details on dosing	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text template	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing
No. of animals per dose group	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Rationale for selection of dose group	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.RationaleForSelectionOfDoseGroup
Analysis of feed and water	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.AnalysisOfFeedAndWater
Further details on study design	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AdministrationExposure.FurtherDetailsOnStudyDesign

	in the XML-file attached to this record).		
Sampling and analysis		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis
Sample collection	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection
Sample information no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.SampleInformationNo
Type of samples collected		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.TypeOfSamplesCollected
Frequency of sample collection		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.FrequencyOfSampleCollection
Amount / number produced during normal production		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.AmountNumberProducedDuringNormalProduction
Excreta and cage wash collected		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.ExcretaAndCageWashCollected
Interval from last dose to sacrifice		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.IntervalFromLastDoseToSacrifice
Tissues harvested		Text	ENDPOINT_STUDY_REC

and analysed			ORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.SampleCollection.TissuesHarvestedAndAnalyzed
Sample collection			
Details on sampling	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnSamplingAndAnalyticalMethods
Details on extraction and analysis	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnExtractionAndAnalysis
Details on identification and characterisation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.DetailsOnIdentificationAndCharacterisation
Flowchart of extraction and fractionation schemes	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes
Description		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes.Description
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.SamplingAndAnalysis.FlowchartOfExtractionAndFractionationSchemes.IllustrationPictureGraph
Flowchart of extraction and fractionation			

schemes			
Appendix: Treatment groups		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups
Treatment group			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup
Treatment group	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.TreatmentGroup
Sex		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.Sex
Number		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.Number
Route of administration		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.RouteOfAdministration
Dose nominal		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DoseNominal
Dose measured		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DoseMeasured
Matrix		Open list with remarks	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGr

			oups.TreatmentGroup.Matrix
Test duration		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.TestDuration
Experimental descriptor		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.ExperimentalDescriptor
Dose type		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DoseType
Frequency (on every)		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.FrequencyOnEvery
Duration of treatment		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DurationOfTreatment
Remarks		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.Remarks
Reference (citation)		Literature reference list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.ReferenceCitation
Radiolabel no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.RadiolabelNo
Animal information no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethod

			s.AppendixTreatmentGroups.TreatmentGroup.AnimalInformationNo
Dietary regime no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DietaryRegimeNo
Dosing regime no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.DosingRegimeNo
Sample information no.		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AppendixTreatmentGroups.TreatmentGroup.SampleInformationNo
Treatment group			
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block Field not mandatory. In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	fields 'Overall remarks' and 'Executive summary' allow rich text entry.		
		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion
Total radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues
Extraction efficiency of radioactive residues using enforcement method	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod
Type of method		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.TypeOfMethod
Recovered equivalents (mg/kg)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.RecoveredEquivalentsMgKg
Overall extraction efficiency (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod

			.OverallExtractionEfficiency
Defined residue (mg/kg)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.DefinedResidueMgKg
Defined residue extraction efficiency (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.ExtractionEfficiencyOfRadioactiveResiduesUsingEnforcementMethod.DefinedResidueExtractionEfficiency
Extraction efficiency of radioactive residues using enforcement method			
Quantitation	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.Quantitation
TRR results	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.RadiolabelNo
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices
Matrix		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResid

			ues.TRRResults.TRRsInMatrices.Matrix
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.TRRPpm
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRResults.TRRsInMatrices.RemarksOnResult
TRRs in matrices			
TRR results			
TRRs reached plateau at end of dosing	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsReachedPlateauAtEndOfDosing
TRRs as a function of time	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime
Type of samples		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TypeOfSamples
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.RadiolabelNo
TRRs at time			ENDPOINT_STUDY_REC

intervals			ORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TRRsAtTimeIntervals
Interval		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TRRsAtTimeIntervals.Interval
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TRRsAtTimeIntervals.TRRPpm
TRR (% of dose)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TRRsAtTimeIntervals.TRROfDose
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TRRsAsAFunctionOfTime.TRRsAtTimeIntervals.RemarksOnResult
TRRs at time intervals			
TRRs as a function of time			
Graphical plot of TRRs as a function of time	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.GraphicalPlotOfTRRsAsAFunctionOfTime
Description		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.GraphicalPlotOfTRRsAsAFunctionOfTime.Description

Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.GraphicalPlotOfTRRsAsAFunctionOfTime.IllustrationPictureGraph
Graphical plot of TRRs as a function of time			
Other details on total radioactive residues (TRRs)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.TotalRadioactiveResidues.TotalRadioactiveResidues
Extraction, characterisation, and distribution of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues
Distribution of parent and metabolites	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.RadiolabelNo
Metabolite fraction		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.MetaboliteFraction
Identity of parent or metabolite		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfRe

			sidues.DistributionOfParentAndMetabolites.IdentityOfParentOrMetabolite
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices
Matrix		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.Matrix
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.TRRPpm
Remarks on result		Multi select open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfParentAndMetabolites.TRRsInMatrices.RemarksOnResult
TRRs in matrices			
Distribution of parent and metabolites			
Other details on distribution of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ExtractionCharacterisationAndDistributionOfResidues.DistributionOfRes

	to this record).		idues
Storage stability of residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues
Summary of storage conditions			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions
Matrix (RAC or extract)		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.MatrixRACOrExtract
Storage temperature		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.StorageTemperature
Actual study duration		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.ActualStudyDuration
Interval / Limit of demonstrated storage stability		Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.SummaryOfStorageConditions.IntervalLimitOfDemonstratedStorageStability
Summary of storage conditions	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		
Storage stability of residues (Sample integrity)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.StorageStabilityOfResidues.StorageStability

	in the XML-file attached to this record).		
Summary of characterisation and identification of radioactive residues		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues
Characterisation and identification of radioactive residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues
Radiolabel no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.RadiolabelNo
Metabolite fraction		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.MetaboliteFraction
Identity of parent or metabolite		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.IdentityOfParentOrMetabolite
TRRs in matrices			ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResi

			dues.TRRsInMatrices
Matrix		Open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.Matrix
TRR (%)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.TRR
TRR (ppm)		Range (Decimal)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.TRRPpm
Remarks on result		Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentificationOfRadioactiveResidues.TRRsInMatrices.RemarksOnResult
TRRs in matrices			
Characterisation and identification of radioactive residues			
Other details on characterisation and identification of residues	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.CharacterisationAndIdentifi

			cationOfResidues
General health of animals	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Multi-line text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.SummaryOfCharacterisationAndIdentificationOfRadioactiveResidues.GeneralHealthOfAnimals
Proposed metabolic pathway		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway
Identification of compounds from metabolism study	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy
Identity of compound		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.IdentificationOfCompoundsFromMetabolismStudy.IdentityOfCompound
Identification of compounds from metabolism study			
Metabolic pathway	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicPathway
Metabolic map (picture/graph)	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).	Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.ProposedMetabolicPathway.MetabolicMapPictureGraph
Appendix: Metabolites and their parents in treatment groups		Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesA

			ndTheirParentsInTreatmentGroups
Metabolites in treatment groups	Field not mandatory. To be reported via the MSS composer (please make sure that this information is available in the XML-file attached to this record).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups
ID no.		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.IDNo
Identity of compound		Entity reference field	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.IdentityOfCompound
Parent compound(s)		Entity reference list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.ParentCompoundS
Treatment group (Test no.)		Link to repeatable entry	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.TreatmentGroupTestNo
Expertise		Closed list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatmentGroups.MetabolitesInTreatmentGroups.Expertise
Type of expertise		Multi select open list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AppendixMetabolitesAndTheirParentsInTreatm

			entGroups.MetabolitesInTreatmentGroups.TypeOfExpertise
Metabolites in treatment groups			
Any other information on results incl. tables	Field not mandatory. In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments
Overall remarks	Field not mandatory. In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.RemarksOnResults

	also upload any htm or html document. If you entered in the study in the MSS composer and/or if the XML-file created with the MSS-composer is available to you, please generate a word report from the MSS-composer (using the adequate feature in the MSS-composer software) and copy/paste this report in this field. Additional text can be added to complement the basic report generated by the MSS-composer.		
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).		ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for		Attachments list	ENDPOINT_STUDY_RECORD.MetabolismInLivest

publication			ock.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion
Conclusions	Mandatory field. Write here the Applicant's conclusion of the metabolism study in context of the application.	Text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Mandatory field. Briefly summarise the relevant aspects of the study including the conclusions reached in the context of the application.	Rich text area	ENDPOINT_STUDY_RECORD.MetabolismInLivestock.ApplicantSummaryAndConclusion.ExecutiveSummary

Links to support material:

Please find specific instructions on who to structure the results of metabolism studies plants and livestock under the following link:

https://www.efsa.europa.eu/en/applications/pesticides/tools

From the page, users will find all instructions to download the MSS composer (part of the Metapath software package), link to the technical manual for the MSS-composer, detailed information on the data flow for metabolism studies and access to the databases of metapath files.

6.3 Magnitude of residues in plants – Endpoint summary

Endpoint summary for "PRIMARY CROPS":

Purpose:
To provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant commodities for the critical GAP(s), to summarize risk assessment values and the MRL proposals and to conclude whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlant

			s.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation
	Please make a statement whether the magnitude of residues in plant (primary crops) was sufficiently elucidated in the context of the present dossier (according to the relevant data requirements and to OECD TG No 509) and highlight data gap(s) and the non-standard uncertainty(ies), if any. If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. Respective detailed parameters on the available key trials used for risk assessment should be reported in the repeatable block "Summary of residues data from the supervised residue trials", following the instructions below.	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.KeyInformation
Summary of residues data from the supervised residue trials	Repeat this block to create one "new item" per GAP under assessment.		ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL…) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Link
Relevant GAP	Link to the critical GAP from which the MRL and risk assessment values are derived.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Releva

			ntGap
Commodity(ies) for which MRL and risk assessment values are derived	Please select from the picklist the commodity(ies) of plant origin to which MRLs apply according to Part A of Annex I of Regulation (EC) 396/2005. The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items. For feed items not listed, select `Other` and specify.	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.CommodityForMrl
Commodity(ies) used in the residue trials	Please select from the picklist the commodity(ies) of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed (multi-selection is possible) The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Commodity
Residue levels: RD RA	Report here all results from supervised residue trials for one crop raw agricultural commodity (RAC), e.g. for wheat grain, including the components of the residue definition for risk assessment (RA). Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated.	Multi-line text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResiduLevelsRiskAssessment

	For chemicals, values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.		
Residue levels: RD MO	If residue definition (RD) for risk assessment (RA) and RD for monitoring are different, please report here all results from supervised residue trials relevant for each RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. For chemicals, values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.	Multi-line text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResiduLevelsMonitoring
Mean conversion factor (CF)	If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). CF= [residue concentration] according to RD-RA / [residue concentration] according RD-MO To derive the mean CF, you need to derive the CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.	Decimal	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MeanConversionFactor
Highest residue	Enter supervised trials highest residue value (HR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.HighestResidue
STMR	Enter supervised trials	Unit measure with	ENDPOINT_SUMMARY.

	median residue value (STMR) [default unit is mg/kg]	Closed List (Decimal)	MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Stmr
MRL derived	Enter here the MRL as derived from the submitted residue trials for the commodities listed under `Commodity(ies) for which MRL and risk assessment values are derived`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MrlDerived
Remarks	Please insert here any other remarks, if necessary, relevant for the residue trials data. If the results reported in the block refer to single trial results for pulp (e.g. orange pulp), this should be specified here in the remarks: e.g. "detailed results and risk assessment values derived from pulp". In such a case, no MRL needs to be derived.	Text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Remarks
Results applicable to	Select "primary plant".	Multi select closed list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResultsApplicableTo
Summary of residues data from the supervised residue trials			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion
	Use this field to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.Discussion

Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). In support of the MRLs calculated for plant commodities, please also attach here the OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm The uploaded file should not contain confidential material.	Attachments list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedSanitisedDocsForPublication

Endpoint summary for "ROTATIONAL CROPS":

Purpose:
Provide a summary overview of the residue levels of all components of monitoring (MO) and risk assessment (RA) residue definitions (RD) in the relevant rotational crops at various plant back intervals (PBI) covering the maximum soil concentration expected for the active substance (and its soil metabolites) for the use pattern on primary crop under assessment, to summarize risk assessment values and the MRL proposals (if relevant) and to conclude whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier and whether restrictions in crop rotation are required.

ENDPOINT_SUMMARY.MagnitudeResiduesPlants			
Name	**Instructions**	**Type**	**Field path**

Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation
	Please make a statement whether the magnitude of residues in rotational crops was sufficiently elucidated in the context of the present dossier (according to the current data requirements and to OECD TG 504) and highlight data gap(s) and the non-standard uncertainty(ies), if any. If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. Please indicate here: 1) Whether significant residues are expected in rotational crops, in the context of the present application (i.e. based on the GAP on primary crops under assessment). If no: please provided rationale. If yes: please specify if specific studies investigating the magnitude of residues in rotational crops were reported. 2) If specific studies on the magnitude of	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.KeyInformation

	residues in rotational crops were reported, please make a statement: - as to whether the study parameters cover the maximum soil concentration expected for the active substance (and its soil metabolites), considering the use pattern on primary crop under assessment. - as to whether those studies can be used to derive MRL and risk assessment values (HR and STMR). Respective detailed parameters and results on the eventual available key trials used for risk assessment should be reported in the detailed table below.		
Summary of residues data from the supervised residue trials	Repeat this block to create one box per crop group for which risk assessment value and MRLs may be derived from rotational crops.		ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData
Study name / type	Provide here the link to the relevant study(ies) used to derive the endpoints (HR, STMR, MRL…) reported in this table.	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Link
Relevant GAP	Please select the GAP considered for the assessment of magnitude of residues in rotational crops (e.g. the GAP on primary crop leading to highest residues in soil in the next growing season).	Endpoint reference list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.RelevantGap
Commodity(ies) for which MRL and risk assessment values are derived	Please select from the picklist the commodity of plant origin to which MRLs apply according to Part A of Annex I of	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.CommodityForMrl

	Regulation (EC) 396/2005. The picklist contains also relevant feed items, to be selected when residue trials provide data on residues in feed items. For feed items not listed, select `Other` and specify.		
Commodity(ies) used in the residue trials	Please select from the picklist the commodity of plant origin according to Part A and B of Annex I of Regulation (EC) 396/2005 on which the residue trials were performed. The picklist contains also relevant feed items, to be selected when residue trials provide residue data in feed items, used to derive STMR, HR and CF for feed items. For feed items not listed, select `Other` and specify.	Multi select open list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Commodity
Residue levels: RD RA	Report here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for risk assessment. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated. Values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.	Multi-line text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResiduLevelsRiskAssessment
Residue levels: RD MO	If RD for RA and RD for monitoring differ report	Multi-line text	ENDPOINT_SUMMARY.MagnitudeResiduesPlant

	here all results from supervised residue trials for one crop RAC, e.g. for wheat grain, including the components of the residue definition for monitoring. Values should be separated by semicolon and sorted by magnitude starting with the lowest value. The residue values below LOQ shall be indicated (for example, <0.01 mg/kg). Values are reported under the default unit [mg/kg]. For example: <0.01; <0.01; 0.02; 0.03; 0.03; 0.05; 0.06; 0.23.		s.KeyInformation.SummaryResiduesData.ResiduLevelsMonitoring
Mean conversion factor	If RD for RA differ from RD for monitoring insert here the mean conversion factor (CF). CF= [residue concentration] according to RD-RA / [residue concentration] according RD-MO To derive the mean CF, you need to derive the CF for each pair of results (RD-RA/RD-MO) individually and to calculate the average of the series of values.	Decimal	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MeanConversionFactor
Highest residue	Enter supervised trials highest residue value (HR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.HighestResidue
STMR	Enter supervised trials median residue value (STMR) [default unit is mg/kg]	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Stmr
MRL derived	If MRL is derived, please enter here the MRL as derived from the submitted residue trials for the commodities	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.MrlDerived

	listed under `Commodity(ies) for which MRL and risk assessment values are derived`. Not mandatory for commodities exclusively used as feed items (e.g. wheat straw).		
Remarks	Please insert here any other remarks, if necessary. Please specify which PBI (plant back interval) and which eventual mitigation measures were considered to derive the endpoints above. Indicate whether a rotational crop was planted/sown following a treatment and harvest of primary crop. Indicate whether the proportionality principle was applied to derive the key endpoints (HR, STMR, MRL) and how the scaling factors were derived (e.g. based on soil samples analysis compared to plateau expected concentration (PEC) calculated for the critical GAPs under assessment). Please elaborate on the approach used to derive the MRL proposal and risk assessment values for rotational crops and indicate if any extrapolations are proposed.	Text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.Remarks
Results applicable to	Select "rotational crops". Optional: If results are given for the aggregated residues or primary and rotational crops, please select both "primary plant", "rotational crops".	Multi select closed list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.KeyInformation.SummaryResiduesData.ResultsApplicableTo

Summary of residues data from the supervised residue trials			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.Discussion
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). In support of the MRLs calculated for plant commodities, please also attach here the OECD calculator Excel, available for single and multiple data sets here: https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm The uploaded file should	Attachments list	ENDPOINT_SUMMARY.MagnitudeResiduesPlants.Discussion.AttachedSanitisedDocsForPublication

	not contain confidential material.		

6.3 Magnitude of residues in plants – Endpoint study record

Purpose:

- Primary crops: Magnitude of residue trials in plants shall allow to quantify the highest likely residue levels of all components of the different residue definitions in treated crops at harvest or outloading from store, in accordance with the proposed GAP, and, to determine, where appropriate, the decline rate of plant protection product residues in plants.
- Rotational crops: Magnitude of residue trials in rotational cops shall permit an evaluation of the magnitude of residues in rotational crops, to decide on restrictions in crop rotation, provide information for assessing the overall relevancy of the residues for dietary risk assessment and to decide on the necessity of MRLs for rotational crops

ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataProtection
Endpoint	For primary crop supervised residue trials select `residues in crops (field trials)` For rotational crop studies select `residues in rotational crops (limited field studies)`	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.PurposeFlag
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.Reliability

Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.AdministrativeData.CrossReference.Remarks

Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method		Text template	ENDPOINT_STUDY_REC

if other than guideline			ORD.ResiduesInRotationalCrops.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Analytical methods		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods
Analytical method			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod
Method ID	Create an ID for the method. This ID should be used in the summary of the residue trials to unambiguously refer to the method used in the trial. In the field "related information", please create a link towards the study record of the used analytical method and its validation. If the	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.MethodID

	study record referred to is duly compiled and contain the data on method validation, the rest of this block is not required.		
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.RelatedInformation
Details on analytical methods		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.DetailsOnAnalyticalMethods
Combinations of substance and analysed sample portion			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalyteIdentity
Analysed sample portion ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionID
Analysed sample portion description		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.AnalysedSamplePortionDescription
Fortification			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMet

			hods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification
Fortification level		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.FortificationLevel
Recovery (%)		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnalyticalMethods.AnalyticalMethod.CombinationsOfSubstanceAndSamplePortion.Fortification.Recovery
Fortification			
Combinations of substance and analysed sample portion			
Analytical method			
Residue trials	This field contains detailed information of supervised residue trials on primary crops performed according to the critical GAP. For rotational crops the residue trials reflect the accumulation of residues in rotational crops via soil uptake following the realistic agricultural practices on primary crops.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern
Trial ID no.	Insert the trial specific, unequivocal identification code	Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialIdNo
Trial information	Option 1: Possibility to use the repeatable block to report individual trial information. Copy this block of fields for recording the results of		ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation

	each sampling. This option could be deployed in case of small data sets. Option 2: Report the detailed residue trial information directly in the Excel file Residues trial table to be attached in the field below "Attached sanitized documents" (See detailed instructions in "Attached sanitized documents"). For option 2, any additional information which is relevant for the residue trial but not captured in the Excel residue trial tables should be reported in the field `Any other information on materials and methods, incl.tables`.		
Geographic location and soil characteristics		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics
Test site type		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TestSiteType
Geographic location		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GeographicLocation
Trial deviation		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.Geograp

			hicLocationAndSoilCharacteristics.TrialDeviation
Year		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Year
Country or territory		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Country
Geographic region		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GeographicRegion
State/Province		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.StateProvince
County		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.County
City		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.City
GPS coordinates		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.GPSCoordinates

Type of crop		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TypeOfCrop
Type of trial		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.TypeOfTrial
Crop grouping (primary)		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroupingPrimary
Crop group		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropGroup
Crop		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.Crop
Crop code		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropCode
Crop variety		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropVariety
Replant no. (1, 2)		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMet

			hods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.ReplantNo
Date of planting		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfPlanting
Date of seeding		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfSeeding
Date of flowering (beginning)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringBeginning
Date of flowering (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfFloweringEnd
Date of harvest (beginning)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestBegin
Date of harvest (end)		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.DateOfHarvestEnd
Crop plant back interval		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMet

			hods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropPlantBackInterval
Crop information / history		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.CropInformation
Soil characterization		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.SoilCharacterization
Other details on test crops		Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.GeographicLocationAndSoilCharacteristics.OtherDetailsOnTestCrops
Plot description		Header 3	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription
Plot			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot
Plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotID
Control plot		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.ControlPlot

Corresponding control plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.CorrespondingControlPlotID
Plot description		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.PlotDescription
Environmental conditions		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.EnvironmentalConditions
Other details on test site		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.DetailsOnTestSite
Application		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application
Application			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application
Application no. (1, 2)		Integer	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.ApplicationNo
Bare soil		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDesc

			ription.Plot.Application.Application.BareSoil
Growth stage code (BBCH) at application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStageCode
Growth stage description at application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.GrowthStage
Date of application		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.DateOfApplication
Method of application		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.MethodOfApplication
Seeding rate		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.SeedingRate
Thousand grain weight		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.ThousandGrainWeight
Applied test material			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDesc

			ription.Plot.Application.Application.TestItem
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.TestMaterialInformation
Description of test item		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.DescriptionOfTestItem
Formulation type		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.FormulationType
Trade name		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.TradeName
Active ingredients (a.i.)			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients
Related substance information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.RelatedSubstanceInfo
Name of a.i.		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotation

			alCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.NameOfAI
Nominal a.i. content		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.NominalAIContent
Applied amount (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountActual
Amount a.i./seed (actual)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountAISeedActual
Applied amount (cumulative nominal)		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AppliedAmountCumulative
Adjuvant added		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AdjuvantAdded
Amount of water		Unit measure with Open	ENDPOINT_STUDY_REC

used in spray application (nominal)		List (Decimal)	ORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.Application.TestItem.ActiveIngredients.AmountOfWaterUsedInSpray
Active ingredients (a.i.)			
Applied test material			
Application			
Other details on application		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.Application.OtherDetailsOnApplication
Sampling		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology
Details on sample collection		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Sampling and analysis of soil		Header 4	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil

Details on sampling of soil		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnSamplingOfSoil
Details on analytical methodology for soil residues		Text template	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.StudyUsePattern.TrialInformation.PlotDescription.Plot.SamplingAndAnalysisOfSoil.DetailsOnAnalyticalMethodologyForSoilResidues
Plot			
Trial information			
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or which could not be reported in the Excel residue trial tables or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For example, tables summarizing the details on sampling time (age of crop in days) for rotational crop RACs; stages of crop development at each sampling point (e.g., at forage hay and grain stages), number of samples/replicates. For	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	rotational crop trials if soil residues were determined, in `Sampling and analysis of soil` include details on the sampling, sampling method and handling and preparation of soil samples.		
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Provide here the information on how long the residue field samples were stored prior to analysis and under which conditions. Specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated. Provide justification for deviations, if any. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in plant commodities have been	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.StorageStability

	reported. By reference to the endpoint summary on storage stability (Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.		
Summary of residues	Option 1: Possibility to use the repeatable block to report individual results, for each sampling and for each relevant analyte. Copy this block of fields for recording the results of each sampling. This option could be deployed in case of small data sets. Option 2: Report the detailed residue trial information directly in the Excel file Residues trial table to be attached in the field below "Attached sanitized documents" (See detailed instructions in "Attached sanitized documents").	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops
Sampling and residues			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues
Trial ID no.		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TrialIDNo
Plot ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscu

			ssion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.PlotID
Sampling ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingID
Sampling timing		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingTiming
Growth stage code (BBCH) at sampling		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.GrowthStageCode
Growth stage description at sampling		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.GrowthStage
Date of sampling		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.DateOfSampling
Sampling information		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SamplingInformation
Sampled material / commodity (Field RAC sample) code		Open list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SampledMaterialCommodity

Sampled material / commodity (Field RAC sample) description		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.SampledMaterialCommodityDescription
Residue levels			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels
Method ID		Link to repeatable entry	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.MethodID
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalyteIdentity
Analysis sample portion ID		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisSampleDescription
Extraction date		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.AnalysisDate

Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.StorageStabilityFactor
Use of storage stability factor		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ReferencePortion
Residue level (measured)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevel

			Measured
Calculated analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.CalculatedAnalyteIdentity
Residue level (calculated)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelCalculated
Residue level (calculated and corrected)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.ResidueLevels.ResidueLevelCorrected
Residue levels			
Total / mean		Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.SummaryOfRadioactiveResiduesInCrops.SamplingAndResidues.TotalMean
Sampling and residues			
Any other information on results incl. tables	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ResultsAndDiscu

			ssion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	If you did not use the option 1 to report the detailed results for each sample, please upload here the Excel file Residues trial table (primary and rotational crops). An empty template of the Excel file Residues trial table (primary and rotational crops) is	Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.OverallRemarksAttachments.AttachedSanitisedDocsForPublication

	available on the 'knowledge junction' [cf. residue Template 6.3 (http://doi.org/10.5281/zenodo.4621116)]. The uploaded file should not display confidential material.		
Applicant's summary and conclusion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion
Interpretation of results	Select applicable conclusion from the picklist	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.InterpretationOfResults
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.Conclusions
Executive summary	The assessment and conclusion of the applicant should be reported here. Briefly summarise the relevant aspects of the study(ies) including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document. Example for supervised residue trials on primary crops: [Number] field trials for [active ingredient] on [crop(s)] were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application; formulation used, rate, treatment interval and seasonal application rates of [xx] g ai/ha].	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInRotationalCrops.ApplicantSummaryAndConclusion.ExecutiveSummary

	An adjuvant [was or was not] added to the spray mixture for all applications. [Crops] were harvested at a preharvest interval (PHI) of [xx] days. In [one] trial, samples were collected at different time intervals (PHIs of x, xx, xxx days) to monitor residue decline. All samples were maintained frozen at the testing facility, during shipping to the laboratory, and were stored frozen until analysis. The maximum storage interval for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials. Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] per analyte for [matrices].		

	Individual sample (and per-trial average) residues in [matrix] ranged from [xx] mg/kg to [yy] mg/kg. [Include for each matrix and/or variation in use pattern in the study]. Residue decline data show that residues of [active ingredient/metabolite] [increase/decrease/are unchanged/are too variable to assess decline] in [commodities] with increasing PHIs. Example for rotational crop field trials: [Number] field trials for [active ingredient] on [crop(s)] as rotational crops were conducted in [country] during the [year] growing season. At each trial location, [describe timing and method of application (specify bare soil or primary crop); formulation used, rate, treatment interval and seasonal application rates of [xx] g ai/ha). An adjuvant [was or was not] added to the spray mixture for all applications. [Describe growth/maintenance of primary crop, if applicable]. [Crops] were planted into treated plots at plant-back intervals (PBIs) of [xx, yy, and zz] days. Crops were harvested at maturity and prepared for residue analysis. All samples were maintained frozen at the testing facility, shipped and stored frozen until		

	analysis. The maximum storage duration for samples between harvest and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [crops] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current trials. Samples in the current study were analyzed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices]. The results from these trials show that quantifiable residues of [list analytes] are not expected to occur at PBIs greater than [xx] days. At a PBI of [yy] days, individual sample residues ranged from [xx] ppm to [yy] ppm (Crop 1), [xx] ppm to [yy] ppm (Crop 2), and [xx] ppm to [yy] ppm (Crop 3). [Address other PBIs as needed.]		

