EUROPEAN FOOD SAFETY AUTHORITY

IUCLID 6.7 MICROBIAL ACTIVE SUBSTANCE APPLICATIONS MINI-MANUAL

European Food Safety Authority (EFSA)

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EUROPEAN FOOD SAFETY AUTHORITY

INTRODUCTION

This manual is intended to support applicants in compiling Microbial Pesticide Active Substance applications in line with the new applicable rules and with the relevant changes released with IUCLID 6.7.

Documents no longer included in the updated table of contents within the IUCLID dossier are available in Section "11: Previously used documents now obsolete, kept until April 2024" (active dataset) or "14: Previously used documents now obsolete, kept until April 2024" (product dataset). Please note that the retention time for the obsolete documents will be extended.

Regulations and data requirements

Regulatory background for microbial pesticide active substances applications

The procedures for approval and renewal of approval of active substances are set by **Regulation (EC) No 1107/2009**[1] for rules governing plant protection products and the active substances contained in those products, as amended by **Regulation (EU) 2019/1381**[2] (**Transparency Regulation**), and as implemented **by Commission Implementing Regulation (EU) 2021/428**[3] and by **Commission Implementing Regulation (EU) No 2020/1740**[4] – that applies as from 27 March 2021 and replaces the previous procedure under Implementing Regulation (EU) No 844/2012[5] – respectively.

Active substances (including micro-organisms) can only be approved for use in plant protection products if they fulfil the approval criteria that are laid down in **Regulation (EC) No 1107/2009**[1], as amended by Commission Regulation (EU) 2022/1438[6], where relevant, subject to conditions or restrictions. Companies may apply for amendments of conditions of approval, which follow the same regulatory process.

The initial approval of an active substance is valid for a limited period and the approval of an active substance needs to be reviewed periodically. A renewal of approval is only granted after the substance is re-evaluated and at least one safe use of the substance is demonstrated.

Data Requirements for Microbial Pesticide Active Substances Applications

Following the entry into force of the **Transparency Regulation**, Regulation (EC) No 178/2002[7] (General Food Law Regulation) was amended by introducing **new requirements regarding transparency of submitted data**, including the **submission of dossiers** for pesticide active substances (including micro-organisms) **applications using IUCLID format**.

[1] 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

[2] 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

[3] Commission Implementing Regulation (EU) 2021/428 of 10 March 2021 adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council

[4] Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012

[5] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in 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

[6] Commission Regulation (EU) 2022/1438 of 31 August 2022 amending Annex II to Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards specific criteria for the approval of active substances that are micro-organisms

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

These new requirements, as implemented by the Practical Arrangements[8] 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"[9] and apply to all pesticides applications submitted as of 27 March 2021.

Four implementing Regulations amending the current rules relevant to micro-organisms are applicable from 21 November 2022 onwards (https://food.ec.europa.eu/plants/pesticides/micro-organisms_en).

The new rules reflect the latest scientific developments and are based on the specific biological properties of micro-organisms.

- Commission Regulation (EU) 2022/1438, amending Annex II to Regulation (EC) No 1107/2009 as regards specific criteria for the approval of active substances that are micro-organisms
- `Commission Regulation (EU) 2022/1439, amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms
- Commission Regulation (EU) 2022/1440, amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms
- Commission Regulation (EU) 2022/1441, amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms

Information on the updated tables of content in alignment with the new data requirements and the transition phase is available in the Crosswalks EU PPP Micro-organisms - active substance application (product) to New Data Requirements (Commission Regulation (EU) 2022/1439 & Commission Regulation (EU) 2022/1440):https://zenodo.org/doi/10.5281/zenodo.7188149.

Confirmatory information dossiers

In case the (renewal of) approval of an active substance is subject to the condition of the submission of further **CONFIRMATORY INFORMATION** to Member States, the Commission and EFSA, studies necessary to meet that condition are likewise subject to the obligation to use the IUCLID software for their submission[10].