6.4 Feeding studies – Endpoint summary

Purpose:
To provide a summary overview of the residue levels of all components of enforcement (MO) and risk assessment (RA) residue definitions (RD) in the relevant animal matrix for the calculated livestock dietary burdens, to summarize risk assessment values and the MRL proposals and to conclude whether the magnitude of residues in products of animal origin was sufficiently elucidated in the context of the present dossier.

Fill in the 'Description of key information' field. Expected key information: MRL proposals, median and highest residue levels (STMR and HR) for each animal matrice (i.e muscle, fat, liver, kidney, milk, eggs, etc). Please make use of the Animal calculator Excel to derive these end points using the results of the feeding studies (i.e. residue concentrations for each dose level) and comparison with dietary burden calculation. The animal calculator.xls should be uploaded as an attachment.

ENDPOINT_SUMMARY.ResiduesLivestock			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.ResiduesLivestock.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in commodities of animal origin are derived.	Endpoint reference list	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.ResiduesLivestock.LinkToRelevantStudyRecord.Results
Description of key information		Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.KeyInformation
	Please make a statement whether the magnitude residues in commodities of animal origin was sufficiently investigated in the	Rich text area	ENDPOINT_SUMMARY.ResiduesLivestock.KeyInformation.KeyInformation

	context of the present dossier (according to the current data requirements and OECD GD on residues in livestock, Series on Pesticides No 73) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Respective detailed parameters on the available key studies used for risk assessment should be reported in attachment (see instruction below). If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. Please indicate here: 1) Whether significant residues are expected in commodities of animal origin, in the context of the present application (i.e. based on the critical GAPs under assessment). If no: please provided rationale. If yes: please specify if specific studies investigating the magnitude of residues in livestock commodities were reported. 2) If specific studies on the magnitude of residues in livestock commodities were reported, please make a statement as to whether the study were		

	used to derive MRL and risk assessment values in commodities of animal origin.		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.Discussion
Attached background material	Add any additional document that support the above key results (e.g. calculation tables, graphs).		ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs). Please upload the Excel file which was eventually used to: 1) Calculate the livestock dietary burden (DB) relevant for the present application (including detailed input values and detailed results for each group of livestock). 2) Report the detailed results of the livestock feeding studies used to assess the magnitude of	Attachments list	ENDPOINT_SUMMARY.ResiduesLivestock.Discussion.AttachedSanitisedDocsForPublication

	residues in commodities of animal origin (those studies that are cross-referred in the above block). 3) Calculate MRLs and risk assessment values for all animal tissues and products based on 1 and 2, in the context of the present application. Please attach the "Excel Animal calculator" available on knowledge junction [cf. residue Template 6.4 (https://doi.org/10.5281/zenodo.661713)]. This Excel file is essential for the EMS/RMS to understand which input values were used to assess the livestock DB and how study results were considered by the Applicant to support the above key results. RMS/EMS may modify it during the risk assessment phase. The uploaded file should not contain confidential material.		

6.4 Feeding studies – Endpoint study record

Purpose:
Residues in Livestock studies are conducted in order to quantify levels of residues in meat, milk, eggs and edible meat by-products (e.g. fat, liver, kidney), following the use of a pesticide product on feed plant commodities. The studies are conducted according to OECD TG 505 and provide data on the quantitative transfer of residues, i.e. factor between residue level in the diet and residue levels in edible commodities (milk, eggs, tissues).

Residues in Livestock studies are typically conducted in ruminants (cattle) and poultry (laying hen). In general, the results of cattle feeding studies may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and laying hen feeding studies to other types of poultry (turkey, goose, duck and others). Please create one Endpoint study record per feeding study. Extrapolations should be specified in the endpoint summary above.

If feeding studies are not required in the context of the present application, please specify

NB: If you used a metabolism study as a proxy to conclude that residues exceeding the LOQ are expected in some matrices or if the calculated intakes indicate that existing MRLs have to be changed, additional calculations based on the livestock feeding study data have to be performed in order to set/update the MRL values for products of animal origin.

ENDPOINT_STUDY_RECORD.ResiduesInLivestock			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist, here: "Residues in livestock"	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.RationalReliability

Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.AdministrativeData.CrossReference.Remarks

Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods
Background information		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.BackgroundInformation
Product type	The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.ProductType
Type of study		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TypeOfStudy
Test guideline			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Guideline

Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Test animals		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals

Species	Select name of species. Multiple selection is possible, but it is strongly recommended to use separate records for each animal species studied. You can include a cross-reference, in field 'Same study also described in chapter:', to the record where the methodology is described in detail.	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.Species
Details on housing conditions and test animals	Include details on housing conditions and test animals. Use free text template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following information should be addressed: HOUSING / HOLDING AREA: Describe the test facilities, i.e. animal housing including size of enclosures, individual vs. group housing, food and water containers, temperature, lighting, and waste handling. TEST ANIMALS: Include information on breed, age, weight, stage of development, health status and condition of test animals.	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnHousingConditionsAndTestAnimals
Details on dietary regime	Include details on dietary regime. Use free text template and delete/add elements as appropriate, upload	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.TestAnimals.DetailsOnDietaryRegime

	predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following information should be addressed: - Composition of diet: Describe the diet of animals during acclimation and the dosing period regarding: (1) Types of feed (e.g., corn grain, layers mash, alfalfa pellets) and liquids; (2) Quantities provided (i.e., specific amounts or ad libitum). - Feed consumption: Report the feed consumption (dry weight for ruminants) on an individual or treatment group basis throughout the study. - Water: Report water consumption - Acclimation period: specify		
Administration / exposure		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure
Treatment type (route of exposure)	Select the treatment type used which determines the primary route of exposure in the study. Multiple selection is possible if, in specific situations, direct application of a product	Multi select open list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.TreatmentTypeRouteOfExposure

	to livestock was studied in addition to exposure through feeding of treated crops. Most frequent options in the context EU PPP assessments: Oral: "capsule" or "applied on feed"		
Duration and frequency of dosing	Indicate the total length of the dosing period (e.g. 20 days) including withdrawal periods where applicable, and the frequency of application / dosing if the test material is not incorporated into the total diet or feed.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DurationAndFrequencyOfDosing
Doses / concentrations	Indicate the dose rates (feeding levels) as "mg/kg bw per day" (also possible mg/kg diet, mg/animal/day). If diet is the route of administration, the level of the test material in the total diet may be reported in parts per million (mg/kg feed) (dry weight basis for ruminants).	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DosesConcentrations
Details on dosing	Include further details on the preparation of dose and the dosing regimen. If diet is the route of administration, use free text template (delete/add elements as appropriate) or formulate otherwise or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). PREPARATION OF	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.DetailsOnDosing

	DOSE: Describe the method of preparation of the dose (mixing with feed or concentrate ration, gelatine capsule, bolus, etc.). Indicate the date of dose preparation and storage conditions prior to its administration. RATIONALE FOR SELECTION OF DOSE LEVELS: Briefly describe, i.e. Level of intake expected, Exaggerated levels. Provide justification for other than the recommended dosing scheme. ANALYSIS OF SPIKED FEED: Describe the method used to analyse spiked feeds and the results of such analyses. If the methodology is described in chapter 'Analytical methods', you can include a cross-reference to that record in the block 'Cross-reference'. DOSING REGIME: Using an appropriate predefined table indicate the dosing regimen used.		
No. of animals per dose group	Report the number of animals per dose group, e.g. 3 cows per feeding level.	Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.NoOfAnimalsPerDoseGroup
Control animals	Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AdministrationExposure.ControlAnimals

Further details on study design		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign
Further details on study design	Include any further relevant details on the study design.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.FurtherDetailsOnStudyDesign
Details on sampling and analytical methods	Include details on the sampling, handling and preparation of samples and the analytical methodology applied. Use freetext template and delete/add elements as appropriate, or upload predefined table(s), if any, in rich text field 'Any other information on materials and methods incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). The following information should be addressed: IN-LIFE SAMPLING - Milk / eggs collected: Explain the collection of milk and eggs with any deviations from normal practice explained. Note compositing or pooling of samples; no pooling of milk from animals within a dosage group. - Amount of milk and number of eggs produced during normal production: Provide data as indicated.	Text template	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.FurtherDetailsOnStudyDesign.DetailsOnSamplingAndAnalyticalMethods

	- Urine, faeces, cage wash collected: For feed-through pesticides, include data on urine, feces and cage wash. POST-SLAUGTHER SAMPLING - Mode of sacrifice: Describe - Interval from last dose or treatment to sacrifice: Describe the time interval in hours or days between time of sacrifice and administration of last dose or application of final treatment. Give an explanation of intervals longer than 24 hours and consideration of their effect on residues. - Tissue harvested and their weights: Indicate the tissues taken after sacrifice, their type (e.g., thigh muscle, omental fat, etc.), and their weights. - Specification of and combining of samples from different animals: Indicate if pooling was done (usually acceptable for poultry, but not ruminants). SAMPLE HANDLING AND PREPARATION: Describe the handling of tissues, eggs and milk between sample collection and storage addressing at least following items: - Sample preparation		

	prior to storage: e.g., chopping - Containers - Storage temperature - Length of storage: Include dates of collection, shipping, analysis, etc. - Mode of shipping, if applicable: ANALYTICAL METHODOLOGY If the method has been reported in Section 4 of the dossier `Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required. If no study record was created for this method (and its validation) in Section 4 of the dossier, please provide here: - Description of instrumentation, equipment and reagents used: Give a detailed description of the analytical method employed to measure residues and listing of which chemical species were measured (parent pesticide, metabolites). If the methodology is		

	described in chapter 'Analytical methods', you can include a cross-reference to that record in the block 'Cross-reference'. - Extraction schemes: state 'see graphic attached' if a figure is attached in field 'Illustration (picture/graph)' in 'Overall remarks, attachments'. - Description of extraction and fractionation of radioactivity in each matrix - Chromatographic and spectroscopic behaviour of radioactive residues in extracts of animal matrices, parent, metabolites, and reference standards - The LOQ for all animal matrices analysed and, if available, the LOD and a description of how the LOQ and LOD were determined.		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

	any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.		
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion
Storage stability	Where samples were not analysed within 30 days, provide evidence showing that the storage did not affect the results of the study. Typically, reference should be made to Section 6.1 where storage stability data showing the behaviour of residues as a function of time in tissues, milk, and eggs have been reported. By reference to the endpoint summary on storage stability (Section 6.1), please specify whether the conditions of storage of the samples of the present studies are covered by the most limiting storage conditions for which stability of the relevant residues has been demonstrated.	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.StorageStability
Residue data	Option 1: Possibility to use the repeatable block to report individually the residue levels, for each tissue at each sampling time for each feeding level for each relevant analyte. Copy this block of fields for recording the results of each sampling. Option 2: If more convenient, you may		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData

	skip this field and directly report the detailed results in the field below "Any other information on the results including tables". In such a case, simply copy/paste free text and Table(s) (see detailed instructions below).		
Sampling no.		Multi select closed list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingNo
Matrix / tissue sampled		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.MatrixTissueSampled
Sampling time		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.SamplingTime
Dose / feeding level		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.DoseFeedingLevel
Residue levels			ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.AnalyteIdentity
Residue level (measured)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelMeasured
Residue level (calculated)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelCalculated

Residue level (calculated and corrected)		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.ResidueLevelCorrected
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.ResidueLevels.Remarks
Residue levels			
Total / mean	Specify the total (mean) of the parent compound and the metabolites, for instance if the residue definition was determined for enforcement purposes.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueData.TotalMean
Residue data			
Recoveries	Provide recovery percentages (all values, not just averages or ranges) for the test substance and/or its metabolites for tissues, milk, and eggs fortified with these compounds. If the method is described in another record, you can include a reference to that method description using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Recoveries

Depuration	Provide the results of depuration studies, if any. If a separate depuration study was done, you can include a reference to that record using the 'Cross-reference' feature. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.Depuration
Residue transfer	Outline the conclusion reached as to whether residues of the pesticide transfer from feed items, direct application to meat, milk and eggs. If so, discuss the extent of transfer. Indicate the time needed to reach a plateau level in eggs and milk, respectively. The results can be summarized in a table (the preferable format) showing either the ranges or maximum residues in type each of sample for each feeding level. As appropriate, upload predefined table(s), if any, in rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.ResidueTransfer
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOn

			ResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each sample, please report it in one/several table(s) of results. Please use the recommended formats, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.4]. Please repeat the tables as much as necessary.	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file. Do not upload the "Excel Animal		ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial

	calculator" here as this should be done at the level of the endpoint summary.		
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion
Conclusions	Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any).	Text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. Example: [Active ingredient] was administered [method of administration] to	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesInLivestock.ApplicantSummaryAndConclusion.ExecutiveSummary

	[number and breed] of [animal] for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed]. [Report details on depuration study, if applicable.] Milk/egg samples were collected twice daily [provide details on sampling method]. Animals were sacrificed on Day xx within [xx] hours of last dose. Tissue samples of [liver, kidney, muscle, and fat] were taken from each sacrificed animal. All samples were maintained frozen at the testing facility, during shipping to the laboratory and were stored frozen until analysis. The maximum storage interval for samples between collection and analysis was [xx] days/months. Residues of [active ingredient] have been shown to be stable in [livestock matrices] for up to [xx] days under frozen conditions. Adequate storage stability data are therefore available to support the storage conditions and intervals for samples in the current study. Samples in the current study were analysed using Method [Method ID], a [describe method] to determine residues of [list analytes]. Acceptable [method validation and]		

	concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] ppm, thus validating the method. The limit of quantitation (LOQ) was [xx] ppm per analyte for [matrices]. Following a pre-slaughter interval of [xx] hours, individual sample residues ranged from xx ppm to yy ppm [list matrices and residue levels]. [Describe, qualitatively and quantitatively, the relationship between residue levels and dosing levels for the matrices addressed in the study.] Depuration results indicated that residues of [analytes(s)] will [describe depuration results, noting especially matrices where there appears to be little reduction of residues with time.]		

6.5 Effects of processing – Endpoint summary

Purpose:
Purpose of document on the effects of processing on the nature of residues: To provide a summary on the nature of the active substance/metabolites under standard hydrolysis study and to conclude whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.

Purpose of document on the effects of processing on the magnitude of residues: To provide an overview on the quantitative distribution of residues in various processed commodities (PC) and the derived processing factors (PF). Pesticide residues to be measured in processing studies are determined by the residue definition which is derived from studies on the nature of the residue in processing and/or in plant and livestock.

ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResidues

	block		ProcessedCommodities.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation
	Please make a statement whether: 1) the nature of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current data requirements and OECD Guideline No 507) and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please also clarify if the reported conclusions on stability/non stability of the residues under hydrolytic conditions refer to the parent compound only and/or to any relevant metabolites found in plant and animals. In the latter case, please specify the metabolites covered by this conclusion. 2) the magnitude of residues in processed commodities was sufficiently investigated in the context of the present dossier (according to current data requirements and to OECD Guideline No 508) and highlight data gap(s) and the non-	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.KeyInformation

	standard uncertainty(ies), if any. If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here. Key results used for the risk assessment should be reported in the detailed tables below.		
Nature of residues in processed commodities	Repeat this block to create one row per key result (e.g. one row for each hydrolytic condition investigated by the study/ies).		ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities
Relevant studies	Provide here the link to the most relevant study(ies) from which the key results for nature of residues in processed commodities.	Endpoint reference list	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.RelevantStudies
Conditions	Select the standard hydrolysis conditions (e.g. sterilisation) for which a conclusion can be derived.	Multi select open list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Conditions
Stable	Select a statement whether the residues are stable or not when undergoing hydrolytic conditions mentioned above. Please use the field "remark" to further specify the conclusion (e.g. if the answer is "no", please specify which are the main degradation products expected, e.g. if the answer is "inconclusive", please specify the eventual data gaps).	Closed list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ResidueNatureProcessedCommodities.Stable
Nature of residues in processed	Repeat this block to create one row per key		

commodities	result (e.g. one row for each hydrolytic condition investigated by the study/ies).		
Processing factors	Repeat this block to create one box per combination raw agricultural commodity (RAC)/processed commodity (PC) for which processing factors could be derived. This section can also be used to capture the distribution of residues in peel/pulp by derivation of process factor pulp/RAC.		ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors
Relevant studies	Provide here the link to the most relevant study(ies) from which the key values (e.g. processing factors) for magnitude of residues in process commodities are derived.	Endpoint reference list	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RelevantStudies
Raw agricultural commodity (RAC)	Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing. The term RAC means the same as "primary food commodity" or "primary feed commodity". Indicate the raw agricultural commodity (RAC) for which the processing factor is derived (e.g. apple). If not available, select 'other:' and specify.	Open list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.RawCommodity
Processed commodity (PC)	Processed commodity (PC) means the products - resulting from the application of physical, chemical or biological processes or	Open list with remarks (2000)	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessedCommodity

	combinations of these to a "primary food commodity" - intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. A primary processed commodity is derived from mechanical or chemical processing of the RAC and is not a multicomponent product. Indicate the processed commodity (PC) for which the processing factor is derived (e.g. apple juice). If not available, select 'other:' and specify.		
Number of trials	Indicate here the number of independent tests used to derive processing factors.	Integer	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.NoTrials
Median processing factor: RD MO	Processing factor (PF) is the ratio of the residue level identified in the processed commodity according to the residue definition for enforcement (RD MO) and the residue level identified in the raw agricultural commodity according to enforcement residue definition (RD MO): PF MO = [residue concentration in Processed Com] RD MO/ [residue concentration in RAC] RD MO This factor is valid for the combination `procedure/commodity` , which was investigated in the processing study.	Decimal	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorMo

	Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC). If the residue definition for enforcement purposes in processed products differs from the residue definition in the RAC, the processing factor should be calculated taking into account the molecular weights of the different substances. If that is not feasible, the processing factors shall reflect the enforcement residue definition in processed commodity.		
Median processing factor: RD RA	Insert here the mean (of two studies) or median (of more than 2 studies) value of all available processing factors for a given combination raw agricultural commodity (RAC)/processed commodity (PC) according to following formula: PF RA = [residue concentration in Processed Com] RD RA/ [residue concentration in RAC] RD MO. If the residue definition for risk assessment purposes in processed products differs from that in the RAC, the processing factor should	Decimal	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.ProcessingFactorRa

	be calculated taking into account the molecular weights of the different substances. If that is not feasible, the processing factors shall reflect the risk assessment residue definition in processed commodity.		
Remarks	Please enter any additional remark for the processing factor, for example if the processing factor is tentative.	Multi-line text	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.KeyInformation.ProcessingFactors.Remarks
Processing factors			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion
	This section can be used to add any additional useful text. A discussion could be provided as to the significance of the residues in the processed commodities and the distribution behavior of the active ingredient and metabolite/degradation products, i.e., in which processed commodities and at what levels quantifiable residues can be expected. Comparison of processing factors should also be discussed if two or more tests are conducted within one study and described in one final report. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities.Discussion.Discussion
Attached background	You can attach here any		ENDPOINT_SUMMARY.N

material	useful document that support the above statement. However, do not repeat the attachments that are already reported in the respective endpoint summaries of the detailed sections.		atureMagnitudeResidues ProcessedCommodities. Discussion.AttachedBack groundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.N atureMagnitudeResidues ProcessedCommodities. Discussion.AttachedBack groundMaterial.Attached Document
Remarks		Text	ENDPOINT_SUMMARY.N atureMagnitudeResidues ProcessedCommodities. Discussion.AttachedBack groundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY.N atureMagnitudeResidues ProcessedCommodities. Discussion.AttachedSani tisedDocsForPublication

6.5.1 Nature of the residue – Endpoint study record

Purpose:
Studies concerning the nature of the residue to establish whether or not breakdown or reaction products arise from residues in the raw agricultural commodity (RAC) during processing, which may require a separate risk assessment.

ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_REC ORD.NatureResiduesInP rocessedCommod.Admin istrativeData
		Confidentiality	ENDPOINT_STUDY_REC ORD.NatureResiduesInP rocessedCommod.Admin istrativeData.DataProtec tion
Endpoint	Select relevant endpoint from picklist: - Nature of the residues in processed commodities: high	Closed list with remarks	ENDPOINT_STUDY_REC ORD.NatureResiduesInP rocessedCommod.Admin istrativeData.Endpoint

	temperature hydrolysis. Or - Nature of the residues in processed commodities: other. If `other` is selected, please specify in the remark field the type of the study.		
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataWaiving

Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInP

	block		rocessedCommod.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.Guideline.Deviation

Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Radiolabelling	Select the appropriate product from the picklist (yes; no; other:; not specified). Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Specific details on test material'. Any other useful information to include in the remark field.	Open list with remarks	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.Materi

			alsAndMethods.StudyDesign
Test strategies	Brief description of testing guideline conditions used.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.TestStrategies
Experimental procedure	Describe experimental procedure applied by using the existing templates. Brief outline of study design, i.e. test facility, environmental/ hydrolytic conditions, amount and concentrations of test substance applied, use of solvent, etc. Use freetext template and delete/add elements as appropriate. If applicable, discuss unusual experimental problems encountered, attempts made to alleviate these problems which resulted in deviations from the intended test protocol and the effects, if any, of those deviations on the results of the study.	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.StudyDesign.ExperimentalProcedure
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample handling and storage conditions	Include details on the sampling, sample handling and storage conditions. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction. Use the existing templates to report the necessary information.	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndStorageConditions

Details on analytical methodology	If the method has been reported in Section 4 of the dossier `Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required. If no study record was created for this method (and its validation) in Section 4 of the dossier, you have 2 options how to report the data: Option 1: please use the existing templates to report the following details on analytical method: method validation data, recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per	Text template	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted. Option 2: Summarize the details on analytical methodology in table(s) as reported in the field `Any other information on materials and methods incl.tables`		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For reporting details on analytical methodology, if you did not use Option 1, please report here the details on the analytical methods in one/several table(s). Please use the recommended formats as available in the knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5].	Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

		Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion
Storage stability (Sample Integrity)	Please provide a statement on the sample integrity against storage conditions. Where relevant, provide storage stability data for all major components of the total radioactive residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.StorageStability
Total radioactive residues (TRR)	Option 1: possibility to use the repeatable block to report individual results for each identified compound per test condition. Copy this block of fields for recording the results for each test compound per test condition. Option 2: report directly the detailed information on the results of hydrolysis study and on the identity of TRR components in table(s) in the field `Any other information on results incl. tables`.		ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR
TRR component no.		Closed list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRComponentNo

Test conditions		Multi-line text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TestConditions
Identity of TRR component		Entity reference field	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.IdentityOfTRRComponent
TRR concentration		Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRConcentration
TRR percentage		Range (Decimal)	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.TotalRadioactiveResiduesTRR.TRRPercentage
Total radioactive residues (TRR)			
Other details on TRRs	Provide any other relevant details related to the characterisation and/or identification and distribution of TRRs.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.OtherDetailsOnTRRs
Metabolic pathway	Discuss the routes of degradation observed and describe the metabolic pathways and/or attach figures in field "Illustration (picture/graph)"	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.MetabolicPathway
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation

	document, provided it was converted to the HTML format. If you did not use the option 1 to report the detailed results for each analyte determined for given processing condition, please report it in one/several table(s) of results. Please use the recommended formats, available in [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5].		
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.AttachedStudyReport
Illustration		Image	ENDPOINT_STUDY_REC

(picture/graph)			ORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. Example: The effect of processing on the nature of [active substance/metabolite] was investigated in standard hydrolysis study simulating [include here the process, temperature, pH] conditions. The results showed that the [active substance/metabolite] is hydrolytically stable OR progressively degrades to [indicate degradation product, % applied radioactivity, amount in mg/kg] OR almost totally degraded to [indicate degradation product, % applied radioactivity, amount in mg/kg] under [indicate processing condition]. Further considerations on the nature of identified degradation	Rich text area	ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod.ApplicantSummaryAndConclusion.ExecutiveSummary

	products, if any, could be provided here.		

6.5.3 Magnitude of residues in processed commodities – Endpoint study record

Purpose:
Studies concerning the effects of processing on the magnitude of residues in processed commodities to determine the quantitative distribution of residues in the various processed commodities used as food or feed, to estimate processing factors and to allow a more realistic estimation of dietary intake of residues.

ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: magnitude of residues in processed commodities	Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInP

			rocessedComm.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.ReasonPurpose

Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInP

			rocessedComm.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.Material

			sAndMethods.StudyDesign
Bulk raw agricultural commodity (RAC)	Raw agriculture commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. The term RAC means the same as "primary food commodity" or "primary feed commodity". Select the raw agricultural commodity (RAC). If not available, select 'other:' and specify.	Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.BulkRawAgriculturalCommodity
Details on test commodity	Include details on the test commodity, including a description of the general condition (e.g. immature/mature, green/ripe, fresh/dry). Use existing template and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.DetailsOnTestCommodity
Sample processing	Briefly describe how the RAC was processed into the processed commodity(ies). As appropriate and relevant, attach or upload the processing flow chart in 'Illustration (picture/graph)'.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.SampleProcessing
Further details on study design	Include any further relevant details on the study design. Use existing templates and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign
Sampling and analytical methodology		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology
Details on sample	Include details on	Text template	ENDPOINT_STUDY_REC

collection	sampling time (age of raw commodity in days), number of samples/replicates. Use existing templates and delete/add elements as appropriate.		ORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleCollection
Details on sample handling and preparation	Include details on the sample handling and preparation. Use existing template and delete/add elements as appropriate. The following information should be addressed: handling and shipping of commodities, storage conditions, length of storage, any preparation done prior to extraction.	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnSampleHandlingAndPreparation
Details on analytical methodology	If the method has been reported in Section 4 of the dossier `Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and contain the data on method validation, further information is not required. If no study record was created for this method (and its validation) in Section 4 of the dossier, you have 2 options on how to report the data: Option 1: please use the existing templates to report the following details on analytical method: method validation data, recovery and method sensitivity data. Preparation and handling of the sample throughout the method described in detail. Note that methods for metabolites may also be	Text template	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.SamplingAndAnalyticalMethodology.DetailsOnAnalyticalMethodology

	needed. Recovery data should be obtained concurrently with the residue analyses to validate the method and establish its sensitivity (lowest reliable quantification limit). State the LOD and LOQ. Experimental design of these validation studies described including: (1) Identity of the test compounds and crop substrates, (2) Magnitudes of fortification levels, (3) Number of replicates per test compound per level. Identify instrumentation, equipment and reagents used and the operating conditions of the instrumentation. If the extraction/clean-up procedure is complex, a flow diagram should be submitted. Option 2: summarize the details on analytical methodology in table(s) as reported in the field `Any other information on materials and methods incl.tables`		
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. For reporting details on analytical methodology, if you did not use Option 1, please report here the details on the analytical methods in one/several table(s). Please use the recommended formats as available in [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5].	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion
Storage stability of residues (Sample integrity)	Provide storage stability data for all major residues, including conditions and length of storage of samples following receipt in laboratory and conditions and length of storage of extracts prior to identification of residues (Note: Handling, pre-shipping storage and shipping procedures for harvested samples to be described in field 'Details on sampling and analytical methodology').	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.StorageStabilityOfResiduesSampleIntegrity
Residues in RAC prior		Header 2	ENDPOINT_STUDY_REC

to processing			ORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing
Bulk RAC sub-sample sample no.	Option 1: possibility to use the repeatable block to report individual results for each RAC. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets. Option 2: report directly the detailed information on the results in RAC in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] to be attached in the field below "Attached background material"		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo
Date of sub-sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.DateOfSubSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesIn

			RACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInP

			rocessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampleNo.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInRACPriorToProcessing.BulkRACSubSampleSampl

			eNo.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Bulk RAC sub-sample sample no.			
Residues in processed fractions (PF) and aspirated grain fractions (AGF)		Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF
Processing information	Description of processing method(s). Processed fraction: Special attention should be given to, but not limited to, processing order, pressures, temperatures, and the corresponding yield-weights of each fraction. Processed fraction handling (e.g. samples were frozen within 24 hours after processing). A description of the process method is necessary and the use of flow chart diagrams is helpful.	Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessingInformation
Processed fraction	Option 1: possibility to use the repeatable block to report individual results for each processed commodity/fraction. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets. Option 2: report directly the detailed information on the results for each processed commodity/fraction in the Excel file Processing trials table [cf. residue		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction

	Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents"		
Processed fraction (PF sample)		Open list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.ProcessedFractionPFSample
PF sample no.		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.PFSampleNo
Date of processing		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.DateOfProcessing
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleID
Analysis sample description		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalysisSampleDescription
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsA

			ndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsA

			ndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.CorrectionByRecovery
Reference portion		Multi-line text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ReferencePortion
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInP

			rocessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResiduLevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.ProcessedFraction.AnalyteMeasured.ResiduLevelCalculatedAndCorrected
Analyte measured			
Processed fraction			
Aspirated grain fractions (AGF sample)	Option 1: possibility to use the repeatable block to report individual results for each AGF sample. Copy this block of fields for recording the results for each test compound per test condition. This option could be deployed in case of small data sets. Option 2: report directly the detailed information on the results for each AGF sample in the Excel file Processing trials table [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)] for residues in processed commodities to be attached in the field below "Attached sanitized documents".		ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample
AGF analysis sample		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AGFAn

			alysisSample
Date of AGF sample		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.DateOfAGFSample
Analysis sample ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalysisSampleID
Analyte measured			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured
Analyte identity		Entity reference field	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalyteIdentity
Extraction date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ExtractionDate
Analysis date		Date	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAn

			dAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.AnalysisDate
Method ID		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.MethodID
Storage stability factor		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.StorageStabilityFactor
Use of factor		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.UseOfFactor
Correction by storage stability		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByStorageStability
Recovery		Decimal	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.Recovery
Correction by recovery		Closed list	ENDPOINT_STUDY_RECORD.MagnitudeResidInP

			rocessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.CorrectionByRecovery
Residue level (measured)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelMeasured
Residue level (calculated)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculated
Residue level (calculated and corrected)		Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.AspiratedGrainFractionsAGFSample.AnalyteMeasured.ResidueLevelCalculatedAndCorrected
Analyte measured			
Aspirated grain fractions (AGF sample)			
Distribution of residues	Report quantitative information on the recovery of the residue from the processed commodities.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.ResiduesInProcessedFractionsPFAndAspiratedGrainFractionsAGF.DistributionOfResidues
Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also	Header 2	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsA

	open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.		ndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.IllustrationPicGraph

Attached (sanitised) documents for publication	Please upload here the Excel file Processing trials table. An empty Excel file to report Residues in Processed commodities is available on the 'knowledge junction' [cf. residue Template 6.5 (http://doi.org/10.5281/zenodo.4621130)]. The uploaded file should not contain confidential material.	Attachments list	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. Example: [crop] field trial for [active ingredient] was conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] and harvested xx days after final treatment. The [RAC samples] were processed into [processed food/feed fractions] using [simulated commercial practices]. All samples were frozen at the testing facility and remained frozen during shipping and	Rich text area	ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm.ApplicantSummaryAndConclusion.ExecutiveSummary

	storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions. Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of [list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices]. A comparison of the residues in the raw agricultural commodity (RAC) with those in each processed fraction resulted in processing factors of [processing factors] for [processed fractions], respectively. These processing factors [conform/did not conform] with the theoretical concentration factors.		

6.7 Proposed residue definitions and maximum residue levels

6.7.1 Proposed residue definitions – Endpoint summary

Purpose:
provide a summary overview on the residue definitions for commodities of plant and animal origin as derived on the basis of available metabolism studies in plant, livestock and processed commodities; and to provide conclusions on which compounds are to be included in the residue definitions for enforcement and risk assessment. In this endpoint summary, you should also highlight the tentative/indicative residue definitions and their relevant data gaps.

ENDPOINT_SUMMARY.ResidueFood			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.ResidueFood.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	ENDPOINT_SUMMARY.ResidueFood.KeyInformation
	Optional text box to specify any particular issue related to the residue definitions, that could not be reported in the following tables.	Rich text area	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.KeyInformation
Food / feed of plant origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect each combination "crop group/metabolism group/treatment type/provisional or not" residue definitions for risk assessment derived for this substance.		ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa
Crop group	Indicate if the residue definition covers primary crops and/or processed and/or rotational	Multi select closed list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.CropGroup
Metabolism group	If the residue definition is for primary crops or rotational crops, then select the metabolism group for which the RD is applicable (from list	Multi select open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.MetabolismGroup

	OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)		
Treatment type	Indicate the type(s) of treatment for which the RD is applicable (e.g. seed treatment or foliar application)	Multi select open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.TreatmentType
Residue definition risk assessment	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRisk
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.ResidueDefinitionRiskComp
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox references value of compound 2…).	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeedPlantOriginResidueRa.Remarks
Food / feed of plant origin residue definition risk assessment			
Food / feed of plant origin residue definition for	Use the repeatable block to create as many rows as necessary to		ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOrigi

monitoring	reflect each combination "metabolism group/ provisional or not" residue definitions derived for this substance. Please note that for monitoring RD, no distinction be made between primary and rotational crops.		nMonitoring
Metabolism group	Select the metabolism group for which the RD is applicable (from list OECD list Crops and Crop Groups for Purposes of Metabolism in Crops Studies)	Multi select open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.MetabolismGroup
Residue definition monitoring	Write here the full name of the residue definition for monitoring; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.MonitoringResidueDefinitionLoq
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)…)	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.Remarks

Validated method	Indicate if there is a validated method for Monitoring (including inter-laboratory validation ILV) is available	Check box	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.ValidatedMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.FoodFeeedPlantOriginMonitoring.LinkToValidatedMethod
Food / feed of plant origin residue definition for monitoring			
Food of animal origin residue definition risk assessment	Use the repeatable block to create as many rows as necessary to reflect each combination "animal commodity/provisional or not" residue definitions for risk assessment derived for this substance.		ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa
Animal	Select the animal group (e.g ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants and pigs), multi-selection feature can be used.	Open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Animal
Commodity	Select that animal product (e.g. liver or eggs) for which the proposed residue definition is applicable. If the same residue definition is applicable to several commodities (e.g. r all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Commodity
Residue definition risk assessment	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessment

	current standards (e.g. sum of parent and metabolite 01, expressed as parent).		
Residue definition risk assessment components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.ResidueDefinitionRiskAssessmentComponents
Provisional	Indicate if the residue definition for risk assessment is provisional, if yes a remark field will open where the data gaps should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Provisional
Remarks	Any additional remarks regarding the proposed RD for risk assessment (e.g. common RD with other substances, RD1 associated with tox references value of compound 1, RD2 associated with tox references value of compound 2…).	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginRa.Remarks
Food of animal origin residue definition risk assessment			
Food of animal origin residue definition monitoring	Use the repeatable block to create as many rows as necessary to reflect each combination "animal commodity/provisional or not" residue definitions for monitoring derived for this substance.		ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring
Animal	Select the animal group (e.g ruminants) for which the proposed residue definition is applicable. If the same residue definition is applicable to several animals (e.g. ruminants	Open list	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Animal

	and pigs), multi-selection feature can be used.		
Commodity	Select that animal product (e.g. liver or eggs) for which the proposed residue definition is applicable. If the same residue definition is applicable to several commodities (e.g. r all tissues of ruminants and pigs), multi-selection feature can be used.	Multi select open list with remarks	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Commodity
Residue definition monitoring	Write here the full name of the residue definition for risk assessment; please use the exact wording in line with the current standards (e.g. sum of parent and metabolite 01, expressed as parent).	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoring
Residue definition monitoring components	Select the substance(s) (parent and/or metabolites/breakdown products) that is/are part of the residue definition written above	Entity reference list	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.ResidueDefinitionMonitoringComp
Monitoring residue definition LOQ (mg/kg)	Limit of quantification (LOQ) for the residue definition for monitoring and enforcement	Decimal	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.MonitoringResidueDefinitionLoq
Provisional	Indicate if the residue definition for monitoring is provisional, if yes describe a remark field will open where the data gap(s) should be reported. Please note that if there is a data gap, the RD should be considered provisional.	Closed list with remarks (2000)	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Provisional
Remarks	Any additional remarks regarding the proposed RD monitoring (e.g. common RD with other substance(s)…)	Multi-line text	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.Remarks
Validated method	Indicate if there is a validated method for	Check box	ENDPOINT_SUMMARY.ResidueFood.KeyInformat

	Monitoring (including inter-laboratory validation ILV) is available		ion.AnimalFoodFeedPlantOriginMonitoring.ValidatedMethod
Link to validated method	Link to the study describing method for monitoring and its validation	Endpoint reference field	ENDPOINT_SUMMARY.ResidueFood.KeyInformation.AnimalFoodFeedPlantOriginMonitoring.LinkToValidatedMethod
Food of animal origin residue definition monitoring			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.ResidueFood.Discussion
	Provide any additional information, this can be in the format of tables	Rich text area	ENDPOINT_SUMMARY.ResidueFood.Discussion.Discussion
Attached background material	Upload any additional material to support the residue definition proposal		ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of the attachment/s must be provided for publication	Attachments list	ENDPOINT_SUMMARY.ResidueFood.Discussion.AttachedSanitisedDocsForPublication

6.7.2 Proposed maximum residue levels and justification – Flexible summary record

Purpose:
provide a summary overview on the proposed MRLs for commodities of plant and animal origin as derived on the basis of supervised residue field trials (for plants) or from livestock feeding studies (for animal commodities). In this endpoint summary, you should also highlight the tentative/indicative MRLs and their relevant data gaps, indicate the proposed extrapolations and discuss the eventual non-standard uncertainty.

FLEXIBLE_SUMMARY.MRLProposal			
Name	Instructions	Type	Field path

Administrative data	Administrative data summary – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.MRLProposal.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation
	Optional text box to specify any particular issue related to the proposed MRL(s), that could not be reported in the following table.	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.KeyInformation
Maximum residue level	Use the repeatable block to create as many rows as necessary to report each MRL proposed in this application. Please report only one MRL proposal per combination "commodity/residue definition for monitoring". If for a given plant commodity, different MRLs could be derived in section 6.3 (based different GAPs), please only report the MRL to be proposed for inclusion in the Regulation (i.e. highest MRL for which no safety concerns are identified). A MRL proposal should be linked to a GAP, at least one commodity and to a residue definition for monitoring (RD MO). If more than one RD MO are derived for this active substance, please propose one MRL per RD MO.		FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel
Rationale for MRL proposal	Please indicate the reason why a new MRL is proposed, by choosing one or more	Open list with remarks (2000)	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.RationaleForMrl

	rationale(s). Repeat this action for each MRL proposed in this table. Examples: - if an MRL on wheat grain is directly derived from a GAP on wheat, please select "use on primary crop". - If an MRL on commodity of animal origin is derived because the GAP on wheat leads to a significant increase of the dietary burden, please select "increase of the livestock dietary burden".		
Critical GAP	This entry refers to the critical GAP(s), on which the MRL proposal is based. If rationale for the MRL proposal is "use on primary crop", cross ref to the critical GAP. In case of several GAPs for the same commodity/crop (e.g. SEU, NEU, indoor, third countries) only one link to GAP resulting in the highest MRL proposal not leading to consumer safety concerns should be made. If the MRL proposal is based on a combined dataset linked to several GAPs, links to all these GAP forms should be made. If rationale for MRL proposal is "residue in rotational crops from soil uptake", please cross refer to the GAP leading to highest residue in soil.	Endpoint reference list	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.CriticalGap
Commodity	Indicate the commodity(ies) for which MRL is derived. Please repeat this block for each MRL proposal. In case of	Multi select open list	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.Commodity

	extrapolations, with similar MRL for different commodities, the extrapolated commodities can be selected using the multi-selection (e.g. apples, pears, quinces).		
MRL proposal	This field refers to the MRL proposal (in mg/kg) in the commodity(ie)y of plant or animal origin. In case of multiple GAPs, the highest MRL (expressed on RD for monitoring) and not leading to consumer safety concerns should be inserted here.	Unit measure with Closed List (Decimal)	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlProposal
Residue definition monitoring	Enter the monitoring residue definition relevant for the selected commodities of plant or animal origin. This is the residue definition on which the MRL is derived.	Multi-line text	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.ResidueDefinitionMonitoring
MRL at LOQ	Tick this box to indicate if the MRL is proposed at the enforcement LOQ (equivalent to symbol * in the EU MRL database.	Check box	FLEXIBLE_SUMMARY.MRLProposal.KeyInformation.MaximumResidueLevel.MrlLoq
Maximum residue level			
Additional information	Discussion(Header 1) – common block	Header 1	FLEXIBLE_SUMMARY.MRLProposal.Discussion
	Provide any additional information related to the MRL proposal(s), e.g., cases were MRL proposal are based on results from other crops.	Rich text area	FLEXIBLE_SUMMARY.MRLProposal.Discussion.Discussion
Attached background material	Upload any additional material to support the residue definition proposal. Copy this block of fields for attaching more than one file.		FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMaterial
Attached document		Single file attachment	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMate

			rial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of the attachment/s must be provided for publication. In support of the MRLs proposed for plant commodities, please attach here the OECD calculator Excel file, available on https://www.oecd.org/env/ehs/pesticides-biocides/oecdmaximumresiduelimitcalculator.htm , including the residue values used to derive the MRL proposal(s). The MRLs proposed for animal commodities, should be justified by the Animal Calculator Excel, which is uploaded in the endpoint summary of Section 6.4 (Feeding studies). The uploaded file should not contain confidential material.	Attachments list	FLEXIBLE_SUMMARY.MRLProposal.Discussion.AttachedSanitisedDocsForPublication

6.9 Estimation of the potential and actual exposure through diet and other sources – Flexible summary

Purpose:
To provide an overview of the estimated potential or actual exposure to the active substance/metabolite(s) to humans through the intake of food and other means from the uses under consideration (e.g. representative/intended GAP and/or MRLs) and highlighting whether a risk for consumer is expected. In the long-term (chronic) risk assessment, the estimated chronic dietary exposure is compared with the acceptable daily intake (ADI) value which gives the concentration of a chemical that can be consumed over a long period without unacceptable negative health effects. For the short-term (acute) risk assessment, the Acute Reference Dose (ARfD) is used to identify possible consumer health risks. The ARfD gives the concentration of a chemical that can be ingested over a short period of time (one meal, one day) without appreciable risks. EFSA PRIMo (Pesticide Residue Intake Model), an Excel-based calculation spreadsheet, is the standard tool used at EU level to perform the dietary risk assessment for pesticide residues in the framework of setting and reviewing of maximum residue levels for pesticides under Regulation(EC) No 396/2005 and in the peer review of pesticides under Regulation (EU) No 1107/2009. EFSA guidance on the Use of EFSA PRIMo rev 3, available https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147.

FLEXIBLE_SUMMARY.ExpectedExposure			
Name	Instructions	Type	Field path
Administrative data		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.ExpectedExposure.AdministrativeDataSummary.DataProtection
Description of key information		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation
	Optional text box to specify any particular issue related to the exposure assessment that could not be reported in the following tables. Make reference to the risk assessment residue definition reported in the Proposed residue definitions document, th e toxicological reference values reported in the Toxicological reference values document and Processing/peeling factors reporting in the Nature and magnitude of residues in processed commodities document. When estimating the exposure it shall be born in mind that the risk assessment has to take into account the residue definition established for risk assessment. Describe if relevant, the possible presence of pesticide residues arising from sources other than current plant protection uses of active	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.KeyInformation

	substances (for example use of active substances resulting in common metabolites, use as biocide or veterinary drug), and how their aggregate exposure shall be taken into account. Describe the method and results, if cumulativ e exposure to more than one active substance has been performed.		
Exposure from dietary sources		Header 2	FLEXIBLE_SUMMARY.Ex pectedExposure.KeyInfo rmation.ExposureDietary Sources
	Please summarize in the table the key results of the consumer exposure assessment by PRIMo, indicating the uses under consideration (e.g. representatives and/or MRLs) and highlighting whether a risk for consumer is expected. -Highest Theoretical Maximum Daily Intake (TMDI): % of ADI, diet and highest contributing commodities -Highest International Estimated Short-Term Intake (IESTI) *: % of ARfD, highest contributing commodities, consumer group -Highest IESTI New**: % of ARfD, highest contributing commodities, consumer group, threshold value (in case IESTI New >100% ARfD) * Scenario 1 should reflect the currently	Rich text area	FLEXIBLE_SUMMARY.Ex pectedExposure.KeyInfo rmation.ExposureDietary Sources.field3689

	used EU risk assessment methodology using variability factors agreed by EU risk managers and the highest residue (HR) or the Supervised Trials Median Residue (STMR) according to case 1, 2a/2b and case 3 as defined in the FAO Manual (FAO, 2016, available in http://www.fao.org/3/i5452e/i5452e.pdf) ** scenario 2, the acute exposure should be calculated in line with the recommendations of the international workshop on revisiting the IESTI equations (see EFSA guidance on the Use of EFSA PRIMo rev 3, available https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5147) Please use the recommended formats, available on knowledge junction ([cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.9]. Please repeat the tables as much as necessary.		
Exposure from other sources (drinking water)		Header 2	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources
	Exposure from other sources (drinking water). Please report in the Table the additional contribution to consumer intake	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.KeyInformation.ExposureOtherSources.field4124

	through drinking water resulting from groundwater metabolites expected to be present above 0.75 µg/L. Indicate any metabolites include d in the exposure assessment. Report PECgw or make reference to the information reported in Estimation of concentrations in ground water. Please use the recommended formats, available on knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.9]. Please repeat the tables as much as necessary.		
Additional information		Header 1	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion
	Provide any additional information, this can be in the format of tables. Indicate any deviations applied in the exposure calculation (changes in consumption data, variability factors, etc.). If conversion factors (CF) from enforcement to risk assessment applied, please specify to which commodities/commodity groups. Indicate whether various scenarios of the dietary exposure were calculated. Summarise assumptions for input values. Indicate risk mitigation measures applied.	Rich text area	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.Discussion
Attached background			FLEXIBLE_SUMMARY.Ex

material			pectedExposure.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	A sanitised version of the attachment/s must be provided for publication. Please upload here the PRIMo calculation. In case different scenarios are assessed, please repeat the block as much as necessary and explain the different scenarios in the remark field. An empty template of the PRIMo file is available on `knowledge junction (Residue Template 6.6: PRIMo rev.3.: http://doi.org/10.5281/zenodo.1137758]. The uploaded file should not contain confidential material.	Attachments list	FLEXIBLE_SUMMARY.ExpectedExposure.Discussion.AttachedSanitisedDocsForPublication

6.9 Estimation of the potential and actual exposure through diet and other sources – Endpoint study record

Purpose:
The reporting of the Endpoint Study record is not required and the main conclusions of the consumer exposure calculation, including the methodology applied, deviations considered and overall conclusions, should be reported in the Endpoint Summary.

6.10 Other studies – Endpoint summary

ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs			
Name	**Instructions**	**Type**	**Field path**
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.LinkToRelevantStudyRecord.Link
Description of key information		Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation
		Rich text area	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.KeyInformation.KeyInformation
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion
	Provide a brief description of additional study(ies) and of the key conclusions derived from this/these study(ies).	Rich text area	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.Discussion
Attached background material	Provide the original version of any additional useful document that contains confidential material		ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the	Single file attachment	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedi

	file in Attached (sanitised) documents for publication.		ngstuffs.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Provide any document for publication	Attachments list	ENDPOINT_SUMMARY.AdditionalInformationOnResiduesInFoodAndFeedingstuffs.Discussion.AttachedSanitisedDocsForPublication

6.10 Other studies – Endpoint study record

Purpose:
Use this section to report any study that does not fit into other specific endpoints study records or endpoints study summaries of the Section 6 (e.g. specific studies used to refine the consumer risk assessment such studies on variability factors).

ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood			
Name	Instructions	Type	Field path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataProtection
Endpoint	Select from picklist 'additional information on residue chemistry'	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Endpoint
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.PurposeFlag

Robust study summary		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.DataWaivingJustification
Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification

Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource
Reference		Literature reference list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.DataSource.DataProtectionClaimed

Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods
Background information		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.BackgroundInformation
Product type	Field not mandatory. The product type is already reported in Section 3.2 (Effect on harmful organism, function, mode of action and possible resistance). This field is optional.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.ProductType
Test guideline			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Qualifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.MethodNoGuideline

GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Study design		Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign
Details on study design		Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.StudyDesign.FurtherDetailsOnStudyDesign

Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.DetailsOnResults

Any other information on results incl. tables	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument

Remarks		Text	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached.	Rich text area	ENDPOINT_STUDY_RECORD.AdditionalInfoOnResiduesInFood.ApplicantSummaryAndConclusion.ExecutiveSummary

6.10.1 Effect on the residue level in pollen and bee products – Endpoint summary

Purpose:
provide a summary overview on the transfer of residues into pollen and bee products when active substance is applied on melliferous crop according to the intended/critical use pattern and whether any adverse risk to bee health was observed in the context of the present dossier.

Please report the key results on the residue levels in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_SUMMARY.SupplementaryStudies v.1.1 (Final)

Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block	Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary
		Confidentiality	ENDPOINT_SUMMARY.SupplementaryStudies.AdministrativeDataSummary.DataProtection
Link to relevant study record(s)		Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord
Study name / type	Provide here the link to the most relevant study(ies) from which the key values for magnitude of residues in honey and setting of MRLs in honey are derived.	Endpoint reference list	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord.Link
Results		Read-only	ENDPOINT_SUMMARY.SupplementaryStudies.LinkToRelevantStudyRecord.Results
Description of key information		Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.KeyInformation
	Please make a statement whether the magnitude residues in bee products was sufficiently investigated (according the current data requirements and to the latest version of the Technical Guideline SANTE/11956/2016) in the context of the present dossier and highlight data gap(s) and the non-standard uncertainty(ies), if any. Please report here the type of the experimental study according to the latest version of the Technical Guideline SANTE/11956/2016 (e.g., experimental studies via syrup feeding, field residue	Rich text area	ENDPOINT_SUMMARY.SupplementaryStudies.KeyInformation.KeyInformation

	trials or tunnel trials), which was designed with an objective to determine the inadvertent residue in honey arising from pesticide use, in order to allow a dietary risk assessment and to establish scientifically-based MRLs. The relevance of results should be discussed in relation to the proposed uses of the plant protection product, including a critical appraisal of the study and its results. In particular the following points must be addressed: - A residue at or above the LOQ (a value of 0.05 mg/kg or lower is favoured) in control samples - Adverse effects on health of the honeybees - MRL proposal and risk assessment values If studies reported in this summary are not guideline or GLP compliant, if deviation from guidance are observed (e.g. not validated analytical method), please report it here.		
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.SupplementaryStudies.Discussion
	Possibility to add any additional useful text on this section. If there is no additional information to be reported this field may be left empty.	Rich text area	ENDPOINT_SUMMARY.SupplementaryStudies.Discussion.Discussion
Attached background material	Add any additional document that support		ENDPOINT_SUMMARY.SupplementaryStudies.Di

	the above key results (e.g. calculation tables, graphs).		scussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	ENDPOINT_SUMMARY.SupplementaryStudies.Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_SUMMARY.SupplementaryStudies.Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Add any additional document that support the above key results (e.g. calculation tables, graphs).	Attachments list	ENDPOINT_SUMMARY.SupplementaryStudies.Discussion.AttachedSanitisedDocsForPublication

6.10.1 Effect on the residue level in pollen and bee products – Endpoint study record

Purpose:
Studies to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities			
Name	Instructions	Type	Field Path
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData
		Confidentiality	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataProtection
Endpoint	Select relevant endpoint from picklist: - residues in honey or residues - residues in pollen - residues in other bee products Once selected the endpoint, in the Remark field indicate the type of experimental study, according to the latest	Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.Endpoint

	version of the Technical Guideline SANTE/11956/2016, i.e., - Experimental study via syrup feeding - Experimental field data - Experimental tunnel data		
Type of information		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.StudyResultType
Adequacy of study		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.PurposeFlag
Robust study summary		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.RobustStudy
Used for classification		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.UsedForClassification
Used for SDS		Check box	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.UsedForMSDS
Study period		Text	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.StudyPeriod
Reliability		Open list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.Reliability
Rationale for reliability incl. deficiencies		Open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.RationalReliability
Data waiving		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataWaiving
Justification for data waiving		Multi select open list with remarks (32000)	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.DataWaivingJustification

Justification for type of information		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.JustificationForTypeOfInformation
Attached justification			ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification
Attached justification		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference			ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.AdministrativeData.CrossReference.Remarks
Cross-reference			
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource
Reference	Literature reference v.5.1 (Final)	Literature reference list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.Reference
Data access		Open list with remarks	ENDPOINT_STUDY_REC

			ORD.ResiduesProcessedCommodities.DataSource.DataAccess
Data protection claimed		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.DataSource.DataProtectionClaimed
Materials and methods	Material and methods – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods
Test guideline	Indicate according to which test guideline the study was conducted. (There are two options referring to the same guideline "Residue Levels in honey SANTE/11956/2016 rev. 9" and "Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey". If the study was performed according to this guideline, by convention please select "Residue Levels in honey SANTE/11956/2016 rev. 9"). If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).		ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline
Qualifier		Closed list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Qu

			alifier
Guideline		Open list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Guideline
Version / remarks		Multi-line text	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.VersionRemarks
Deviations		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.Guideline.Deviation
Test guideline			
Principles of method if other than guideline		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.MethodNoGuideline
GLP compliance		Closed list with remarks	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.GLPComplianceStatement
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials
Test material information		Entity reference field	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Please describe here any information relevant to a specific experimental study not mentioned elsewhere as required according to the latest version of the Technical Guideline SANTE/11956/2016. You can report data according to two options: Option 1: use the free	Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	text to describe specific experimental study, or Option 2: to report data in a table format to be inserted in the section` Any other information on materials and methods incl. tables`, ensuring that the following information is reported: For the experimental study via syrup feeding please provide the information on the formulation type, the content of a.s. in feeding solution [g/L], water solubility, LogPow, photolytic degradation, content of sugar in feeding solution [g/L], application method and test duration, incl. period prior to feeding. Information on the matrix used (feeding solution), sampling method, dates of sampling, number of replicates, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%), days from start of feeding until honey shall also be reported. For the experimental study field test /tunnel test ("semi-field test") please provide information on the number of bee colonies (for tunnel trials), number of bee hives (for field trials), health effects on honeybees, formulation type, content of active substance in the formulation, water solubility, LogPow,		

	photolytic degradation, the crop/variety, date of flowering, date of application, site parameters, including crops growing in the surroundings, method of application, application details and rate per treatment (kg a.s./ha), weather data for the application, growth rate of the crop (BBCH stage), species tested, duration of bee's exposure (days). Information on the matrix (e.g. plant, flower), sampling date, sampling method, days after last treatment (DALA), growth stage of crop (e.g. BBCH) at sampling, sugar content in nectar/honey (% BRIX), water content in nectar/honey (%) shall be also reported here. Additionally, please provide information related to sampling (sample material, weight, periods of drying, sugar content (%)), and storage of field samples (duration, temperature, storage conditions, honey conditioning, etc. For details of the analytical method validation data, please make a reference to Section 4 of the dossier `Analytical methods' and leave this field empty. Reference to the corresponding endpoint study record (UUID) is sufficient. If the method has not beet reported in Section 4 of the dossier,		

	include table with validation data in the field `Any other information on materials and methods incl. tables`).		
Specific details on test material used for the study (confidential)		Text template	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document. If you did not use the option 1 to report the detailed information for each experimental study, please report it here in one/several table(s). For the analytical method validation data: if the method has been reported in Section 4 of the dossier `Analytical methods', please refer to it, providing the UUID of study record of the used analytical method and its validation. If the study record referred to was duly compiled and	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables

	contain the data on method validation, further information is not required. If no study record was created for this method (and its validation) in Section 4 of the dossier, please use recommended format available in knowledge junction [cf. residue Template 6.1 (http://doi.org/10.5281/zenodo.4621833), Table 6.5]. Please repeat the tables as much as necessary.		
		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion
Any other information on results incl. tables	Discuss and evaluate the reported measurements and the relevance of results in relation to the proposed uses of the PPP, including a critical appraisal of the study and its results. The results of the study can be also presented in a table format. In particular the following points must be addressed: - a residue at or above the LOQ (a value of 0.05 mg/kg or lower is favoured) in control samples. - MRL proposal, with reasoning, and derived risk assessment values.	Header 2	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
		Rich text area	ENDPOINT_STUDY_REC

			ORD.ResiduesProcessedCommodities.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments
Overall remarks		Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.RemarksOnResults
Attached background material			ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document		Single file attachment	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument
Remarks		Text	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)		Image	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication		Attachments list	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.OverallRemarksAttachments.AttachedSanitisedDocsForPublication
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicantSummaryAndConclusion

Key result		Read-only	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicantSummaryAndConclusion.KeyResult
Conclusions	The assessment and conclusion of the applicant should be reported here.	Text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicantSummaryAndConclusion.Conclusions
Executive summary	Briefly summarise the relevant aspects of the study including the conclusions reached. In case new compounds have been identified in bee product, which are not included in the risk assessment residue definition in plant commodities please report this information here. Example: In case of field test/tunnel test: The residue trials for the determination of residues of [test substance] in [bee product] from [name crop] were conducted in [country, location] during the [year] growing season. [Active ingredient, % ai, formulation type] was applied to [crop] at [rate of application (xx g ai/ha)] under [specify trial conditions (field/tunnel]. In case of syrup feeding study: [residue of concern] was administered via syrup [application method] to bees for [duration] consecutive days. Dosing was made at [list dosing levels in mg/kg feed].	Rich text area	ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities.ApplicantSummaryAndConclusion.ExecutiveSummary

	[Bee product] samples were collected at [conditions of sampled product (maturity, water content (%) etc.] at [crop growth stage]. Residues of [active substance/metabolites] were present at the level of [xx] mg/kg in control samples of [bee product]/not present in control samples of [bee product] above the LOQ of [xx] mg/kg in control samples. In [bee product] the residues of [active substance/metabolites] were present at the level of [xx] mg/kg. All samples were frozen at the testing facility and remained frozen during shipping and storage prior to processing and analysis. The maximum storage interval for samples was [xx] days/months [specify period from harvest to processing and from processing to analysis]. Storage conditions and durations are supported by studies showing that residues of [active ingredient] are stable in [crops/processed commodities] for up to [xx] days under frozen conditions. Samples in the current study were analyzed using Method [Method ID], a [describe method] method to determine residues of		

	[list analytes]. Acceptable [method validation and] concurrent recoveries were reported for [matrices] samples at fortification levels of [xx] mg/kg, thus validating the method. The limit of quantitation (LOQ) was [xx] mg/kg per analyte for [matrices].		

6.11 Migration of residues into and their behaviour on food or feeding stuffs

Purpose:
This section is inherited from OHT 85-1 but is not requested in the context of an MRL application, provided that the specific sections 6.1 to 6.10 allows to report all the data supporting the application. It is highlighted that all relevant data on the nature and magnitude of residues in food or feeding stuffs should be reported in the respective sections above (6.2, 6.3, 6.4, 6.5) but not here.

Section 7: Fate and behaviour in the environment

The following documents are located under section 7 'Fate and behaviour environment'

7. Fate and behaviour in the environment– Endpoint summary

- 7.1 Fate and behaviour in soil
    - 7.1.1 Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies)
        - Biodegradation in soil (EU PPP): Rate of degradation in soil, aerobic and anaerobic (laboratory studies) – Endpoint summary
        - Route of degradation in soil (EU PPP): Route of degradation in soil, aerobic and anaerobic (laboratory studies) – Endpoint summary
        - Biodegradation in soil: Route and rate of degradation in soil, aerobic and anaerobic (laboratory studies) – Endpoint study record
    - 7.1.2 Route and rate of degradation in soil
        - 7.1.2.1 Route of degradation in soil (soil photolysis)
        - Phototransformation in soil: Route of degradation in soil (soil photolysis) – Endpoint summary
        - Phototransformation in soil: Route of degradation in soil (soil photolysis) – Endpoint study record
        - 7.1.2.2 Rate of degradation in soil (field studies)
        - Field studies: Rate of degradation in soil (field studies) – Endpoint summary
        - Field studies: Rate of degradation in soil (field studies) - Endpoint study record
    - 7.1.3 Adsorption and desorption in soil – Endpoint summary
        - 7.1.3.1 Adsorption and desorption – Endpoint study record
        - 7.1.3.2 Aged sorption – Endpoint study record
    - 7.1.4 Mobility in soil, leaching and lysimeter studies
        - Other distribution data: Mobility in soil, leaching and lysimeter studies – Endpoint summary
        - Other distribution data: Mobility in soil, leaching and lysimeter studies – Endpoint study record

Environmental fate and pathways - Endpoint Summary

ENDPOINT_SUMMARY.EnvironmentalFateAndPathways			
Name	Instructions	Type	Field path
Administrative data	Administrative data summary – common block Enter a short description of the most relevant endpoint data. The short description could include for example: -the test guideline used, -the test organism, -the exposure duration, -the contextual information of the origin of the value, -qualitative characterisation of some properties Examples: -"Melting point: 54.6-55.8 °C at 1,013 hPa (EEC Guideline A.1: Thermal analyses (Differential scanning calorimetry (DSC))" -"Short term toxicity to fish: LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203, static)"	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.EnvironmentalFateAndPathways.Discussion

7.1.1 Biodegradation in soil (EU PPP) - Endpoint Summary

Purpose:
Summarise the results of the laboratory studies on the rate of degradation in soil reporting all relevant information on the properties of the soils, the rates of degradation for persistence and modelling for active substance and its metabolites, and the correspondent kinetic models used.

ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Report Information to support the persistence /rate of degradation in soil. Make reference to the studies used to conclude on the rate of degradation in soil.	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.AdministrativeDataSummary
Key value for chemical safety		Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_

assessment			PPP.KeyValueCsa
Persistence / rate of degradation in soil			ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Substance
Test conditions	Provide information on the test conditions, aerobic or anaerobic	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.SoilType
pH	Enter the pH value of the soil in the laboratory test system.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water) with which the soil PH value measured in	Multi-line text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.MeasuredIn
Soil moisture (%)	Enter maximum water holding capacity (%) of the soil in the laboratory test system or pF2 (%) or pF 2.5 (%) values.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.SoilMoisture
Half-life in soil (DT50)	Enter the DT50 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.HalfLifeSoil
DT90 in soil	Enter the DT90 value for persistence.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.DtNinetySoil
at the temperature of	Enter the temperature of the soil in the laboratory test system.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.Persist

			enceDegradationSoil.Temperature
Chi-square (χ2)	Chi-square value of the method of calculation used for deriving the degradation rates for persistence.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving the degradation endpoints (DT50 and DT90) for persistence.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.CalculationMethod
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Precursor
Remarks	Provide any additional information needed to interpret the reported results	Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.PersistenceDegradationSoil.Remarks
Persistence / rate of degradation in soil			
Modelling rate of degradation in soil			ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Substance

Test conditions	Select the conditions of the study (aerobic/anaerobic).	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.TestConditions
Soil type	Enter the type of soil used in the laboratory test system.	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilType
pH	Measured in e.g. calcium chloride solution, water.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Ph
measured in	Indicate the medium (e.g. calcium chloride solution, water).	Multi-line text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.MeasuredIn
Soil moisture (%)	Enter maximum water holding capacity (%) of the soil in the laboratory test system or pF2 (%) or pF 2.5 (%) values.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.SoilMoisture
Normalised (DT50)	Enter the DT50 value for modelling. Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7; values are DegT50matrix. Temperature 20 degree centigrade and pF2/10kPa.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.NormalisedDtFifty
Chi-square (χ2)	Chi-square value of the method of calculation used for deriving the DT50 for modelling. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.ChiSquare
Method of calculation	Enter the kinetic model (e.g. SFO, FOMC, DFOP, HS) used for deriving modelling endpoint (normalised DT50); when biphasic kinetic	Text	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.CalculationMethod

	model is used, it should be specified how the DT50 was derived (DT90 FOMC/3.32, DFOP slow phase, etc...).		
Kinetic parameters	Where the rate of degradation endpoints result from a biphasic fit (FOMC, DFOP) enter the values of the proper kinetic parameters (alpha, beta, k1, k2 and g).	Multi select open list with remarks	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticParameters
Kinetic formation fraction	Kinetic formation fraction (f. f. kf/kdp) of transformation products.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.KineticFormationFraction
Precursor	For metabolites, when relevant, select the precursor substance (e.g. the active substance or another metabolite).	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Precursor
Remarks		Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.ModellingDegradationSoil.Remarks
Modelling rate of degradation in soil			
Key value for safety assessment			ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa
Parent / metabolite	Indicate whether the DT50 is reported for the parent or the metabolite.	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.ParentMetabolite
Substance	Select the substance for the DT50 value.	Entity reference field	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Substance
Half-life in soil (DT50)	Indicate the geometric mean (if not pH dependent) of the normalised DT50 values.	Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.HalfLifeSoil
Mean formation fraction	Indicate the arithmetic mean of the formation fraction (f.f. kf/kdp) values for the metabolite.	Decimal	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.FormationFraction

pH dependence	Select 'yes' or 'no' to indicate whether the result is pH dependent	Closed list	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.PhDependence
Remarks		Text area	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.KeyValueCsa.KeyValueCsa.Remarks
Key value for safety assessment			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.BiodegradationInSoil_EU_PPP.Discussion

7.1.1 Route of degradation in soil (EU PPP) - Endpoint Summary

Purpose:
Summarise the results of studies on the aerobic and anaerobic route of degradation in soil and identify the metabolites requiring further consideration for risk assessment.

ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and metabolites that should be considered for risk assessment	Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa
Route of degradation in soil	The route of degradation consists in: 1) determining the amount mineralization; 2) determining the amount of non-extractable residues; 3) identifying metabolites above the regulatory trigger.		ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil
Parent / metabolite	Rows should be created for the active substance and each metabolite	Closed list	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.ParentMetabolite
Substance	Select the relevant labelled parent or metabolite.	Entity reference field	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.Substance
Test conditions	Indicate whether the results are for aerobic conditions, anaerobic conditions. A summary can be completed for each type of test condition.	Closed list	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.TestConditions
Sterile conditions	Indicate if the results were obtained under sterile conditions	Check box	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.SterileConditions
Mineralisation (%)	Indicate the mineralization	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.Ke

	percentage after 100 days.		yValueCsa.DegradationSoil.Mineralisation
Non extractable residues (%)	Indicate the non-extractable residues percentage after 100 days.	Range (Decimal)	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.NonExtractableResidues
Maximum occurrence (%)	Indicate the maximum occurrence of each metabolite (X% after Y days) observed in the parent-dosed study.	Decimal	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.MaximumOccurrence
Day maximum occurrence observed (days)	Report the time point in days when the maximum occurrence was observed.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.DayMaximumOccurence
Actual duration (days)	Report the duration of the study in days.	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.ActualDuration
Radio label	Provide information on the radio labelling used to obtain these results	Text	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.RadioLabel
Number soils	Report the number of soil analysed to obtain these results	Integer	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.NumberSoils
Remarks		Text area	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.KeyValueCsa.DegradationSoil.Remarks
Route of degradation in soil			
Additional information	Discussion(Header 1) – common block	Header 1	ENDPOINT_SUMMARY.RouteDegSoil_EU_PPP.Discussion

Links to support material:
DG SANCO Working Document on "Evidence Needed to Identify POP, PBT and vPvB Properties for Pesticides" (25.09.2012 – rev. 3)
ECHA Guidance on information requirements and chemical safety assessment Chapter R 11: PBT Assessment (revision 1)

7.1.1 Biodegradation in soil – Endpoint study record

Purpose:
These experiments are performed to determine the route and the rate of transformation of the test substance in soil, and to determine the nature and rates of formation of transformation products.
Principle of the study:
- The microbial biomass of soils used for laboratory degradation studies shall be determined immediately before the commencement and at the end of the study.
- The soils used for degradation studies shall be representative of the range of agricultural soils typical of the various regions of the Union where use exists or is anticipated.
- The soils shall fulfil the following conditions: they shall cover a range of organic carbon content, particle size distribution and pH (preferably measured in CaCl2) values, and where on the basis of other information, degradation or mobility are expected to be pH dependent, for example solubility and hydrolysis rate (see points 2.7 and 2.8), they shall cover approximately the following pH (preferably measured in CaCl2) ranges: 5 to 6, 6 to 7 and 7 to 8.
- Soils used shall, wherever possible, be freshly sampled. If use of stored soils is unavoidable, storage shall be carried out for a limited time (at the most three months) under defined and reported conditions, which are adequate to maintain soil microbial viability. Soils stored for longer periods of time may only be used for adsorption/desorption studies.
- A soil having extreme characteristics with respect to parameters such as particle size distribution, organic carbon content and pH shall not be used used.

ENDPOINT_STUDY_RECORD.BiodegradationInSoil – v6.4 (Final) [October 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.DataSource
Materials and methods	Material and methods – common block Note: OECD Guideline 307, Aerobic and Anaerobic Transformation in Soil is relevant for this endpoint	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods
Test type	Indicate whether the study was a field trial or laboratory study.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestType
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling

Study design		Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.OxygenConditions
Soil classification	Select as cited in the study report. If not available from picklist, select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilClassification
Year	Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field 'Report date'.	Integer	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.Year
Soil properties	Repeat this block of fields for each different soil used as indicated by the Soil No. Enter soil type as cited in the study report and the respective soil properties.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilNo
Soil type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.SoilType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Clay
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Sand
% Org. C	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAnd

	both numeric fields together with the appropriate qualifier(s) if applicable.		Methods.StudyDesign.SoilProperties.OrgC
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.CEC
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.BulkDensityGCm
% Moisture content	Moisture content of the soil (at pF 2 or at Maximum Water Holding Capacity). Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.SoilProperties.MoistureContent
Soil properties			
Details on soil characteristics	For each soil type, specify soil collection and storage and properties of the soil as far as not indicated in the defined fields. Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating the study or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoilCharacteristics
Duration of test (contact time)	Specify duration of test in terms of contact time. Repeat block for each soil type. If different test runs have different durations, enter lower and upper value in respective subfields.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.SoilNo
Duration	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestContactTime.Duration

Duration of test (contact time)			
Initial test substance concentration	Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field. If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.SoilNo
Initial conc.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.InitialConc
Based on	Select the parameter on which the initial concentration is based from drop-down list.	Open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.InitialTestSubstanceConcentration.BasedOn
Initial test substance concentration			
Parameter followed for biodegradation estimation	Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use free text template in field 'Details on analytical methods'.	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ParameterFollowed
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use free text template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods

Experimental conditions	For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.SoilNo
Temp.	Specify test temperature including mean and range values during test if available or temperature assumed in the model, if estimated. Use °C; convert other units and indicate original data in parentheses if applicable.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Temp
Humidity	Indicate soil humidity in % moisture content or g water/100g soil dry weight.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.Humidity
Microbial biomass	Indicate initial and final microbial biomass / microbial population of control and treated soil, if provided. Specify unit, e.g., mg biomass/100 g soil dry weight or µg C/g soil.	Text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.ExperimentalConditions.MicrobialBiomass
Experimental conditions			
Details on experimental conditions	Include Soil No. in parentheses if conditions were not identical for all soil types tested. Use free text template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnExperimentalConditions
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion

Material (mass) balance	If applicable, indicate mean total recovery of test material as percentage of applied amount +/- standard deviation. Copy this block of fields for each soil type as appropriate.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SoilNo
Sampling date	Enter the date the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.SamplingDate
% Total extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.TotalExtractable
% Non extractable	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.NonExtractable
% CO2	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.CO2
% Other volatiles	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.OtherVolatiles
% Recovery	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.Recovery
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMassBalance.StDev
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is	Open list with remar	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.MaterialMass

	provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	ks (2000)	Balance.RemarksOnResults
Material (mass) balance			
% Degradation	For each soil type, indicate percentage of degradation of test substance including standard deviation at the end of the study period. Also indicate on what parameter the degradation rate is based on (e.g. 'radiochemical measurement'). If required, copy block of fields to include values based on different parameters.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation
Parent/product	Indicate if the result reported is for the active substance/parent or the product/metabolite. The identify of the substance can be selected below	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.ParentProduct
Name or code for product	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.NameOrCodeForProduct
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SoilNo
Sampling date	Enter date when the sample was taken	Date	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingDate
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.Degr
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.StDev
Parameter	From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field.	Open list with remar	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.

		ks	Parameter
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.SamplingTime
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Half-life / dissipation time of parent compound	For each soil type, include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life).		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.KeyResult
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.SoilNo
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.HalfLife
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.StDev
Type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfPar

			entCompound.Type
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.Temp
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.HalfLifeOfParentCompound.RemarksOnResults
Half-life / dissipation time of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on	Indicate any relevant supplementary information on transformation products. Use free text template and	Text templ	ENDPOINT_STUDY_RECORD.Biodegradatio

transformation products	delete/add items as appropriate. If useful attach a figure in the corresponding field.	ate	nInSoil.ResultsAndDiscussion.TransfProductsDetails
Evaporation of parent compound	Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.EvaporationOfParentCompound
Volatile metabolites	Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.VolatileMetabolites
Residues	Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate.	Closed list with remarks	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.Residues
Details on results	Indicate any further relevant details of test results. Use freet ext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). In field 'Attached background material', attach graph(s) with the full degradation or elimination curves. TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments: SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.	Text template	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.DetailsOnResults
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.ResultsWithReferenceSubstance
Any other information on results incl.	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsIncl

tables			Tables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments
Kinetic evaluation	The filled "IUCLID templates for PPP Risk Assessment - Template 7.1 - Template for presentation of kinetic fitting" (https://doi.org/10.5281/zenodo.4557253) shall be uploaded here.	Attachments list	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.BiodegradationInSoil.ApplicantSummaryAndConclusion

Links to support material:
Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)
EFSA (2007). Scientific Opinion on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.
FOCUS (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration(SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014)

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint summary

Purpose:
Summarise the results of the route and rate of degradation in soil photolysis studies and identify the metabolites requiring further consideration for risk assessment.

ENDPOINT_SUMMARY.PhototransformationInSoil

Name	Instructions	Type	Field Path
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. In study name/type the type of soil used in the laboratory test system should be provided	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment
Half-		Unit	ENDPOINT_SUMM

life in soil		measure with Closed List (Decimal)	ARY.PhototransformationInSoil.KeyValueForChemicalSafetyAssessment.HalflifeInSoil
Additional information	Discussion(Header 1) – common block For the DT50 value reported above include information on the conditions e.g. soil type, pH, temperature. The method of calculation should also be described. Table in the format of the List of Endpoints: Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3) is recommended	Header 1	ENDPOINT_SUMMARY.PhototransformationInSoil.Discussion

7.1.2.1 Route of degradation in soil (soil photolysis) – Endpoint study record

Purpose:
A soil photolysis study shall be submitted unless the applicant shows that deposition of the active substance on the soil surface is unlikely to occur or that photolysis is not expected to contribute significantly to the degradation of the active substance in soil for example due to low light absorbance of the active substance.

ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: The OECD Guideline for the Testing of Chemicals, Draft Document, "Phototransformation of Chemicals on Soil Surfaces"; adopted January 2002.	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material should be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.TestMaterials.Radiolabelling
Study design		Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign
Analytical	Indicate whether test substance was monitored in the test solutions.	Closed list	ENDPOINT_STUDY_RECORD.PhotoTransforma

monitoring	For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	with remarks	tionInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMonitoring
Analytical method	Reference to the Analytical Method endpoint study record describing the method can be included in the remarks	Multi select open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.AnalyticalMethod
Details on sampling	Enter details on sampling regime and method. Use freetext template as appropriate.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnAnalyticalMethods
Details on soil	Using freetext template give details on the soil used. As an alternative option, attach a document e.g. excerpt from the study report. Note: If applicable, indicate the title and year of the soil classification system used after the respective prompt, i.e. Canadian System of Soil Classification / DIN 19863 (Deutsche Industrie-Norm) / NF X31-107 (Norme francaise) / USDA (US Department of Agriculture) / WRB (World Reference Base for Soil Resources) / or other (to be specified).	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnSoil
Light source	Select light source used.	Open list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.LightSource
Light spectrum: wavelength in nm	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.LightSpectrumWavelengthInNm
Relative light intensity	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.RelativeLightIntensity
Details on light source	Enter any relevant details on the light source. Use either of the two freetext templates as appropriate. As an alternative option, attach a document e.g. excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.D

			etailsOnLightSource
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DetailsOnTestConditions
Duration of test at given test condition	Indicate the test duration and % moisture, temperature and initial test substance concentration at which test was conducted. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Duration
% Moisture	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Moisture
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.Temp
Initial conc. measured	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DurationOfTestAtGivenTestCondition.InitialConcMeasured
Duration of test at given test condition			
Reference substance	Indicate if test(s) with a substance with known photolysis was performed. If yes, report the identity of the substance in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ReferenceSubstance

Dark controls	Indicate if dark, i.e. negative controls were used in parallel studies. Remarks can be included in the supplementary remarks field.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.DarkControls
Computational methods	Enter details on computational methods used to calculate relevant parameters.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.StudyDesign.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion
Preliminary study	Describe results from preliminary study performed, if any (e.g., adsorption of test material to the walls of the test container).	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.PreliminaryStudy
Test performance	Report on any unusual observations during test, deviations from test procedure or any other information affecting results.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TestPerformance
Spectrum of substance	Select spectral parameter from picklist and enter value in the subsequent subfield. Any notes can be included in subfield 'Remarks'. Copy block of fields for each parameter cited in the study report. If the substance absorbs light at wavelengths >295 nm, give the wavelength (lambda value) of maximum absorption at wavelengths >295 nm and the maximum molar absorption (extinction) coefficient (epsilon value). If there is no absorption maximum at >295 nm, give the molar extinction coefficient at 295 nm. An alternative to the above is to attach a file that depicts graphically or in tabular form the complete UV/VIS absorption spectrum (include reference to respective Figure or Table No. in subfield 'Remarks').		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum
Parameter	Select parameter from drop-down list and enter the corresponding value or range with unit (unless dimensionless) in the related text field, together with any explanation if necessary, e.g. on the study group the result refers to. Explanations:	Open list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Parameter

	AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time); Cmax: Maximum (peak) concentration; C(time): Maximum concentration at a specified time after administration of a given dose; Tmax: Time to reach peak or maximum concentration following administration.		
Value	Enter numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Value
Remarks	Enter any remarks related to the recorded value as appropriate.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Spectrum.Remarks
Spectrum of substance			
% Degradation	Specify percentage of degradation or range and sampling time. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.KeyResult
% Degr.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.DegradationPercent
St. dev.	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.StDev
Sampling time	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TimePoint

Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.Degradation.RemarksOnResults
% Degradation			
Quantum yield (for direct photolysis)	Give the reaction quantum yield of the test substance (values between 0 and 1).	Decimal	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.QuantumYield
Dissipation half-life of parent compound	Provide the half-life / DT50 or range as appropriate. Copy this block of fields for recording results at different test conditions.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.KeyResult
DT50	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.HalfLife
Test condition	If results at different test conditions are reported, specify test condition (e.g. different temperatures). Otherwise leave this subfield empty.	Text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.TestCondition
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.DissipationHalfLife.RemarksOnResults
Dissipation half-			

life of parent compound			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'.		ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on results	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1'). Explanations on freetext prompts: TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered. HALF-LIFE: Include a table with detailed results for dark and irradiated samples including Regression equation, r²' and DT90 if available. MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major	Text template	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsDetails

	transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table. Distinguish between dark and irradiated samples; compare the transformation products formed in the dark and irradiated samples, and identify and quantify the products that are formed by phototransformation only. As appropriate attach Figure showing the pathway of phototransformation of the test substance. SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any.		
Results with reference substance	Indicate whether the results with the reference substance(s) are valid.	Multi-line text	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.ResultsReferenceSubstance
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.PhotoTransformationInSoil.ApplicantSummaryAndConclusion

7.1.2.2 Rate of degradation in soil (field studies) – Endpoint summary

Purpose:
Summarize the results of the field studies providing information on the transformation of the active substance, and if re
under representative actual use conditions.

ENDPOINT_SUMMARY.FieldStudies			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.FieldStudies.AdministrativeDataSummary

Additional information	Discussion(Header 1) – common block Table in the format specified in The list of Endpoints Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1) is recommended.	Header 1	ENDPOINT_SUMMARY.FieldStudies.Discussion

Links to support material:

FOCUS Group (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014)

EFSA European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

7.1.2.2 Rate of degradation in soil (field studies) – Endpoint study record

Purpose:
The soil dissipation studies shall provide estimates of the time required for dissipation of 50 % and 90 % (DisT50field and DisT90field) and, if possible, of the time required for degradation of 50 % and 90 % (DegT50field and DegT90field), of the active substance under field conditions. Where relevant, information on metabolites, breakdown and reaction products shall be provided

ENDPOINT_STUDY_RECORD.FieldStudies			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.DataSource
Materials and methods	Material and methods – common block In test guideline indicate according to which test guideline the study was conducted: US EPA, (2009) OCSPP 836.6100 Terrestrial field dissipation document or OECD Guidance Document	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods

	If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline. Applicable test guideline (guideline field): OECD Test Guideline 232: Guidance document for conducting pesticide terrestrial field dissipation studies.		
Type of measurement	Indicate the type of measurement applied.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TypeOfMeasurement
Media	Indicate the media investigated.	Multi-line text	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. See Appendix A of EFSA guidance on the estimation of degradation rates Page 35 (DegT50matrix) from field experiments in the soil compartment EFSA (2014) You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion
Any other information on results	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.FieldStudies.ResultsAndDiscussion.AnyOtherInforma

incl. tables			tionOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.OverallRemarksAttachments
Kinetic evaluation	Upload Kinetic evaluation (visual and statistical)	Attachments list	ENDPOINT_STUDY_RECORD.FieldStudies.OverallRemarksAttachments.KineticEvaluation
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.FieldStudies.ApplicantSummaryAndConclusion

Links to support material:
FOCUS (1997). Soil persistence models and Eu registration
FOCUS (2006). Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration (SANCO/ 10058/2005-v. 2.0, 434 pp Version 1.1, 18 December 2014).
EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2014.3662

7.1.3 Adsorption and desorption in soil – Endpoint summary

Purpose:
Summarize the results of the adsorption/desorption studies to provide the adsorption coefficients of the active substance and its metabolite in the soil.

ENDPOINT_SUMMARY.AdsorptionDesorption v.6.0 (Final)			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data summary – common block Provide a brief description of relevant studies and effects. Reference can also be made to the results of aged sorption studies if available.	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.AdministrativeDataSummary
Key value for chemical safety assessment		Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafety

			Assessment
Koc at 20 °C	Report the organic carbon adsorption coefficient (Koc)	Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.KocAt20Celsius
Other adsorption coefficients	If the value for Koc is missing, provide information on other adsorption coefficients.		ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients
Type	Select additional adsorption coefficients. Other can be used in case of a coefficient value which is not in the list	Open list	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.Type
Value in L/kg		Decimal	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.TypeValue
at the temperature of		Unit measure with Closed List (Decimal)	ENDPOINT_SUMMARY.AdsorptionDesorption.KeyValueForChemicalSafetyAssessment.OtherAdsorptionCoefficients.AtTheTemperatureOf
Other adsorption coefficients			
Additional information	Discussion(Header 1) – common block Provide the original version of any document that contains confidential material. A table in the format from the List of Endpoints Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) is recommended.	Header 1	ENDPOINT_SUMMARY.AdsorptionDesorption.Discussion

Links to support material:
European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)[3]
Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)
EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.1 Adsorption and desorption – Endpoint study record

Purpose:
Adsorption/desorption studies give information on the mobility of active substance and its metabolites in soil.
Studies on adsorption and desorption of the active substance shall be provided, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees

ENDPOINT_STUDY_RECORD.AdsorptionDesorption			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 106: Adsorption - desorption using a batch equilibrium method. Indicate the type of method used regardless of whether it is already specified in the guideline, as this field can be used for query purposes.	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods
Media	Indicate the medium (i.e. soil, sediment or sewage sludge) for which the adsorption (desorption) determination was made. For the HPCL estimation method, select 'soil/sewage sludge'. For any other, select 'other' and specify.	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials
Radiolabelling	Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.TestMaterials.Radiolabelling

Study design		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign
Test temperature	Indicate test temperature values measured during test. Include range, mean, standard deviation and unit.	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.TestTemperature
HPLC method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod
Details on study design: HPLC method	For the HPLC method only, enter any details on the study design that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.HPLCMethod.DetailsOnStudyDesignHplcMethod
Batch equilibrium or other method		Header 3	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod
Analytical monitoring	Indicate whether test substance was monitored in the test solutions. For robust study summaries or as requested by the regulatory programme, provide further details on sampling and analytical methods in the corresponding freetext fields.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.AnalyticalMonitoring
Details on sampling	If the amount of test material in the test solutions was monitored, enter details on sampling. Use freetext template as appropriate and delete/add elements as appropriate.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnSampling
Details on analytical methods	If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Reference Analytical method endpoint study record can be included here	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnAnalyticalMethods
Matrix properties	Repeat this block of fields for each different matrix type used as indicated by the Matrix no. Specify the type of soil, sediment or sludge.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties
Matrix no.	Select a consecutive number from drop-down list if more than one matrix type were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumO

			rOtherMethod.MatrixProperties.MatrixNo
Matrix type	Select from drop-down list.	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.MatrixType
% Clay	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Clay
% Silt	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Silt
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Sand
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.OrgCarbon
pH	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.Ph
CEC	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.CEC
Bulk density (g/cm³)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.MatrixProperties.BulkDensityGCm
Matrix properties			

Details on matrix	Depending on the test system, i.e. water-soil or water-sediment or water-activated sludge simulation system, include details on either the soil, sediment or sludge solids used in the study. Select respective freetext template and delete/add elements as appropriate. As an alternative option, include or attach an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnMatrix
Details on test conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. As appropriate or requested by the regulatory programme include tables in the rich text field 'Any other information on results incl. tables' summarising the study design for the adsorption and desorption phase. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DetailsOnTestConditions
Duration of adsorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), indicate temperature and initial pH and test substance concentration at which adsorption was conducted and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Duration
Initial conc. measured	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.InitialConcMeasured
pH	Enter the initial pH.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfA

			dsorptionEquilibration.Ph
Temp.	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Temp
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfAdsorptionEquilibration.Remarks
Duration of adsorption equilibration			
Duration of desorption equilibration	Indicate sample number (if multiple types of soil/sediment/sludge were used), temperature and amount of test substance concentration in the adsorbed state and the respective test duration. If test runs with different conditions and durations were performed, copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Duration
Conc. of adsorbed test mat.	Enter a numeric value.	Unit measure with Open List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.ConcOfAdsorbedTestMat
pH	Enter the initial pH.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.Stud

			yDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Ph
Temp.	Enter a numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Temp
Remarks	Enter any remarks related to the duration of the adsorption equilibration.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.DurationOfDesorptionEquilibration.Remarks
Duration of desorption equilibration			
Computational methods	Enter details on computational methods used to calculate relevant parameters. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.StudyDesign.BatchEquilibriumOrOtherMethod.ComputationalMethods
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion
Adsorption coefficient			ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.KeyResult
Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.SampleNo
Type	Either of the following parameters can be selected from the drop-down list: adsorption coefficient Koc	Open list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.

	or log Koc, distribution constant Kd or log Kd. Include any explanations in the supplementary remarks field as appropriate. For reporting partition coefficients (Kp / log Kp) please use the next block of fields 'Partition coefficients'.	with remarks	ResultsAndDiscussion.AdsorptionCoefficient.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Value
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Ph
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Temp
Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type ....' etc.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.PercentageOfOrganicCarbon
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionCoefficient.RemarksOnResults
Adsorption coefficient			
Partition coefficients	Include any relevant solids-water partition coefficient Kp or log Kp for the compartment-water system covered (e.g. log Kp solids-water in soil). If required, copy block of fields to include several parameters.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.KeyResult

Sample No.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.SampleNo
Phase system	Indicate the compartment-water system or select 'other:' and specify.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.PhaseSystem
Type	Select 'Kp' or 'log Kp' from the drop-down list. Include any explanations in the supplementary remarks field as appropriate.	Open list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Type
Value	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with open list (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Value
Temp.	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Temp
pH	Enter numeric value.	Decimal	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Ph
Matrix	This free text field can be used to specify the matrix tested if several types were used, e.g. 'Soil no. 1: clay', 'sediment type ....' etc.	Text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.Matrix
% Org. carbon	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.OrgCarbon
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:'	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AdsorptionOther.RemarksOnResults
Partition coefficient			

s			
Results: HPLC method		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsHplcMethod
Details on results (HPLC method)	For the HPLC method only, include further data as indicated in the freetext template.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsHplcMethod.DetailsOnResultsHplcMethod
Results: Batch equilibrium or other method		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod
Adsorption and desorption constants	For each soil used provide adsorption and desorption constants including data on the slope of Freundlich adsorption/desorption isotherms (1/N) and regression coefficient of Freundlich equation (R2). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.AdsorptionAndDesorptionConstants
Recovery of test material	Indicate recovery of test material in supernatant solution and solid phase as well as non-extractable residues after adsorption/desorption, including mean standard deviation. Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.RecoveryOfTestMaterial
Concentration of test substance at end of adsorption equilibration period	Give concentration of test substance in solid and liquid phases at the end of adsorption equilibration period and percent adsorbed test material of applied, including standard deviation; indicate whether the amount on sorbent residue is measured by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.ConcentrationOfTestSubstanceAtEndOfAdsorptionEquilibrationPeriod
Concentration of test substance at end of	Give concentration of test substance in solid and liquid phases at the end of desorption equilibration period and percent desorbed test material of adsorbed, including standard deviation; indicate whether the amount on sorbent residue is measured	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.ConcentrationOfTe

desorption equilibration period	by sorbent residue analysis or calculated by difference (total applied - concentration in solution). Upload predefined table as appropriate or requested by the regulatory programme in the rich text field 'Any other information on results incl. tables' or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the text (e.g. '... see Table 1').		stSubstanceAtEndOfDesorptionEquilibrationPeriod
Mass balance (%) at end of adsorption phase	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of adsorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.Duration
% Adsorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.AdsorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfAdsorptionPhase.RemarksOnResults
Mass balance (%) at end of adsorption phase			
Mass balance	Indicate sample number (if multiple types of soil/sediment/sludge were used), duration of end of		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.

(%) at end of desorption phase	desorption phase and include the respective mass balance as % of the applied test substance. For indicating values for different soil (samples), copy this block of fields as appropriate.		ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase
Sample no.	Select a consecutive sample number from drop-down list if more than one matrix types were used.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.SampleNo
Duration	Enter numeric value.	Unit measure with Closed List (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.Duration
% Desorption	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range (Decimal)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.DesorptionPercentage
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information by selecting 'other:', e.g. details on soil.	Open list with remarks (2000)	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.MassBalanceAtEndOfDesorptionPhase.RemarksOnResults
Mass balance (%) at end of desorption phase			
Transformation products	Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'.	Closed list with remarks	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.TransformationProducts
Identity of transformation products	Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance. Any further details on transformation products can be provided in field 'Any other information on		ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation

	materials and methods incl. tables'.		
No.	For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries.	Closed list	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.No
Reference substance	Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one.	Entity reference field	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.IdentityTransformation.ReferenceSubstance
Identity of transformation products			
Details on results (Batch equilibrium method)	Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report.	Text template	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.DetailsOnResultsBatchEquilibriumMethod
Statistics	Indicate the parameters analyzed, the statistical method used and the statistical test performed.	Multi-line text	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.ResultsBatchEquilibriumOrOtherMethod.Statistics
Any other information on results incl. tables		Header 2	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables.OtherInformation
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.OverallRemarksAttachments
Applicant's summary and	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AdsorptionDesorption.ApplicantSummaryAndConclusion

conclusion			

Links to support material:
European Commission. Scientific Committee on plants SCP/KOC/002-Final. Opinion of the Scientific Committee on Plants on methods for the determination of the organic carbon adsorption coefficient (Koc) for a plant protection product active substance in the context of Council Directive 91/414/EEC (18 July 2002)
Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)
EFSA (2017). Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326

7.1.3.2 Aged sorption EU_PPP – Endpoint study record

Purpose:
As a higher tier option, information on aged sorption may be provided

ENDPOINT_STUDY_RECORD.AgedSorption			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: focus groundwater; OECD 307; -- SANTE/12586/2020 – REV 0 26 January 2021 Guidance on how aged sorption studies for pesticides should be conducted, analyzed and used in regulatory assessments.	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description.	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.TypeOfStudy

	Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate. Fill in fields for Administrative data and Data source as appropriate.		
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsInclTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.AgedSorption.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.AgedSorption.ApplicantSummaryAndConclusion

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint summary

Purpose:
Provide sufficient data to evaluate the mobility and leaching potential of active substance and its metabolites, breakdown and reaction products.
Where studies are provided for more than one endpoint separate summaries can be created for each endpoint. For example one summary for column leaching studies and one summary for lysimeter studies

ENDPOINT_SUMMARY.OtherDistributionData			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block Provide a brief description of relevant studies and effects.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.AdministrativeDataSummary
Additional information	Discussion(Header 1) – common block Provide additional information related to the endpoint. Presentation of the results in the tabular format of the List of Endpoints Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1) and Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3) is recommended If there is no additional information to be reported this field may be left empty.	Header 1	ENDPOINT_SUMMARY.OtherDistributionData.Discussion

Links to support material:

Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010, version 3, 10 October 2014)

7.1.4 Mobility in soil, leaching and lysimeter studies – Endpoint study record

Purpose:
Provide sufficient data to evaluate the mobility and leaching potential of active substance and its metabolites, breakdown and reaction products.

ENDPOINT_STUDY_RECORD.OtherDistributionData			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	Administrative data – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.AdministrativeData
Data source	Data source (Literature Reference) – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.DataSource
Materials and methods	Material and methods – common block Applicable test guideline: OECD Test Guideline 312: Leaching in Soil Columns.	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods
Type of study	Include only information that does not fit into any of the specific chapters. Indicate the type of information, e.g. 'Soil leaching'. If not available from the picklist, use 'other:' and include an appropriate description. Include any relevant information from a study report or publication in fields 'Any other information on materials and methods incl. tables', 'Any other information on results incl. tables' or 'Overall remark' as appropriate. Fill in fields for Administrative data and Data source as appropriate.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TypeOfStudy
Media	Indicate the media addressed.	Open list	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.Media
Test material	Test Material – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.TestMaterials
Any other information on materials and methods incl. tables	Any other information on materials and methods incl. tables - (H2) – common block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.MaterialsAndMethods.AnyOtherInformationOnMaterialsAndMethodsIn

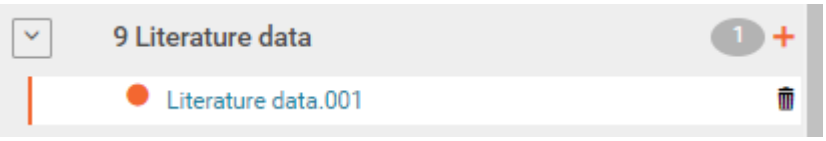
			clTables
Results and discussion		Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion
Any other information on results incl. tables	Any other information on results incl. tables Block	Header 2	ENDPOINT_STUDY_RECORD.OtherDistributionData.ResultsAndDiscussion.AnyOtherInformationOnResultsInclTables
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.OverallRemarksAttachments
Applicant's summary and conclusion	Applicants summary and conclusion – common block	Header 1	ENDPOINT_STUDY_RECORD.OtherDistributionData.ApplicantSummaryAndConclusion

Links to support material:
OECD Guidance Document 22: Guidance Document for the Performance Of Out-door Monolith Lysimeter Studies https://doi.org/10.1787/20777876

Section 9: Literature data

The following documents are located under section 9. 'Literature data':

- "Literature data": Literature search - Flexible Record



9. Literature data – Flexible record

Purpose:
Description of the methodology used for the search for all relevant data from scientific peer reviewed open literature
List of all relevant studies retrieved

FLEXIBLE_RECORD.LiteratureSearch			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	See section on Confidentiality of dossiers	Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData
		Confidentiality	FLEXIBLE_RECORD.LiteratureSearch.AdministrativeData.DataProtection
Link to relevant studies	Link to all Literature Reference entities that were retrieved from the literature search and are considered relevant and reliable after the full text screening step. An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section.	Header 1	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies
Literature reference(s)		Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.LiteratureReference
Description of key information	Summary of all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.KeyInformationDesc

	plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species		
Overall summary of the literature search	Summary of the methodology used to retrieve relevant studies on side-effects on health, the environment and non-target species. Report the criteria used to classify the references as being clearly non-relevant (e.g. not related to pesticides). Report the criteria used to assess the reliability of the studies.	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.RelevantStudies.SearchSummary
Search strategy	Indicate how the literature search was carried out.	Header 1	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy
Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review		FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed
Online search service	Select the database/source where the search was performed. Use other to indicate a database/source that is not included in the list. The remarks field should contain the justification for selecting the database/source. More information on databases/sources Is provided in the supporting materials below	Open list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.SearchService
Date of search	Provide the date when the search was performed using the database.	Date	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Date
Time window of the literature search	The period covered in the literature search	Text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrat

	e.g. 2010 to 2020		egy.DatabasesUsed.TimeWindow
Search string(s) used	The search strings used to retrieve the records e.g. 1. ts=Chlorpyrifos 2. ts=(Brodan or Detmol or Dowco 179 or Dursban or eradex or Lorsban or Paqeant or Piridane) 3. ts=((scout or stipend or empire) and (pesticide* or insect*)) 4. #3 OR #2 OR #1 More examples are provided in the supporting materials below	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Strings
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Filters
Limits	Indicate if any limits were applied in the search, for example only studies in English. If yes is the limits applied must be described	Closed list with remarks	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.Limits
Number of hits	The number of hits for the search in each database/source	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHits
Number of hits after refinement	The number of hits after refinement, if applicable	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsRefinement
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer	FLEXIBLE_RECORD.LiteratureSearch.SearchStrategy.DatabasesUsed.NoHitsDuplicate
Bibliographic databases used in the literature review and search results			
Evaluation of the review		Header 1	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview
Records retrieved	The number of records	Integer	FLEXIBLE_RECORD.Liter

	retrieved when the results for the searches above where combined		atureSearch.EvaluationOfTheReview.RecordsRetrieved
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoAfterDuplicates
Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoRapidAssessment
Records after detailed assessment	Report the number of records retained after full text screening	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.NoDetailAssessment
Reliable studies	Report the number of records retained after the reliability assessment	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ReliableStudies
Evaluated studies	Number of studies included in the dossier, reported in an endpoint study record and used as supporting information. These studies should be listed in the Literature reference(s) field and the number should be the same.	Integer	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.EvaluatedStudies
Publications excluded from the risk assessment after detailed assessment of full-text documents	For each of the studies excluded on the basis of relevance or reliability link to the Literature Reference entity and describe the reason for exclusion		FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications
Literature reference	Link a reference to the excluded publication.	Literature reference list	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.LitReference
Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text	FLEXIBLE_RECORD.LiteratureSearch.EvaluationOfTheReview.ExcludedPublications.ExclusionReason
Publications excluded from the risk assessment after detailed assessment	For each of the studies excluded on the basis of relevance or reliability link to the Literature		

of full-text documents	Reference entity and describe the reason for exclusion		
Additional information		Header 1	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation
Additional information	Any other information needed to interpret the results for the literature research	Rich text area	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.AdditionalInfo
Attached background material	Upload supporting files e.g bibliographic metadata		FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial
Attached document	Upload file by clicking the upload icon. The bibliographic results of literature searches can be uploaded here in RIS format or as an Excel table containing bibliographic information.	Single file attachment	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.Attachment
Remarks	Indicate the source of the contents of the file and the format type.	Text	FLEXIBLE_RECORD.LiteratureSearch.AdditionalInformation.BackgroundMaterial.Remarks
Attached background material			

Link to support material:

Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009

Further guidance on performing and presenting the literature search

Inventory of Sources of Scientific Evidence Relevant to EFSA's Risk

Technical Manual for Performing Electronic Literature Searches in Food and Feed Safety

Section 11: Summary and evaluation

The following documents are located under section 11. 'Summary and evaluation":

- Assessment from other authorities – Flexible record
- Other reports – Flexible record

11.1 Assessment from other authorities – Flexible record

Purpose:
Provide information on previous assessments of the active substance, as a pesticide or under other regulatory processes, both within Europe and outside of Europe.

Listing of EU MRLs (Document E1)

List of MRLs established in exporting countries or in non-EU OECD countries (Document E2)

FLEXIBLE_RECORD.AssessmentOtherAuthorities – v 1.3 (Final) [October 2020]			
Name	**Instructions**	**Type**	**Field Path**
Administrative data	See Administrative data	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdministrativeDataSummary.DataProtection
Assessments in Europe	In this section provide information on previous or ongoing evaluations in Europe	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope
Biocide	Indicate if this active substance has been or is being assessed under the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) Select the status of the application and provide details on the nature of the application	Open list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.Biocide

		(2000)	
Veterinary medicine	Indicate if this active substance has been or is being assessed under the veterinary medicinal products Regulation (EU) 2019/6. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations in Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments
Evaluation	If this active substance has been or is being assessed under any other product or food safety regulations indicate the context of the evaluation.	Open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments.Evaluation
Status	Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.OtherProductSafetyAssessments.Status
Other product safety assessments			
Existing residue definitions		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues
Monitoring purposes (plant)	This is the RD used to express the current MRLs in plant commodities. Please check the current existing RD in the EU MRL data base. The field refers to the enforcement residue definition of plant commodity/ies for which the MRL application is submitted. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesPlant
Risk assessment (plant)	The field refers to the risk assessment residue definitions for plant commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different plant commodities under consideration, this shall be indicated. If for processed commodities residue definitions differ from residue definitions in raw agricultural commodity (RAC), this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentPlant

	If for rotational crops the residue definition differs from the residue definition in primary crops, this shall be indicated. This information is available in EFSA conclusion (list of end points) and Registration reports.		
Monitoring purposes (animal)	This is the RD used to express the current MRLs in animal commodities. Please check the current existing RD in the EU MRL data base. The field refers to the enforcement residue definitions for animal commodity/ies for which the MRL application is submitted. If different enforcement residue definitions are set in different animal commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	The field refers to the risk assessment residue definitions for animal commodity/ies for which the MRL application is submitted. If different risk assessment residue definitions are set in different animal commodities under consideration, this shall be indicated. This information is available in EFSA conclusion (list of end points) and Registration reports.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, …)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.Remarks
EFSA paramCode			FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.EfsaParamCode
RD paramCode	Enter one or more EFSA param codes to identify the substance/s (including metabolites) which comprise the residue definition for monitoring purpose (as used for reporting pesticide residue monitoring data). EFSA paramCodes can be downloaded or accessed by the EFSA catalogue browser application.	Text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingResidues.EfsaParamCode.RdParamCode
EFSA paramCode			
Existing MRL		Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl
EU MRL	Use the repeatable block (“new item”) to create one line for each commodity under assessment.		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl

Commodity	Select the commodity The picklist comprises commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities.	Multi select closed list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.Commodity
MRL value	Enter the MRL value in mg/kg	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.MrlValue
Residue definition monitoring	Enter the enforcement residue definition for the commodity selected into this block	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.ResidueMonitoring
Remarks	Any comment on the existing MRL (provisional, confirmatory data required..)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsEurope.ExistingMrl.EuMrl.Remarks
EU MRL			
Assessments outside Europe	In this section provide information on previous or ongoing evaluations **outside of Europe**	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope
Biocide	Indicate if this active substance has been or is being assessed for use as a biocide outside of Europe. Select the status of the application and provide details on the nature of the application	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.Biocide
Veterinary medicine	Indicate if this active substance has been or is being assessed for use as a veterinary medicine outside of Europe. Select the status of the application and provide details on the nature of the application.	Open list with remarks (2000)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.VeterinaryMedicine
Other product safety assessments	In this section provide information on previous or ongoing evaluations outside Europe under regulations other than Biocides or Veterinary Medicines		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessments
Evaluation	If this active substance has been or is being assessed under any other product or food safety regulations indicate the context of the evaluation.	Open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessments.Evaluation
Status	Indicate if this active substance has been or is being assessed under any other product or food safety regulations. If yes provide details on the nature and status of the application	Open list with remark	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.OtherProductSafetyAssessm

		s (2000)	ents.Status
Other product safety assessments			
Existing residue definitions	Enter the enforcement residue definitions for the MRL in the exporting country, only if they differ from the residue definition used in the EU. This field is not needed if RDs are the same in EU and the third country.	Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues
Monitoring purposes (plant)	The field refers to the enforcement residue definition in the exporting country for the animal commodity/ies for which the MRL application is submitted. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.MonitoringPurposesPlant
Risk assessment (plant)	The field refers to the risk assessment residue definition in in the exporting country in the plant commodity for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated. If the MRL application is submitted to account for residues in rotational crops and the residue definition in rotational crops differs from the residue definition in primary crops, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentPlant
Monitoring purposes (animal)	The field refers to the enforcement residue definition in the exporting country for the animal commodity/ies for which the MRL application is submitted. If different enforcement residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.MonitoringPurposesAnimal
Risk assessment (animal)	The field refers to the risk assessment residue definition in the exporting country for the animal commodity for which the MRL application is submitted. If different risk assessment residue definitions are set in different commodities under consideration, this shall be indicated.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.RiskAssessmentAnimal
Remarks	Any comment on the existing RD for risk assessment (e.g. provisional, clarify the source, data gaps, …)	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.ExistingResidues.Remarks

Existing MRL in the exporting country	This block is relevant for MRL applications dealing with import tolerances	Header 2	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries
Exporting country MRL	Use the repeatable block ("new item") to create one line for each commodity for which an MRL request associated to an import tolerance request is under assessment.		FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl
Country	Select the exporting country from the list	Multi select open list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Country
Commodity	The picklist comprised commodities as listed in Part A of Annex I to Reg. 396/2005 and in addition feed commodities. ONLY in case the tested commodity is not present in the picklist choose "other" and enter manually.	Multi select open list with remarks	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Commodity
MRL value	If MRL setting processes are established in exporting country selected above, please enter the MRL value (in mg/kg) currently in place in this exporting country. If MRL setting processes are NOT established in exporting countries, please report "not relevant" and specify the reason in remark box.	Unit measure with Closed List (Decimal)	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.MrlValue
Residue definition monitoring	Enter the enforcement residue definition for the commodity selected into this block.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.ResidueMonitoring
Remarks	Any additional remark on the MRL in the exporting country.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AssessmentsOutsideEurope.MrlExportingCountries.ExportingCountryMrl.Remarks
Existing MRL in the exporting country	This block is relevant for MRL applications dealing with import tolerances.		
Exporting country MRL	Use the repeatable block ("new item") to create one line for each commodity for which an MRL request associated to an import tolerance request is under assessment.		
Additional information	This section is only relevant for MRL applications dealing with import tolerances.	Header 1	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation
Evidence of registration in the	Please confirm with this checkbox that the evidence of the registration in the exporting country and, if available, the registered use	Check box	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.Registrat

exporting country	pattern in the exporting country were attached.		ionInExportingCountry
Evidence of registration in the exporting country (remark)	Clarification should be given in remark field if no evidence can be provided in attachment.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryRemark
Evidence of registration in the exporting country attached	Upload attachment(s) with evidence of registration in the exporting country (these attachments will be published and should not contain confidential information)	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryAttachment
Registered use pattern in the exporting country	Please upload attachment(s) to report the registered use pattern, as registered in the exporting country. Please note that this use pattern should also be reported in a formatted way, using the Good agricultural practices (GAP) document (Product Section 2).	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.RegistrationInExportingCountryUsePattern
Legislation in the exporting country concerning the MRL	Please confirm with this checkbox that the Legislation in the exporting country concerning the MRL was attached..	Check box	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationInExportingCountry
Legislation in the exporting country concerning the MRL (remark)	Clarification should be given if no MRLs are established in the exporting country.	Multi-line text	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationExportingCountryRemark
Legislation in the exporting country concerning the MRL attached	Upload copie(s) of the Legislation in the exporting country concerning the MRLs.	Attachments list	FLEXIBLE_RECORD.AssessmentOtherAuthorities.AdditionalInformation.LegislationExportingCountryAttachment

Links to support material:
https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN

European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. http://doi.org/10.5281/zenodo.3243215

EFSA Catalogue Browser User Guide 10.2903/sp.efsa.2019.EN-1726
https://github.com/openefsa/catalogue-browser/releases

11.2 Other reports – Flexible summary

Purpose:
Summarise the overall conclusions for the substance or mixture
Provide a place to upload files or reports which could not be attached in other sections but are used to support the evaluation.

FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP			
Name	**Instructions**	**Type**	**Field Path**
Administrative data		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary
		Confidentiality	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdministrativeDataSummary.DataProtection
Reports and administrative information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo
Reports and administrative information			FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo
Type of report	Indicate the type of document that has been uploaded e.g. 'Document C Existing or proposed labels'	Multi-line text	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.TypeOfReport
Attached document	If the file or document uploaded in the 'Attach one or more documents including the sanitised version of the document' contains redacted information upload the original version in this field.	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.AttachedDocument
Attached (sanitised) document for publication	Upload sanitised version of files or documents which could not be uploaded in other sections of the dossier. This would include 'Document C Existing or	Single file attachment	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.ReportsAdministrativeInfo.ReportsAdministrativeInfo.SanitisedDocument

	proposed labels' 'Document G Permission of each formulant in accordance with EU legislation' 'Document I Other data on the formulants' Documents M, N and L - report generator should be used to create these documents when the appropriate report format (ftl file) is available		
Reports and administrative information			
Other references (including SDS)	Link to other reports not referenced in the endpoint study records needed to support the assessment. The bibliographic information should be completed and the PDF uploaded in the literature reference entity This would include: 'Safety datasheets' 'Scientific opinions of national/international regulatory bodies'	Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS
References		Literature reference list	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.OtherReferencesIncludingSDS.References
Additional information		Header 1	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area	FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP.AdditionalInformation.AdditionalInformation

1. Referenced Entities

1.1. Reference substance

Purpose:
Chemicals: Identity of the active substance – ISO common name and synonyms, Chemical name in accordance with IUPAC and CA nomenclature, CAS Reg number EC number, molecular and structural formula, molar mass
Microorganisms: Identity of the microorganism – Name, taxonomy, species description and strain characterisation
The Reference substance inventory gives the possibility to use the same information for the same chemical/microorganism identity avoiding duplicate data entry and to ensure that the data is centrally managed and updated. Each reference substance can be linked to an unlimited number of substance or mixture datasets.
Reference substance/s can be exported and shared from the Reference substance entity manager

Name	Instructions	Type	Field Path
	Set confidentiality and regulatory program flags.	Confidentiality	REFERENCE_SUBSTANCE.DataProtection
Reference substance name	Name of substance, microorganism, metabolite, residue, impurity or other substance included in the dossier For the active substances the ISO common name or proposed ISO name should be reported	Multi-line text	REFERENCE_SUBSTANCE.ReferenceSubstanceName
IUPAC name	IUPAC name (Note that, if a name following the IUPAC nomenclature cannot be derived, you should still provide a name defining the chemical nature of the substance). For **microorganisms** the scientific name (species and strain) should be reported in this field.	Multi-line text	REFERENCE_SUBSTANCE.IupacName
Description	Specify any additional information relevant for the description of the reference substance in	Text template	REFERENCE_SUBSTANCE.Description

	this field For **microorganisms** the taxonomic information family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism should be reported. In addition it should be indicated whether the microorganism - is indigenous or non-indigenous at the species level to the intended area of application - is a wild type - is a spontaneous or induced mutant - has been modified using techniques described in Part 2 of Annex IA and in Annex IB to Directive 2001/18/EC (*) of the European Parliament and of the Council		
Inventory	Can be used to select existing substances with pre-assigned EC numbers.	Header 1	REFERENCE_SUBSTANCE.Inventory
Inventory number	Can be used to select existing substances with pre-assigned EC numbers.	Entity reference list	REFERENCE_SUBSTANCE.Inventory.InventoryEntry
No inventory information available - Justification	Not relevant for EU PPP	Open list with remarks	REFERENCE_SUBSTANCE.Inventory.InventoryEntryJustification
CAS number	CAS Registry Number	Text	REFERENCE_SUBSTANCE.Inventory.CASNumber
CAS name	CAS name	Multi-line text	REFERENCE_SUBSTANCE.Inventory.CASName
CIPAC number	CIPAC number		

Synonyms		Header 1	REFERENCE_SUBSTANCE.Synonyms
Synonyms	List any synonyms for the substance For **microorganisms** alternative names should be added in the table and the accession number/s from internationally recognised culture collections EFSA paramCode should be added in the table		REFERENCE_SUBSTANCE.Synonyms.Synonyms
	Set confidentiality and regulatory program flags	Confidentiality	REFERENCE_SUBSTANCE.Synonyms.Synonyms.DataProtection
Identifier	Select the type of identifier you wish to provide using the picklist. If none of pre-defined items apply, select 'other:'. A text field is then activated next to the list field in which you can specify the type of identifier you wish to provide.	Open list	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Identifier
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text area	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Name
Remarks	Provide additional remarks related to the reported identifier	Text	REFERENCE_SUBSTANCE.Synonyms.Synonyms.Remarks
Synonyms			
Molecular and structural information		Header 1	REFERENCE_SUBSTANCE.MolecularStructuralInfo
		Confidentiality	REFERENCE_SUBSTANCE.MolecularStructuralInfo.DataProtection
Molecular formula	Molecular formula (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the Remarks field at the	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularFormula

	bottom of the section)		
Molecular weight	Molecular weight should be reported as a single numeric value	Range (Decimal)	REFERENCE_SUBSTANCE.MolecularStructuralInfo.MolecularWeightRange
SMILES notation	The SMILES notation should be in the canonical form https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.SmilesNotation
InChI	The IUPAC international chemical identifier https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text	REFERENCE_SUBSTANCE.MolecularStructuralInfo.InChI
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image	REFERENCE_SUBSTANCE.MolecularStructuralInfo.StructuralFormula
Remarks	See molecular formula	Text area	REFERENCE_SUBSTANCE.MolecularStructuralInfo.Remarks
Chemical structure files	Upload chemical structures files (both machine readable and an image file) For machine readable files the format should be .sk2 or .cdx or .mol For image files the format should be jpg or png		REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles
Structure file		Single file attachment	REFERENCE_SUBSTANCE.MolecularStructuralInfo.ChemicalStructureFiles.StructureFile
Remarks on structure file		Text	REFERENCE_SUBSTANCE.MolecularStructuralInf

			o.ChemicalStructureFiles.RemarksChemStruct
Chemical structure files			
Related substances	Not relevant for EU PPP	Header 1	REFERENCE_SUBSTANCE.RelatedSubstances
			REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances
Identifier		Open list	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Identifier
Identity		Text area	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Identity
Remarks		Text	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Remarks
Relation		Open list	REFERENCE_SUBSTANCE.RelatedSubstances.RelatedSubstances.Relation
Group / category information		Multi-line text	REFERENCE_SUBSTANCE.RelatedSubstances.GroupCategoryInfo

Links to support materials:

CIPAC number: https://cipac.org/index.php/code-numbers/navigate-code-numbers

https://www.cas.org/support/documentation/chemical-substances

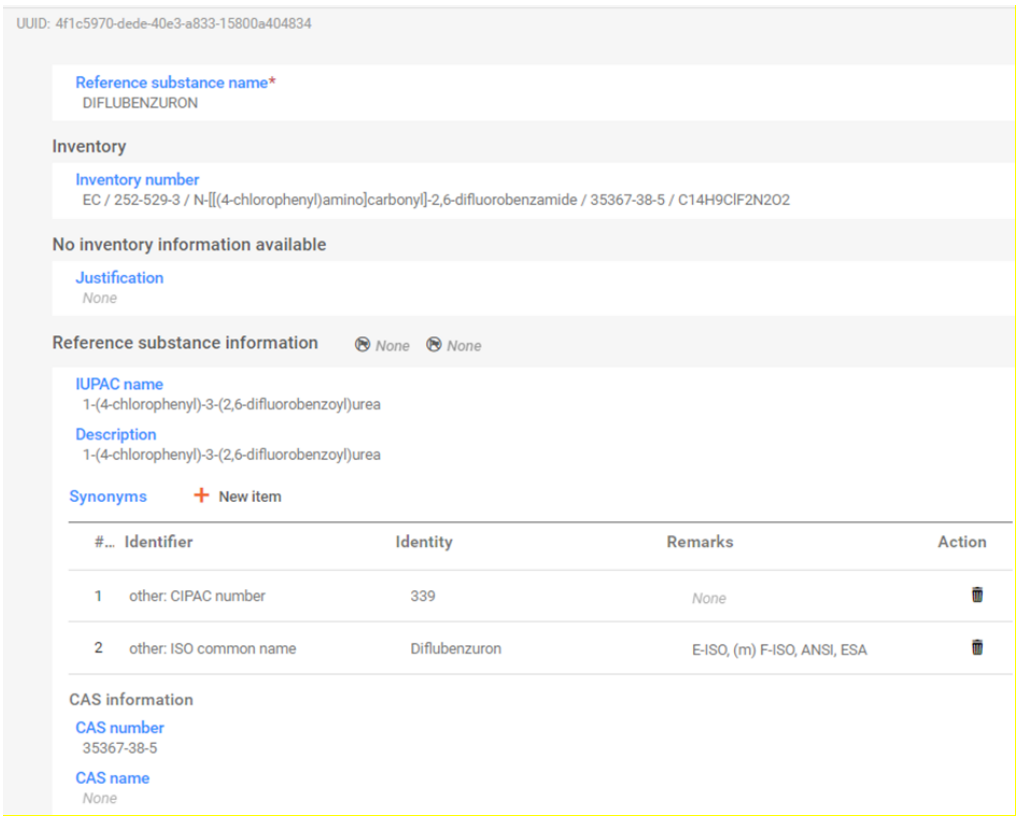
paramCode - European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. http://doi.org/10.5281/zenodo.3243215

https://iupac.org/who-we-are/divisions/division-details/inchi/

https://www.iso.org/committee/50160/x/catalogue/

http://www.alanwood.net/pesticides/index_cn_frame.html

https://cactus.nci.nih.gov/chemical/structure/



1.2. Legal entity (including Contact entity)

Purpose:
Submissions require a Legal entity which has to be defined including contact details prior to submission. A Legal Entity (LE) may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person. LEs are identified by their name, universally unique identifier (UUID), address, country, and general contact information. You can create a LEO via ECHA accounts

It is used for functionalities where it is critical to ensure uniqueness of the Legal Entity information e.g. for specifying data ownership or identify your own company/organisation.

If you are installing a local version of IUCLID, a LEO will have been created during the installation of the client version of IUCLID. You can then export it from IUCLID and import it to you ECHA account. If you have an ECHA account and define a LEO there, you can export the LEO and import it to your own local IUCLID installation.

You can add more legal entities within the IUCLID application via the inventory.

Field name	Instructions	Path
General information		LEGAL_ENTITY.GeneralInfo
Legal Entity name	Name of the legal entity i.e. Company name	LEGAL_ENTITY.GeneralInfo.LegalEntityName
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	LEGAL_ENTITY.GeneralInfo.LegalEntityType
Remarks	Any additional information on the legal entity, if relevant	LEGAL_ENTITY.GeneralInfo.Remarks
Other names	Other names can be specified and if needed these names can be marked as confidential	LEGAL_ENTITY.GeneralInfo.OtherNames
Address	See section on Confidentiality of dossiers	LEGAL_ENTITY.GeneralInfo.ContactAddress.DataProtection
Address 1	Street address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address1
Address 2	Secondary address, if relevant	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address2
Postal Code	Postal code of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Postal
Town	Town of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Town
Region/State	Region/State of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Region
Country	Select the country in which the legal entity is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	LEGAL_ENTITY.GeneralInfo.ContactAddress.Country
Phone	Phone number of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Phone
Fax	Fax number of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Fax
Email	Email address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Email
Website	Legal entity website	LEGAL_ENTITY.GeneralInfo.Cont

		actAddress.WebSite
Identifiers	Optional: Other identifiers can be reported. Legal entity identifiers, Regulatory programme identifiers, and Other IT system identifiers. Each type contains a menu from which relevant sub-types of identifier can be selected. For example, Legal entity has an option for DUNS (Data Universal Numbering System for identification of a Legal Entity. Click on New Item and set values. See section on Confidentiality of dossiers.	LEGAL_ENTITY.Identifiers
Contact information	An address can be defined for a contact person of the Legal entity and links can be made to one or more Contact entities	LEGAL_ENTITY.ContactInfo
Contact Person	This can be managed in the Contact entity manager	
General information		CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	CONTACT.GeneralInfo.Organisation
Department	e.g. Scientific Department	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	CONTACT.GeneralInfo.Title
Phone	Phone number of the contact person	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person	CONTACT.GeneralInfo.Email
Address 1	Street address of the contact person	CONTACT.GeneralInfo.Address1
Address 2	Secondary address, if relevant	CONTACT.GeneralInfo.Address2
Postal Code	Postal code of the street address of the contact person	CONTACT.GeneralInfo.Postal
Town	Town of the contact person	CONTACT.GeneralInfo.Town

Region/State	Region/State of the contact person	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant	CONTACT.GeneralInfo.Remarks

Links to support material:
https://echa.europa.eu/support-echa-accounts-and-eu-login

https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395

https://echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf

https://www.youtube.com/watch?v=4JGsQUbGYqw

1.3. Contact entity

Name	Instructions	Type	Field path
General information		Header 1	CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	Open list	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	Text	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	Text	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	Text	CONTACT.GeneralInfo.Organisation
Department	e.g. scientific department.	Text	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	Text	CONTACT.GeneralInfo.Title
Phone	Phone number of the contact person.	Text	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person.	Text	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person.	Text	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person.	Text	CONTACT.GeneralInfo.Email

Address 1	Street address of the contact person.	Text	CONTACT.GeneralInfo.Address1
Address 2	Secondary address, if relevant	Text	CONTACT.GeneralInfo.Address2
Postal code	Postal code of the street address of the contact person.	Text	CONTACT.GeneralInfo.Postal
Town	Town of the contact person.	Text	CONTACT.GeneralInfo.Town
Region / state	Region/State of the contact person.	Text	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	Open list	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant.	Text area	CONTACT.GeneralInfo.Remarks

1.4. Test Material Information

Purpose:
A detailed description (specification) of the material used shall be provided for each study submitted
For the product: A detailed description of the composition used shall be provided. The specifications and test materials used in the new studies must be clearly identified; If the new (proposed) representative formulation for the renewal is different to the former (reference) formulation, it should be demonstrated by the applicant that differences are minor for the different sections (ecotox, tox…) in case that data from the former (reference) formulation should also be used for the assessment of the new (proposed) formulation.
For the active substance: The test material used should be essentially the same, for the purposes of toxicological, ecotoxicological, environmental and residue testing and assessment. In the case of studies in which dosing extends over a period (for example repeated dose studies), dosing shall be done using a single batch of active substance if stability permits. When tests shall be conducted using purified active substance the purity must be (≥ 980 g/kg) of stated specification otherwise a justification shall be provided in cases where the degree of purity achieved is less than 980 g/kg.
Test material must clearly identify the batches used as test material in the different studies included in the dossier. To facilitate the assessment of the compliance of the batches used in the (eco)toxicological studies with the technical specification (Template 1.1)

Name	Instructions	Type	Field Path
Name	Number of the batch	Multi-line text	TEST_MATERIAL_INFORMATION.Name
Composition		Header 1	TEST_MATERIAL_INFORMATION.Composition
Composition	The Composition block can be claimed confidential in full by		TEST_MATERIAL_INFORMATION.Composition.CompositionList

	using the confidentiality flag in the Administrative Data block in the related Endpoint Study Record.		
Type	Indicate for each component if it is a constituent, impurity or additive	Closed list	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Type
Reference substance	Link to the reference substance for the component	Entity reference field	TEST_MATERIAL_INFORMATION.Composition.CompositionList.ReferenceSubstance
Concentration	Concentration of the component. For the chemical active substance and impurities this should be in g/kg.	Range with open list (Decimal)	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Concentration
Remarks	Specific remarks related to the concentration of the component reported	Multi-line text	TEST_MATERIAL_INFORMATION.Composition.CompositionList.Remarks
Composition			
Composition / purity: other information	'analytical grade' or 'technical grade' can be used to provide a qualitative indication of the purity for active substances where quantification is not technically possible	Open list with remarks	TEST_MATERIAL_INFORMATION.Composition.CompositionPurityOtherInformation
Other characteristics		Header 2	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics
Test material form	Select the form of the test material	Open list with remarks (2000)	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.TestMaterialForm
Details on test material	Provide the expiry date.	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.DetailsOnTestMaterial
Confidential details on test material	The percent difference in concentration from the reference specification can be indicated for the active substance and impurities	Text template	TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.ConfidentialDetailsOnTestMaterial

Links to support materials:

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chem-substances_en.pdf

Template 1.1– Template for presentation the assessment for the equivalence of batches (https://doi.org/10.5281/zenodo.4557366)

1.5. Literature reference

Purpose:
Storage of bibliographic metadata with attached documents including full study reports and published scientific papers
Linking studies to the Notification of Studies Database
Used as the data source in OECD harmonised templates and DOMAIN Endpoint Study Records
It is important to create a Literature reference for all studies used as evidence in the dossier. This would also include all relevant studies selected for full-text assessment identified from a literature search (when required).

Name	Instructions	Type	Field Path
General information		Header 1	LITERATURE.GeneralInfo
Reference Type	Select 'study report' for a full study report used as a data source for an endpoint study record. Select 'published' for relevant studies identified from a literature search to address data requirements The other reference types can also be used	Open list	LITERATURE.GeneralInfo.LiteratureType
Title	Title of the study report, publication or other report type	Text	LITERATURE.GeneralInfo.Name
Author	Author names for the study. These will be redacted from the published dossier for unpublished studies.	Multi-line text	LITERATURE.GeneralInfo.Author
Year	The year the report must be reported (this is used for sorting and filtering)	Integer	LITERATURE.GeneralInfo.ReferenceYear
Bibliographic source	For published studies information on the	Text	LITERATURE.GeneralInfo.Source

	journal, edition volume, page numbers should be completed. This should include the DOI (Digital Object Identifier)		
Testing facility	For study reports information on the testing facility should be completed. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo.TestLab
Report no.	Specify the report number allocated by the testing laboratory. This information will not be published for studies involving tests on vertebrate animals.	Text	LITERATURE.GeneralInfo.ReportNo
Study sponsor	Information on the source of funding of the study can be provided	Text	LITERATURE.GeneralInfo.CompanyOwner
Study no.	Report the company identifier, if it differs from the laboratory report number	Text	LITERATURE.GeneralInfo.CompanyOwnerStudyNo
Report date	Report date or publication date in full. For study reports this must be after the date the study was notified in the notification of studies database	Date	LITERATURE.GeneralInfo.ReportDate
Remarks	Explanatory remarks can be provided	Text area	LITERATURE.GeneralInfo.Remarks
Attached documents	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication. For published studies the article must be uploaded in PDF format if full intellectual property rights have not been obtained and the article can be used for scientific assessment purposes only. The uploaded	Attachments list	LITERATURE.GeneralInfo.AttachedDocuments

	attachment will not be included in published dossier		
Attached (sanitised) documents for publication	For study reports a sanitised version of the full study report must be uploaded in this field in PDF format. For published studies the article must be uploaded in PDF format: if full intellectual property rights have been obtained. If full intellectual property rights have not been obtained, a citation including the abstract should be uploaded in this field. The uploaded attachment will be included in the published dossier	Attachments list	LITERATURE.GeneralInfo.AttachedSanitisedDocsForPublication
Other study identifier(s)	Applies to study reports		LITERATURE.GeneralInfo.StudyIdentifiers
Study ID	Study ID should be used to report the identifier from the Notification of Studies database (NoS_Id).	Text	LITERATURE.GeneralInfo.StudyIdentifiers.StudyID
Remarks	If the Notification of studies identifier is reported in 'Study ID' enter 'NoS_Id'. If the study was not notified provide a justification to explain why the study is included in the dossier to meet the data requirements but was not included in the Notification of Studies database. Example 'Study commissioned before 27 March 2021'. This section should be used to include justifications for study notifications.	Text	LITERATURE.GeneralInfo.StudyIdentifiers.Remarks

Other study identifier(s)			

Links to support material:

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

Practical arrangement for Notification of studies

Additional considerations:

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights (IPRs) for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

2. Endpoint Summaries – Common blocks

Links to support material:

Template to be used for the List of Endpoints SANCO/12483/2014– rev. 3
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_temp-list-endpoints_rev-3.pdf

2.1. Administrative data summary – common block

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeDataSummary
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is	Confidentiality	AdministrativeDataSummary.DataProtection

	set.		
Link to relevant study record(s)	Provide here the link to the most relevant study(ies) from which the key value for chemical safety assessment is extrapolated.	Header 1	LinkToRelevantStudyRecord
Study name / type		Endpoint reference list	LinkToRelevantStudyRecord.Link
Results		Read-only	LinkToRelevantStudyRecord.Results
Description of key information	Report Information to support the most relevant endpoint. Ensure that information presented includes the information specified in the Template to be used for the List of Endpoints.	Header 1	KeyInformation
		Rich text area	KeyInformation.KeyInformation

Links to support materials

https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation

Practical arrangement for Notification of studies

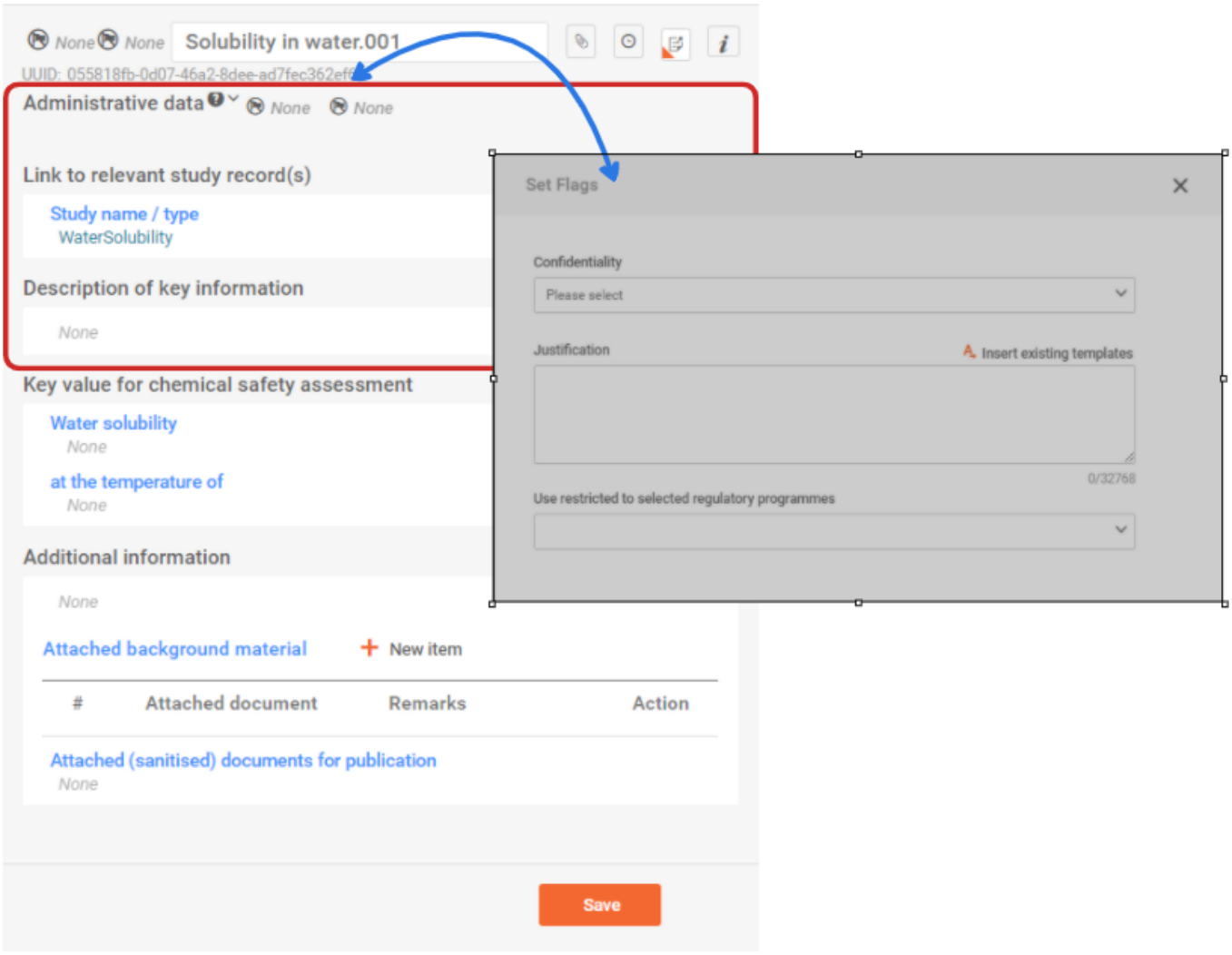


Figure 1.1: Administrative data summary

2.2. For relevant study record – common block

Name	Instructions	Type	Field Path
Link to relevant study records		Header 3	LinkToRelevantStudyRecords
Study name / type	The study giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the robust study summary is selected: quality of the study (e.g. Klimisch score), duration of the	Endpoint reference list	LinkToRelevantStudyRecords.StudyNameType

	study, whether or not the study is GLP. Available epidemiological data are preferred provided that they are reliable and relevant. However, epidemiological studies should be reported under 5.9.4		
Results		Read-only	LinkToRelevantStudyRecords.Results

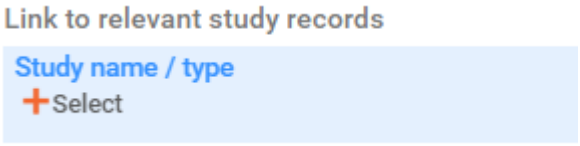


Figure 1.2: Link for relevant study record

2.3. Endpoint conclusion (quality of database) – common block

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Adverse effect observed" should be chosen if mortality or severe effects were observed in any of the studies. "No adverse effect observed" should be chosen if no animals died or no severe effects were observed at limit dose level. If "No study available" is chosen, a justification needs to be provided.	Closed list	EndpointConclusion.EndpointConclusion
Dose descriptor	Type of reference value reported e.g. LD50. Reference value derived from the reported endpoint study records	Closed list	EndpointConclusion.EffectLevelUnit
Value		Range with closed list (Decimal)	EndpointConclusion.EffectLevelValue
Quality of whole database	The following factors should be considered: - To what extent the whole available	Multi-line text	EndpointConclusion.DataBaseQuality

	information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)		

Figure 1.3: Endpoint conclusion (Quality of database)

2.4. Endpoint conclusion (Species version) – common block

Name	Instructions	Type	Field Path
Endpoint conclusion		Header 3	EndpointConclusion
Endpoint conclusion	Add the relevant endpoint conclusions by picking from provided list. In case where no picklist is provided, please add the relevant species / organ / system which was investigated in the study.	Closed list	EndpointConclusion.EndpointConclusion
Dose descriptor		Closed list	EndpointConclusion.EffectLevelUnit
		Unit measure with Closed List (Decimal)	EndpointConclusion.EffectLevelValue

Study duration		Closed list	EndpointConclusion.TestType
Experimental exposure time per week (hours/week)	In this field, you should add the experimental exposure conditions in hours per week. This can be done considering the hours per day and the days per week the animals were exposed.	Decimal	EndpointConclusion.ExperimentalExposureTimePerWeek
Species		Open list	EndpointConclusion.Species
Quality of whole database	The following factors should be considered: - To what extent the whole available information meets the data requirements under EU Pesticide legislation. - Reliability and consistency across different studies (i.e. quality of testing methods, size and statistical power of study design, biological plausibility, dose-response relationships and statistical testing)	Multi-line text	EndpointConclusion.DataBaseQuality
System		Open list	EndpointConclusion.System
Organ		Multi select open list	EndpointConclusion.Organ

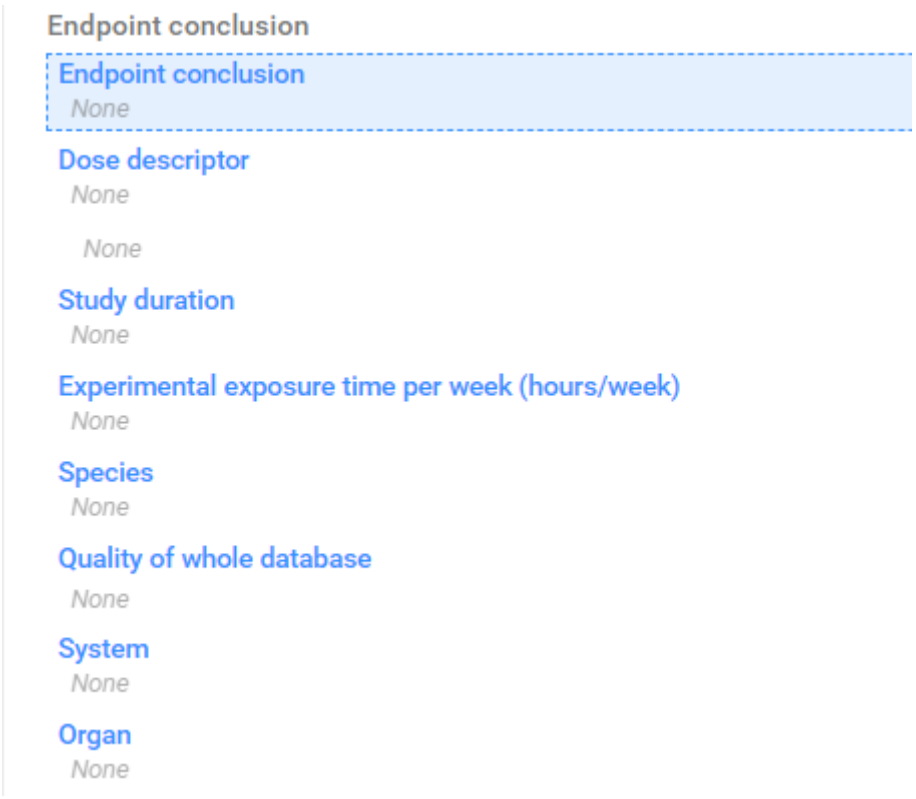


Figure 1.4: Endpoint conclusion (species version)

2.5. Discussion (Header 1) – common block

Name	Instructions	Type	Field Path
Additional information	Provide additional information related to the endpoint, for example: - information on the potential data gaps - relevance of the results for the risk assessment - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - the rationale for any user-derived values for the sake of transparency -the possible reasons for	Header 1	Discussion

	differentiating results when several studies were identified to be relevant for the assessment. If there is no additional information to be reported this field may be left empty.		
	Provide any additional information related to the endpoint.	Rich text area	Discussion.Discussion
Attached background material	Provide the original version of any document that contains confidential material		Discussion.AttachedBackgroundMaterial
Attached document	The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Single file attachment	Discussion.AttachedBackgroundMaterial.AttachedDocument
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	Discussion.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached (sanitised) documents for publication	Provide any document for publication	Attachments list	Discussion.AttachedSanitisedDocsForPublication

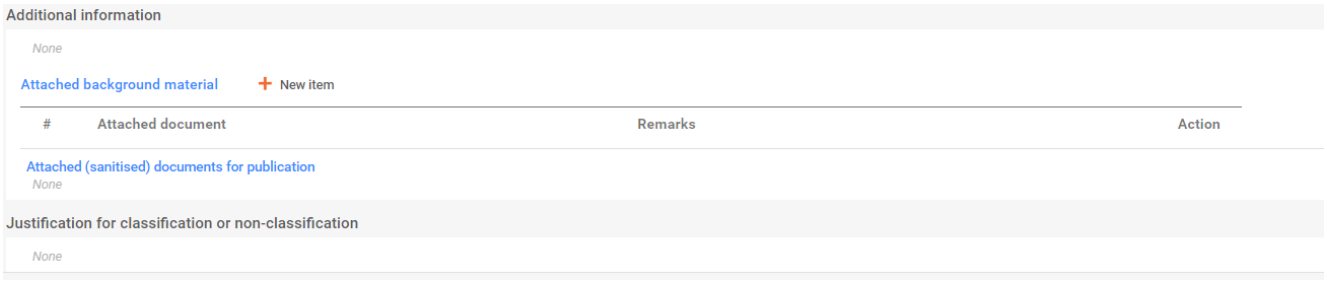


Figure 1.5: Discussion (Header 1)

3. Study naming – best practices

- 'Endpoint study records should not include author names'
- 'It is recommended to use the Year of the study, the endpoint and additional relevant context where a multiple studies exist for an endpoint.'

Examples:

Analytical methods: 2007_Post-approval control and monitoring purposes_cereal

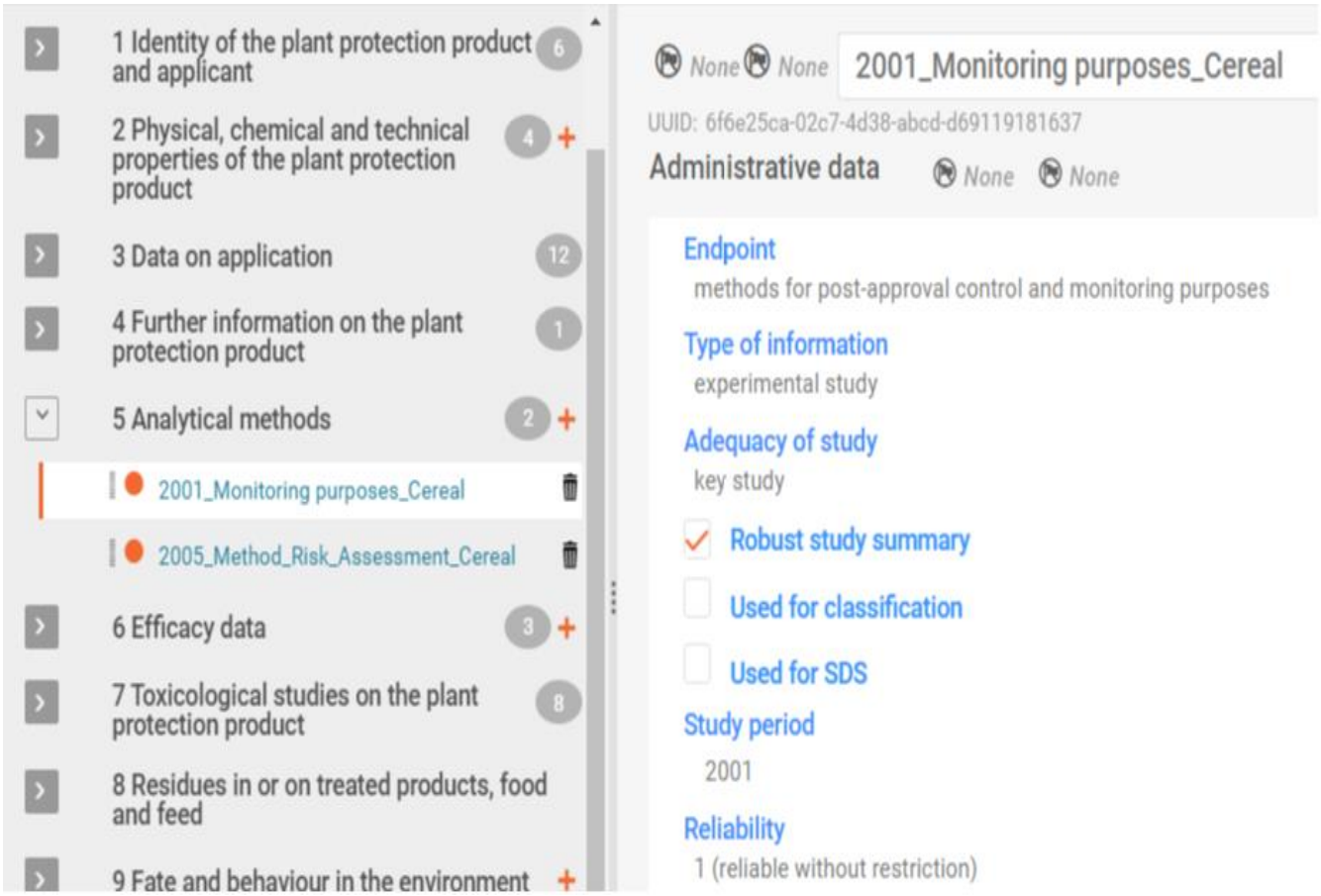
Metabolism in plants: 2009_primary_crop_metabolism_wheat

Feeding studies: 2010_residues in livestock_lactating_cows

Biodegradation in soil: 2011_biodegradation in soil simulation_anaerobic

Toxicity aquatic invertebrates: 2012_short term toxicity_daphnia magna

Good agricultural practices (GAP): Crop_zone.001, ex. Apples_NEU.001



Example: study naming

4. Endpoint studies – Common blocks

4.1. Administrative data – common block

Purpose:
Describes how to fill in all the administrative data available on a particular endpoint study, entered into the pertinent fields. This information relates to the type of information, adequacy of study, study period, reliability, data waiving.

Name	Instructions	Type	Field Path
Administrative data		Header 1	AdministrativeData
	Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants Use the Confidentiality flag and/or the Regulatory purpose flag to filter out data in subsequent operations such as exporting, printing or dossier creation. A justification is required when the confidentiality flag is set.	See section on Confidentiality of dossiers	AdministrativeData.Data Protection
Endpoint	Select from the picklist the relevant endpoint.	Closed list with remarks	AdministrativeData.Endpoint
Type of information	Indicate 'experimental study' or 'read-across from similar mixture/product' or 'read-across from supporting substance (structural analogue or surrogate)' or 'read-across based on grouping of substances (category approach)' unless the information is retrieved from a literature search in this case indicate 'other': 'Study from literature search'	Open list with remarks	AdministrativeData.StudyResultType
Adequacy of study	Indicate the purpose of the record selecting the adequacy in terms of usefulness for fulfilling the information requirements for the	Closed list	AdministrativeData.PurposeFlag

	hazard/risk assessment. • A **key study** is a study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativeness of data. • A **supporting study** provides some additional information to support the conclusions from the key study/ies or the weight of evidence approach. • A **weight of evidence** is selected to indicate that an endpoint study record contributes to a weight of evidence approach. • **Disregarded due to major methodological deficiencies** is a study that is available to the applicant but is not taken into account because of lack of reliability or because the study is obsolete. • **Other information** is other available information which does not directly contribute to the conclusions for the setting the endpoint For each data requirement at least one 'key study' or two		

	records identified as 'weight of evidence' is expected unless data waiving has been indicated. Where 'key study' or 'weight of evidence' is selected, the Validation assistant checks for document completeness.		
Robust study summary	Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. If not relevant, disregard this field. 'Robust Study Summary' or in combination with 'Adequacy of study'. If not relevant, disregard this field.	Check box	AdministrativeData.RobustStudy
Used for classification	Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'. If not relevant, disregard this field.	Check box	AdministrativeData.UsedForClassification
Used for SDS	Not relevant for EU-PPP	Check box	AdministrativeData.UsedForMSDS
Study period	Indicate the period during which the study was conducted, i.e. start and end date. For 'Notified' studies this should be after the date of notification	Text	AdministrativeData.StudyPeriod
Reliability	The term reliability defines the inherent quality of a test report	Open list	AdministrativeData.Reliability

	or publication. In field Reliability, enter a reliability score as judged at your discretion, i.e. 1 (reliable without restriction), 2 (reliable with restrictions), 3 (not reliable) or 4 (not assignable). The "other:" option may be selected if this scoring system is not used. Studies indicated as key study must have a reliability score of 1 or 2. The validation check will verify consistency between 'Adequacy of study' field and 'Reliability' field (EU_PPP_007, EU_PPP_003). Further explanations on the reliability assessment can be provided in the 'Rationale for reliability incl. deficiencies' field. For further details on reliability please consult the following EFSA guidance: 'Appendix to the EFSA guidance document on Submission of scientific peer-reviewed open literature for the approval of pesticide active substance under Regulation (EC) No 1107/2009' In terms of 'Acceptability /		

	Reliability' Key studies and weight of evidence studies are considered to have 'Acceptability / Reliability' = Yes. A supporting study is considered to be 'Supportive only' The others are considered to have 'Acceptability / Reliability' = No.		
Rationale for reliability incl. deficiencies	Describe the rationale for the reliability score chosen considering the possible impact of deficiencies and/or implications on test results. Standard justifications from picklist may be sufficient in some cases. Otherwise select 'Other' and provide for additional explanation in the 'Remarks' field.	Open list with remarks (32000)	AdministrativeData.RationalReliability
Data waiving	If no 'key study' or 'weight of evidence' study is provided for a data requirement then data waiving must be completed. The validation check will flag when this field must be completed (EU_PPP_013). Select the reason for data waiving or other and provide a justification in 'Justification for data waiving' field.	Closed list	AdministrativeData.DataWaiving
Justification for data waiving	In addition to the more generic justification selected in the preceding field 'Data waiving', it is possible to provide here a more	Multi select open list with remarks (32000)	AdministrativeData.DataWaivingJustification

	detailed justification. To this end one of the specific standard phrase(s) can be selected if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving'. Otherwise select 'other:' and enter free text. Validation check will flag uncomplete compiling (EU_PPP_002).		
Justification for type of information	This field can be used for entering free text. Please complete field only when submitting a waiving justification	Text template	AdministrativeData.JustificationForTypeOfInformation
Attached justification	A document can be uploaded to support data waiving, but it is recommended to complete in full the data waiving fields		AdministrativeData.AttachedJustification
Attached justification		Single file attachment	AdministrativeData.AttachedJustification.AttachedJustification
Reason / purpose		Closed list with remarks	AdministrativeData.AttachedJustification.ReasonPurpose
Attached justification			
Cross-reference	In case the study has been reported for another data requirement use cross reference to link to the study to this section.		AdministrativeData.CrossReference
Reason / purpose for cross-reference		Open list with remarks	AdministrativeData.CrossReference.ReasonPurpose
Related information		Endpoint reference field	AdministrativeData.CrossReference.RelatedInformation
Remarks		Text area	AdministrativeData.CrossReference.Remarks
Cross-reference			

Links to support materials:
Guidance on the use of the weight of evidence approach in scientific assessments
https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971

Guidance on the assessment of the biological relevance of data in scientific assessments
https://doi.org/10.2903/j.efsa.2017.4970

Draft of the Scientific Committee guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments. EFSA Journal, EFSA Scientific Committee.
https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2020.6221

Guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal, EFSA Scientific Committee. http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.4971/full

Principles and process for dealing with data and evidence in scientific assessments. EFSA Journal, European Food Safety Authority. 2015;13(5):4121: 36. http://www.efsa.europa.eu/en/efsajournal/pub/4121

GUIDANCE DOCUMENT ON PREPARING LISTS OF TEST AND STUDY REPORTS ACCORDING TO ARTICLE 60 OF REGULATION (EC) No 1107/2009
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_12580.pdf

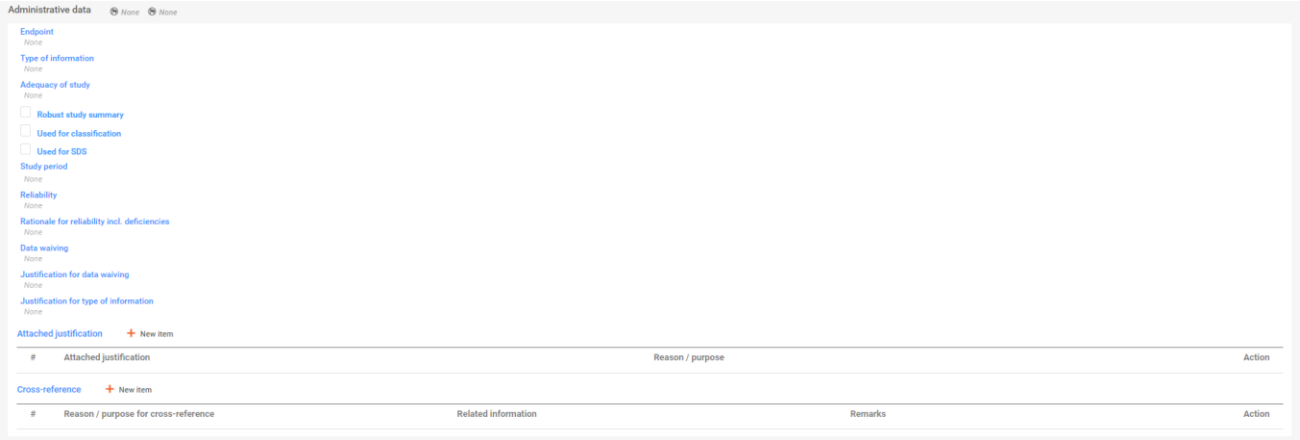


Figure 2.1: Administrative data block

4.2. Data source (Literature Reference) – common block

Name	Instructions	Type	Field Path
Data source		Header 1	DataSource
Reference	Link to Literature reference v.5.1 (Final)	Literature reference list	DataSource.Reference
Data access	Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use. Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive	Open list with remarks	DataSource.DataAccess

	disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publication in the literature reference entity for scientific assessment purposes only and (b) the relevant bibliographic reference/citation where these publications are available to the public in the literature reference entity for public dissemination on the OpenEFSA portal.		
Data protection claimed	Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates). In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or	Closed list with remarks	DataSource.DataProtectionClaimed

	refer to a document attached that provides justification (e.g. 'for justification see attached document X')		

Additional considerations:

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed above. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

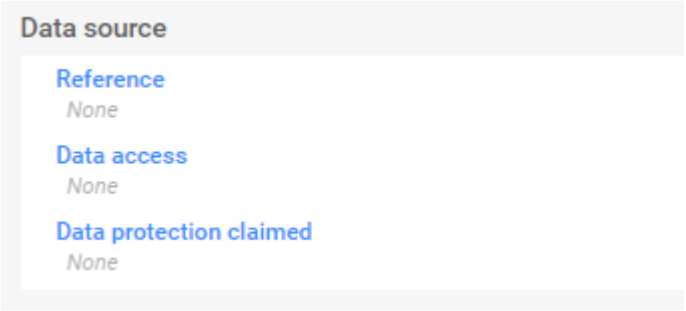


Figure 2.2: Data source block

4.3. Test Material – common block

Name	Instructions	Type	Field Path
Test material	All TM batches should be entered in the TM entity manager and then the appropriate TM selected	Header 2	TestMaterials

Test material information	Select the appropriate Test Material Information v.5.4 (Final) If more than one test batch is used in a study single representative batch can be used	Entity reference field	TestMaterials.TestMaterialInformation
Specific details on test material used for the study	Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. If applicable, relevant available information on the following items should be given: RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test material	Text template	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudy

	- Stability under test conditions - Solubility and stability of the test substance in the solvent/vehicle - Reactivity of the test substance with the solvent/vehicle or the cell culture medium TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding) - Preliminary purification step - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle) FORM AS APPLIED IN THE TEST (if different from that of starting material) Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution. FORMULATED PRODUCT (for biocides/pesticides) Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated		

	product seed treatment; solution in organic solvent seed treatment. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material.		
Specific details on test material used for the study (confidential)	Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. If applicable, relevant available information on the following items should be given: RADIOLABELLING INFORMATION - Radiochemical purity - Specific activity - Locations of the label - Expiration date of radiochemical substance STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of	Text template	TestMaterials.SpecificDetailsOnTestMaterialUsedForTheStudyConfidential

	test material - Stability under test conditions - Solubility and stability of the test substance in the solvent/vehicle - Reactivity of the test substance with the solvent/vehicle or the cell culture medium TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding) - Preliminary purification step - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle) FORM AS APPLIED IN THE TEST (if different from that of starting material) Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution. FORMULATED PRODUCT (for biocides/pesticides) Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil		

	application: formulated product seed treatment; solution in organic solvent seed treatment. OTHER SPECIFICS Provide any other relevant information needed for characterising the tested material.		

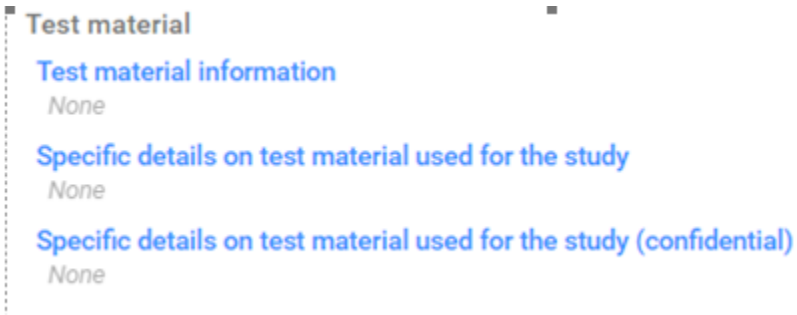


Figure 2.4: Test Material

4.4. Material and methods – common block

Name	Instructions	UI guidelines	Type	Field Path
Test guideline	Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).			Guideline
Qualifier	Select appropriate qualifier, i.e. - 'according to guideline' (if a given test guideline was followed); - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline); - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline'); - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline'). - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline').		Closed list	Guideline.Qualifier

Guideline	Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'. If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields. Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'.	Condition: Field active only if 'Qualifier' is not 'no guideline ...'	Open list	Guideline.Guideline
Version / remarks	In this text field, you can enter any remarks as applicable, particularly: - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline); - To indicate if the study was performed prior to the adoption of the test guideline specified; - To indicate if the methodology used was based on an extension of the test guideline specified; - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section.	Condition: Field active only if 'Qualifier' is not 'no guideline ...'	Multi-line text	Guideline.VersionRemarks
Deviations	In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS.	Condition: Field active only if 'Qualifier' is not 'no guideline ...'	Closed list with remarks	Guideline.Deviation
Test guideline				
Principles of method if other than guideline	If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate. For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate. Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a		Text template	MethodNoGuideline

	justification for using this method if appropriate.			
GLP compliance	Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes' is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed.		Closed list with remarks	GLPComplianceStatement
Other quality assurance	Indicate any non-GLP quality assurance system adhered to, if any.		Open list with remarks	OtherQualityAssurance
Type of method	Indicate which type of method was used according to the options provided in the test guideline or, if no guideline was applied, according to the methodology used.		Closed list with remarks	MethodType

Links to support material:
Communication from the Commission in the framework of the implementation of Commission Regulation (EU) No 283/2013

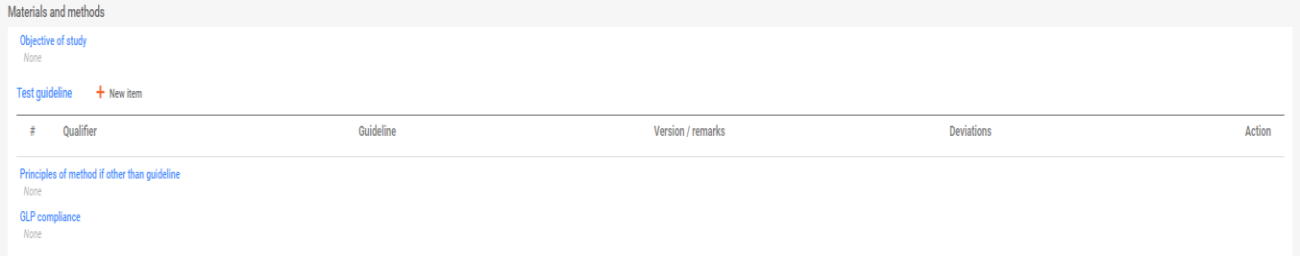


Figure 2.3: Materials and methods

4.5. Test animals (OHT: Repeated dose toxicity) – common block

Name	Instructions	Type	Field Path
Test animals		Header 2	TestAnimals
Species	Select species as appropriate. If not available from picklist, select 'other' and specify.	Closed list	TestAnimals.Species
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.	Closed list	TestAnimals.Strain

		with remarks	
Details on species / strain selection	For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of species and strain. Under the EU pesticides data requirements human data should be reported under 5.9 Medical data.	Multi-line text	TestAnimals.DetailsOnSpeciesStrainSelection
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.	Closed list	TestAnimals.Sex
Details on test animals or test system and environmental conditions	Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof. Explanations: - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum. - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum. - Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study. - IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing).	Text template	TestAnimals.OrganismDetails

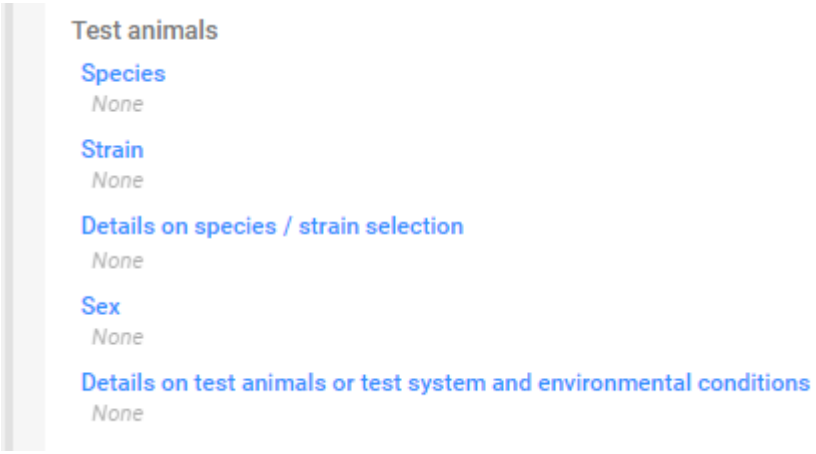


Figure 2.5: Test animals

4.6. Any other information on materials and methods incl. tables - (H2) – common block

Name	Instructions	Type	Field Path
Any other information on materials and methods incl. tables		Header 2	AnyOtherInformationOnMaterialsAndMethodsInclTables
	In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	AnyOtherInformationOnMaterialsAndMethodsInclTables.OtherInformation

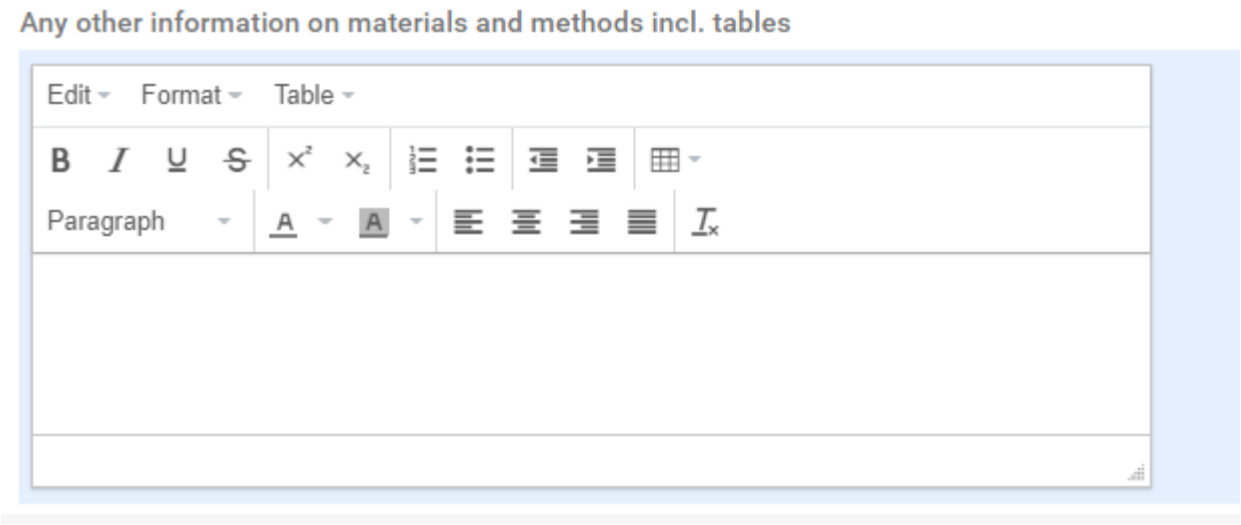


Figure 2.6: Any other information on materials and methods incl. tables

4.7. Any other information on results incl. tables Block

Name	Instructions	DataType	Field Path
Any other information on results incl. tables		Header 2	AnyOtherInformationOnResultsInclTables
	In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	AnyOtherInformationOnResultsInclTables.OtherInformation

4.8. Results of examinations (OHT: Repeated dose toxicity: oral) – common block

Name	Instructions	Type	Field Path
Clinical signs	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservClinSigns
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservClinSigns
Dermal irritation (if dermal study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservDermalIrritationIfDermalStudy

Description (incidence and severity)		Text area	DescriptionIncidenceAndSeverityObservDermalIrritationIfDermalStudy
Dermal irritation		Closed list	ObservDermalIrritation
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservDermalIrritation
Mortality	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list	ObservMortality
Description (incidence)	Describe the incidence of mortality by sex and dose group. An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress.	Text area	DescriptionIncidenceMortality

Body weight and weight changes	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservBodyweight
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservBodyweight
Food consumption and compound intake (if feeding study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservFoodConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description	Text area	DescriptionIncidenceAndSeverityObservFoodConsum

	where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Food efficiency	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservFoodEfficiency
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the	Text area	DescriptionIncidenceAndSeverityObservFoodEfficiency

	rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Water consumption and compound intake (if drinking water study)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservWaterConsum
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on	Text area	DescriptionIncidenceAndSeverityObservWaterConsum

	the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Ophthalmological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservOphthalm
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservOphthalm
Haematological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservHaematol

Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservHaematol
Clinical biochemistry findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservClinChem
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are	Text area	DescriptionIncidenceAndSeverityObservClinChem

	reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Endocrine findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	EndocrineFindings
Description (incidence and severity)	Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).	Text area	DescriptionIncidenceAndSeverityEndocrine

	NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Urinalysis findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservUrin
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservUrin
Behaviour (functional findings)	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not	Closed list	ObservNeurobehaviour

	specified' as applicable.		
Description (incidence and severity)	Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards). Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservNeurobehaviour
Immunological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ImmunologicalFindings
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group.	Text area	DescriptionIncidenceAndSeverityImmunologicalFindings

	At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Organ weight findings including organ / body weight ratios	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservOrganWeights
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with	Text area	DescriptionIncidenceAndSeverityObservOrganWeights

	comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Gross pathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservGrpathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the	Text area	DescriptionIncidenceAndSeverityObservGrpathol

	table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Neuropathological findings	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservNeuropathol
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservNeuropathol
Histopathological findings: non-neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not	Closed list	ObservHistopathol

	examined' or 'not specified' as applicable.		
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.	Text area	DescriptionIncidenceAndSeverityObservHistopathol
Histopathological findings: neoplastic	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable.	Closed list	ObservHistopatholNeoplastic
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse	Text area	DescriptionIncidenceAndSeverityObservHistopatholNeoplastic

	and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Other effects	Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. For micro-organisms information, effects related to clearance, pathogenicity and / or infectiveness should be reported.	Closed list	OtherEffects
Description (incidence and severity)	Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible. Particularly with comprehensive data,	Text area	DescriptionIncidenceAndSeverityOtherEffects

	include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s). NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory.		
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area	DetailsOnResults

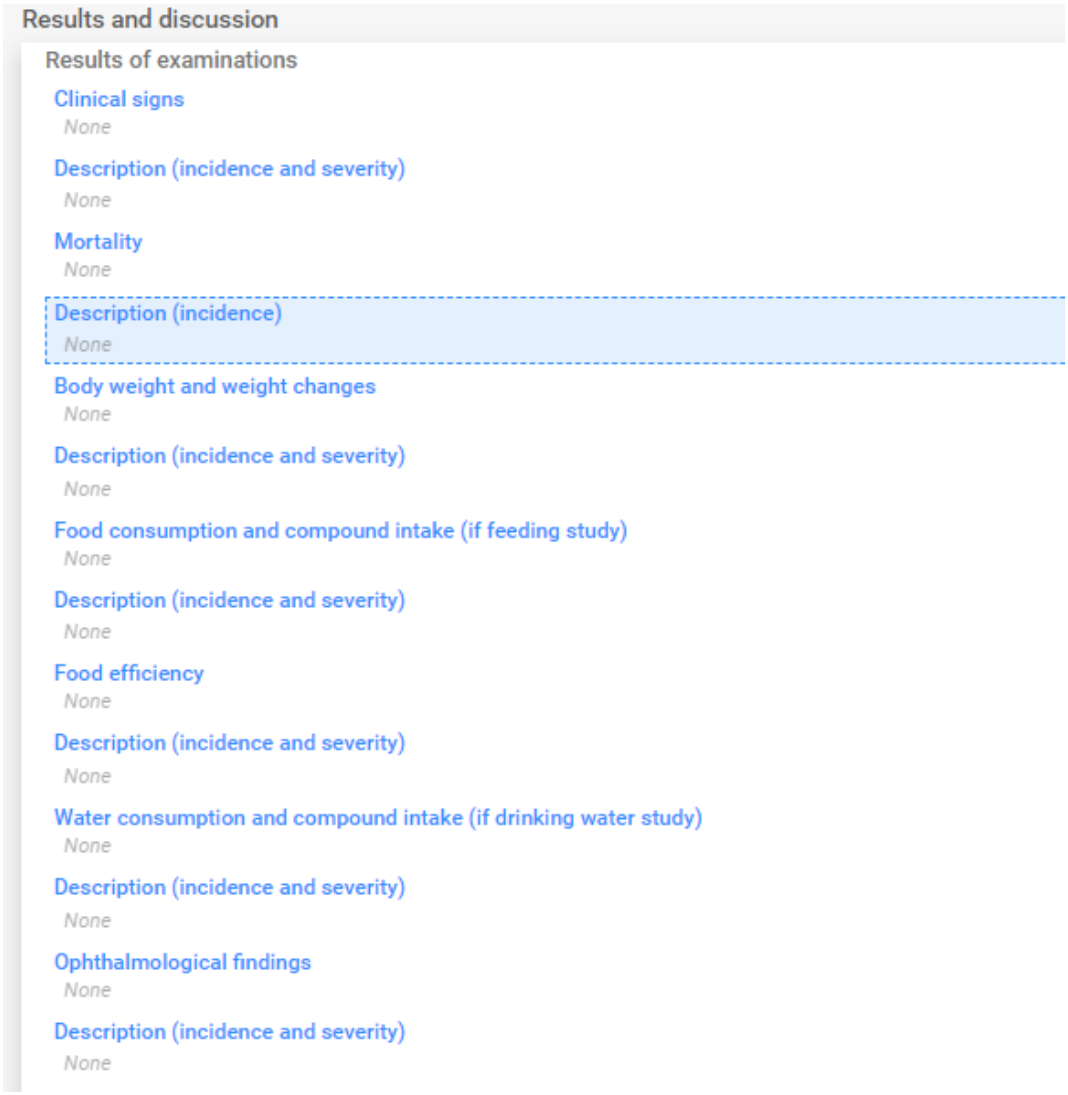


Figure 2.7: Results of examinations

4.9. Effect levels (OHT 67-69, 72-74) – common block

Name	Instructions	Type	Field Path
			Efflevel
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD	Check box	Efflevel.KeyResult

	Programme, EU pesticides, Pesticides NAFTA or EU REACH) on how to use this field.		
Dose descriptor	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Closed list with remarks	Efflevel.Endpoint
Generation	Select the generation (e.g. 'F1 (cohort 1A)') the effect level refers to	Closed list	Efflevel.Generation
Effect level	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Range with closed list (Decimal)	Efflevel.EffectLevel
Based on	Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification. Select 'not specified' if the effect concentration	Open list with remarks	Efflevel.BasedOn

	type is not known.		
Sex	Select from drop-down list.	Closed list	Efflevel.Sex
Basis for effect level	Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field.	Multi select closed list with remarks (32000)	Efflevel.Basis
Remarks on result	This field can be used for: - giving a qualitative description of results in addition to or if no numeric value(s) were derived; - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or - entering any additional information on the effect level by selecting 'other:'	Open list with remarks (2000)	Efflevel.RemarksOnResults

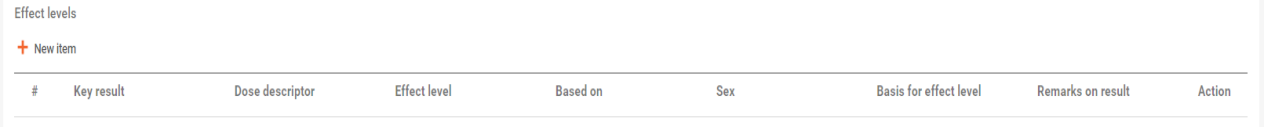


Figure 2.8: Effect levels

4.10. Target system (OHT RepDoseTox etc.) - Target_system_BLOCK_-OHT_67-69-_72-_73-_76-_77- common block

Name	Instructions	Type	Field Path
	Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s). Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans.		TargetSystemOrganToxicity
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) on how to use this field.	Check box	TargetSystemOrganToxicity.KeyResult
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list	TargetSystemOrganToxicity.CriticalEffectsObserved
Lowest effective dose / conc.	Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or	Unit measure with Closed List (Decimal)	TargetSystemOrganToxicity.LowestEffectiveDoseConc

	severe toxic effects on the target organ(s) affected.		
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list	TargetSystemOrganToxicity.System
Organ	Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'.	Multi select open list	TargetSystemOrganToxicity.Organ
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list	TargetSystemOrganToxicity.TreatmentRelated
Dose response relationship	Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner.	Closed list	TargetSystemOrganToxicity.DoseResponseRelationship
Relevant for humans	Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose "no" from the picklist if the effects in target system/organ are species specific and not relevant for humans.	Closed list	TargetSystemOrganToxicity.RelevantForHumans

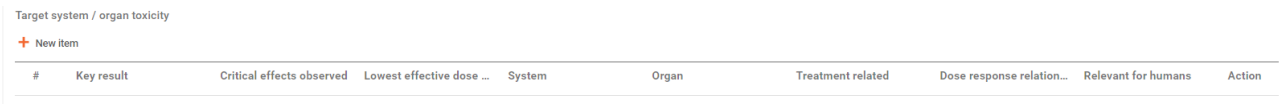


Figure 2.9: Target system / organ toxicity

4.11. Overall remarks, attachments – common block

Name	Instructions	Type	Field Path
Overall remarks, attachments		Header 1	OverallRemarksAttachments
Overall remarks	In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	Rich text area	OverallRemarksAttachments.RemarksOnResults
Attached background material	Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula). Copy this block of fields for attaching more than one file.		OverallRemarksAttachments.AttachedBackgroundMaterial
Attached document	Provide any additional documents relevant for the submission, not already provided under the methods or results section or in the full study report. See IUCLID templates for PPP Risk Assessment Templates on EFSA Knowledge Junction (zenodo).	Single file attachment	OverallRemarksAttachments.AttachedBackgroundMaterial.AttachedDocument

	For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here if not yet done in the results section. Note that the original file only needs to be attached here, if it differs from the file in Attached (sanitised) documents for publication. and can be uploaded here if not yet done in the results section.		
Remarks	As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory.	Text	OverallRemarksAttachments.AttachedBackgroundMaterial.Remarks
Attached background material			
Attached full study report	The full study report should be uploaded in the Literature Reference for the study. However additional background material can be attached here. The original file only needs to be attached here if it differs from the file in Attached (sanitised) documents for publication.	Attachments list	OverallRemarksAttachments.AttachedStudyReport
Illustration (picture/graph)	Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document.	Image	OverallRemarksAttachments.IllustrationPicGraph
Attached (sanitised) documents for publication	The full study report should be uploaded in the Literature Reference for the study. However additional background	Attachments list	OverallRemarksAttachments.AttachedSanitisedDocsForPublication

	material can be attached here. Check individual endpoint study records for information on subject specific attachments e.g. PRIMO model		

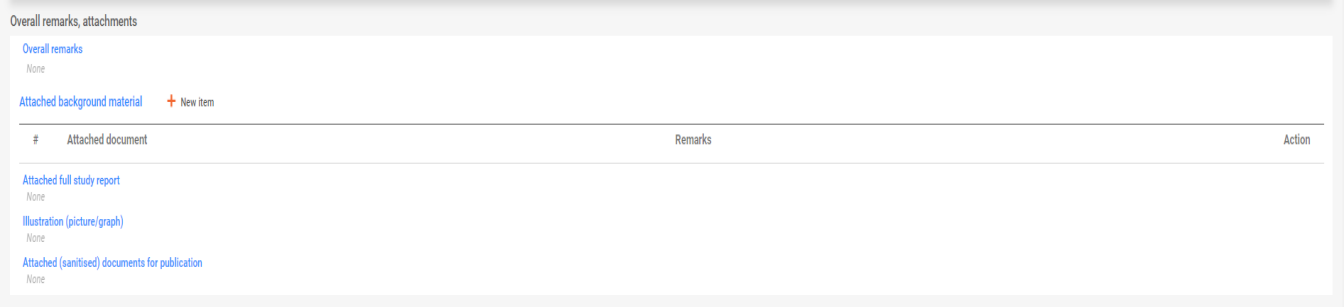


Figure 2.10: Overall remarks, attachments

4.12. Applicants summary and conclusion – common block

Name	Instructions	Type	Field Path
Applicant's summary and conclusion		Header 1	ApplicantSummaryAndConclusion
Validity criteria fulfilled	State whether validity criteria in the test guideline have been fulfilled or not. Use supplementary remarks field to state the criteria and supporting information. Clearly indicate if the criteria used are not consistent with those given by the test guideline. If so, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable.	Closed list with remarks	ApplicantSummaryAndConclusion.ValidityCriteriaFulfilled
Interpretation of results	Conclude if the study results fall under relevant classification criteria of the Globally	Closed list with remarks (2000)	ApplicantSummaryAndConclusion.InterpretationOfResults

	Harmonised System of Classification and Labelling of Chemicals (UN GHS). Further explanations can be entered in the supplementary remarks field. Note that a classification in the strict sense cannot always be based on an individual study, but includes a weight of evidence evaluation of all relevant data. To this end wording such as 'is classified in Category 1' should be used only in the conclusions provided in the relevant classification section.		
Conclusions	This field should be used to summarise the conclusions by the applicant and will be used in study summaries produced using report generator.	Text area	ApplicantSummaryAndConclusion.Conclusions
Executive summary	If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document. Consult the programme-specific guidance (e.g. OECD Programme, EU pesticides, Pesticides NAFTA or EU REACH) thereof.	Rich text area	ApplicantSummaryAndConclusion.ExecutiveSummary

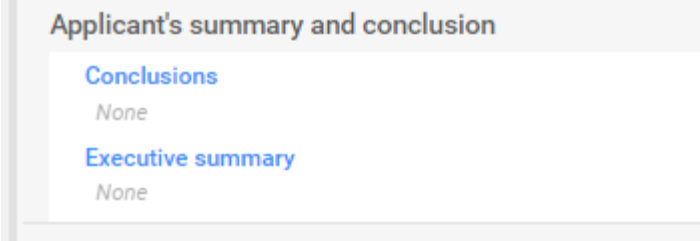


Figure 2.7: Applicant's summary and conclusion

5. Validation Rules

Summary	Issue Type	Message	Target documents	Checked field reference
QLT_PPP_001: Endpoint must be indicated	Quality rules/Warning	'Administrative data' is not complete. The 'Endpoint' addressed by the study record must be indicated.	All endpoint study records	Administrative data – common block
QLT_PPP_002: Data waiving must be justified	Quality rules/Warning	'Administrative data' is not complete. If you want to submit a data waiving then the rationale for waiving the information requirement must be indicated in the field 'Data waiving' and an appropriate justification must be selected in the field 'Justification for data waiving'. If none of the available justifications in the picklist apply, select 'other:' and provide the justification in the below field. If you wish to	All endpoint study records	Administrative data – common block

		provide further information in support of the data waiving, use the field 'Justification for type of information' and/or attach a document under 'Attached justification' heading. A reference to a record with relevant information for the data waiving can be made under 'Cross-reference' heading.		
QLT_PPP_003: Reliability must be provided for KS and WoE	Quality rules/Warning	'Administrative data' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Reliability' must be provided. Note: If you select 'other:' then the below field must be filled in.	All endpoint study records	Administrative data – common block
QLT_PPP_004: Reference must be provided for KS and WoE	Quality rules/Warning	'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the 'Reference' entry must be completed. For each reference, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided:	All endpoint study records	Data source (Literature Reference) – common block

		<Display dynamic message depending on selection in 'Reference type' field> #study report# - If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country) and either 'Report no.', 'Study no.' or 'Title' must be provided. #other company data# - If the data is from a company, either the field 'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'. # publication, review article or handbook, secondary source or grey literature# - If the data is from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.		

		#other: or no selection# <Merge and display all the above>		
QLT_PPP_005: Guideline must be given for KS, WoE and testing proposal	Quality rules/Warning	'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test guideline (to be) used in the study must be indicated in the 'Guideline' under the 'Test guideline' heading. If you add several entries, then the 'Guideline' must be specified for each of them. If the test guideline applied is not found in the picklist, select 'other:' and provide information on the guideline in the below field. If no test guideline can be specified (e.g. because the study is a non-guideline study, or (Q)SAR was applied), a description of the principles of the test protocol or the method must be provided in the field 'Principles of method if other than guideline'.	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Material and methods – common block

QLT_PPP_006: Test material must be given for KS, WoE and testing proposal	Quality rules/Warning	'Materials and methods' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test material (to be) used in the study must be identified by linking a test material information (TMI) record in the 'Test material information' entry. The TMI record should contain sufficient information to allow the understanding of the identity of the tested substance. As a minimum, under 'Composition' at least one 'Constituent' must be reported. Each created component must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. For a read-across target record, the test material information should identify the target substance of the read-across.	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Test Material – common block

QLT_PPP_007: Key studies should have reliability 1 or 2	Quality rules/Warning	Administrative data is inconsistent. This endpoint study record has been indicated with the adequacy 'key study' but the assigned 'Reliability' score indicates that the study is not reliable. A key study is expected to correspond to a robust study summary of sufficient quality and reliability (score 1 or 2) to independently fulfil the information requirements for an endpoint. You are advised to reconsider whether this study is of sufficient quality to be used as key study to fulfil the information requirements for this endpoint.	All endpoint study records	Administrative data – common block
QLT_PPP_008: Deviations in the guideline must be explained	Quality rules/Warning	Materials and methods is inconsistent. In the entry 'Test guideline' the field 'Deviations' has been set to 'yes'. In this case, you are expected to provide a brief explanation summarising the deviations from the guideline in the below 'Remarks' field. More detailed information should be described in the respective fields of	All endpoint study records except of ENDPOINT_STUDY_RECORD.EffectivenessAgainstTargetOrganisms	Material and methods – common block

		the 'Materials and methods' part. Moreover, all possible effects that such a deviation may have on the obtained test results should be analysed and reported in the 'Overall remarks, attachments' part of the endpoint study record.		
QLT_PPP_009: Attached (sanitised) documents for publication must be provided for KS/WoE (all ESR)	Quality rules/Warning	'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' the entry 'Reference' must be completed. For each reference a version of the full study report must be provided under the 'Attached (sanitised) documents for publication' field. - If the information is confidential, a sanitised version should be provided under the 'Attached (sanitised) documents for publication' and the confidential report should be added under the 'Attached documents' field in the Literature reference.	All endpoint study records	Literature reference v.5.1 (Final)
QLT_PPP_010: Study ID and/or Justification (remarks) must be provided	Technical completeness check	'Data source', <'Reference table name>', Other studies identifiers is not complete.	All endpoint study records	Literature reference v.5.1 (Final)

		For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Study ID' under Data source, Reference must be filled in, or a justification for not providing a Study ID must be provided under 'Remarks' field. - If the study has been notified in the Notification of Studies Database then report the number in the 'Study ID' field of the Literature Reference for the study. The type of identifier should be NoS_ID. If the study has not been notified provide a justification in the 'Remarks' field in the Literature reference.		
QLT_PPP_019: KS/WoE must be provided for all required sections (Substance_MRL)	Quality rules/Warning	Section <x.x>: At least one endpoint study record indicated as either a key study, weight of evidence, or data waiving must be provided for this section. Supporting studies should be provided as appropriate, as additional endpoint study records, but they cannot be used to fulfil the information requirement. - To indicate an endpoint study	MRL_ESR_SUBSTANCE: ENDPOINT_STUDY_RECORD.AnalyticalMethods ENDPOINT_STUDY_RECORD.StabilityOfResiduesInStoredCommod ENDPOINT_STUDY_RECORD.MetabolismInCrops ENDPOINT_STUDY_RECORD.MetabolismInLivestock ENDPOINT_STUDY	Administrative data – common block

		record as a key study or as part of a weight of evidence approach, select 'key study' or 'weight of evidence' in the 'Adequacy of study' picklist and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint. Other types of study summaries (e.g. supporting studies) should be filled in as much as possible. - To indicate an endpoint study record as data waiving, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'. #Indicate the section number in the message. A separate message is displayed for each section.#	_RECORD.ResiduesInRotationalCrops ENDPOINT_STUDY_RECORD.ResiduesInLivestock ENDPOINT_STUDY_RECORD.NatureResiduesInProcessedCommod ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedComm ENDPOINT_STUDY_RECORD.ExpectedExposureAndProposedAcceptableResidues ENDPOINT_STUDY_RECORD.ResiduesProcessedCommodities ENDPOINT_STUDY_RECORD.MigrationOfResidues	
QLT_PPP_020: Summaries must be provided for all required sections (Substance_MRL)	Quality rules/Warning	Section <x.x>: At least one endpoint study summary must be provided for this section. #Indicate the section number in the message. A separate message is displayed for	MRL_SUMMARIES_SUBSTANCE: ENDPOINT_SUMMARY.AnalyticalMethods ENDPOINT_SUMMARY.ResiduesInFoodAndFeedingstuffs	N/A

		each section.#	ENDPOINT_SUMMARY.StabilityResiduesCommodities ENDPOINT_SUMMARY.MetabolismPlants ENDPOINT_SUMMARY.MetabolismInLivestock ENDPOINT_SUMMARY.MagnitudeResiduesPlants ENDPOINT_SUMMARY.ResiduesLivestock ENDPOINT_SUMMARY.NatureMagnitudeResiduesProcessedCommodities ENDPOINT_SUMMARY.ResidueFood ENDPOINT_SUMMARY.SupplementaryStudies ENDPOINT_SUMMARY.MigrationOfResiduesIntoAndTheirBehaviourOnFoodOrFeedingstuffs	
QLT_PPP_021: At least one Mix Composition must exist with linked Active (Substance)_PPP_All_Submissions	Quality rules/Warning	Mixture composition is incomplete. At least one Mixture composition must be present in the dossier function. This must include a linked substance which has the the Function = 'active substance'.	FLEXIBLE_RECORD.MixtureComposition	N/A
QLT_PPP_022: At least one valid constituent must exist (for each Active	Quality rules/Warning	For each Active substance composition, at least one constituent must	FLEXIBLE_RECORD.MixtureComposition FLEXIBLE_RECOR	N/A

substance) All_EU_PPP		be defined. All constituents must be identified by linking a reference substance.	D.SubstanceComposition	
QLT_PPP_023: At least one LE composition must exists in Active subsatance dataset_Only Active sub.	Quality rules/Warning	Each substance must be identified by at least one specification of purity. Specify the following information: - Degree of purity of the active substance - Constituents - Impurities, if applicable - Additives, if applicable Each constituent, impurity and additive must be identified by linking a reference substance, complete with available identifiers and molecular and structural information, and by providing the concentration range.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_024: each (active) substance must have a reference substance in section 1.1 All_EU_PPP	Quality rules/Warning	A reference substance must be linked in IUCLID section 1.1.	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A
QLT_PPP_025: All Active substances must be the same (same UUID)_ All_PPP	Quality rules/Warning	Mixture compositions is incomplete. Where more than one mixture (product formulation/preparation) is reported, the components with the Function = 'active substance' must	1.1_Identification FLEXIBLE_RECORD.MixtureComposition SUBSTANCE	N/A

		be the same. This is confirmed by checking that the substance UUID for each active substance is identical.		
QLT_PPP_026: at least one GAP must be created in All_PPP	Quality rules	Section 2, Good Agricultural Practices (GAP) is incomplete. At least one Good Agricultural Practices (GAP) must be created. The following fields must be complete: - Crop / treated object, - Target organisms: at least one row must be created with at least 'Scientific name' or 'Common name' fields being filled in) - Method of application - Growth stage is mandatory if GAP refers to a crop; if GAP refers to treatment of non-crop objects (children of 3NOCFO) or to children codes of 3CRPAO (treatment of crop parts) it is not required; if GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be provided. If number of applications is greater than 1, the information on the	FLEXIBLE_RECORD.GAP	N/A

		growth stage needs to be reported for the first and the last application. Treatment season is not mandatory. - Number of applications (range) - Application rate per treatment (product) – range - Application rate per treatment for target a.s. (range) - Pre-harvest interval (either the days of PHI or 'not applicable').		
QLT_PPP_027: Exactly one literature reference must be provided in KS, WoE ESRs_All_EU_PPP	Quality rules	'Data source' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence' exactly one 'Reference' entry must be provided. The entry must be complete, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided: - If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country) and either 'Report no.', 'Study no.' or 'Title' must be provided. - If the data is	All endpoint study records	Literature reference v.5.1 (Final)

		from a company, either the field 'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'. - If the data is from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.		
QLT_PPP_028: All reference substances in sections 1.1 and 1.2 of Active substance must contain an identifier_Active Sub & MRL	Quality rules/Warning	Reference substance information is not complete. Each reference substance must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. If you use a reference substance to report (a group of) unknown constituents/impurities, you need to enter in the IUPAC name field: "Unknown constituents/impurities". In addition you should specify, as far as possible, the number and nature of these unknown constituents/impuri	1.1_Identification, 1.2_Composition, FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition, SUBSTANCE	Reference substance v.6.4 (Final)

		ties in the 'Remarks' field of the constituent/impurity block.		
QLT_PPP_029: All constituents in the first composition record in Active substance must represent distinct substance identities_All_PPP	Quality rules/Warning	Multiple constituents in the active substance composition/purity specification are identified with the same reference substance. Remove the duplicate entries.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
QLT_PPP_030: Constituents should have a typical concentration_Active Sub & MRL	Quality rules/Warning	The 'Typical concentration' for each Active substance composition constituent should be specified (value and unit). The value should be representative for the substance as manufactured/imported. Active substance composition results shall include quantitative data, in terms of g/kg content, for all components present in quantities of 1 g/kg or more.	FLEXIBLE_RECORD.MixtureComposition, FLEXIBLE_RECORD.SubstanceComposition	N/A
EU_PPP_035: European reference number must be provided in UUID format (MRL)	Business rule, Failure	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.	DOSSIER.EU_PPP_MAXIMUM_RESIDUE_LEVELS	N/A