Important! If the submission contains confirmatory information, the dedicated box in the dossier header must be ticked.

How to build an IUCLID Dossier

Before starting to compile a dossier, it is recommended to check EFSA's Applicants Toolkit for the latest resources available to support its preparation.

For specifics on the IUCLID tool, it is recommended to consult the IUCLID 6 user manual describing the functionality of IUCLID 6, accessible via its web interface.

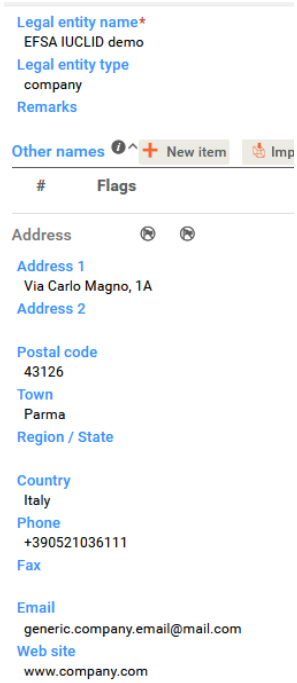
For further details on how to use IUCLID check the "IUCLID for Applicants" training available in EU Academy.[11]

For further details on confidentiality, please refer to the User guide on confidentiality.

The **first step** is to create a Legal Entity for the organisation which is submitting the application and to create **user accounts** for the people authoring the dossier. See the Overview of ECHA Cloud Services section of 'IUCLID Training for applicants, Video 8 and the image below. More details on user management can also be found in ECHA accounts manual.

[8] https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements
[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 https://www.efsa.europa.eu/it/supporting/pub/en-6464
[10] This does not apply to substances conditionally approved under Implementing Regulation (EU) No 844/2012.
[11] Please note that EU Login is required for accessing the training platform

Important! A functional mailbox address and the number of a switchboard must be provided in the 'Legal entity' since this is always published. Personal contact details should be included in the 'Contact' entity.



The **second step** to build a valid IUCLID dossier is to create a new "Mixture" dataset and select the Working context '**EU PPP Micro-organisms – active substance application (product)**'.

Note: Pay attention to the instructions for setting the confidentiality flag/s since a non-confidential version of the dossier will be made publicly available once the application is deemed 'valid for further evaluation'. The public version of any attachment should not be in word/rtf format, but rather in pdf format.

The **third step** is to compile the IUCLID dossier with relevant information.

The **dossier header** must be completed. It should identify the type of submission and provide administrative information to support the processing of the dossier:

- **Purpose of the application**: depending on the process, select: 'approval of an active substance for use in plant protection products' or 'renewal of an active substance for use in plant protection products'. Additional information can be included in the remarks box.
- **Confirmatory information:** this box must be ticked if the submission contains confirmatory information.
- **European Reference Number** – this must be maintained for all submissions within a regulatory action and should only be amended if requested to do so by EFSA.
- Notification of studies pre-application identifiers.
- The Rapporteur Member State (RMS).
- Reason for re-submission (if the dossier is updated).

Two main **datasets** must be completed:

1. one or more **MIXTURE DATASET/s:** with data on the representative mixture/s (including the GAP, as a mandatory document). The mixture dataset and corresponding table of contents (TOC) are equivalent to the data requirements in Reg. (EU) No 284/2013 as amended by Commission Regulation (EU) 2022/1440;
2. one **ACTIVE SUBSTANCE DATASET:** with data on the TARGET active substance. The active substance dataset and corresponding table of contents (TOC) are equivalent to the data

requirements in Reg. (EU) No 283/2013 as amended by Commission Regulation (EU) 2022/1439.

If appropriate, **one/several METABOLITE dataset(s)** can be created in the document FLEXIBLE SUMMARY.Metabolites (Section 1.4.1 Information on metabolites - product dataset), with data on secondary metabolite(s) of (potential) concern produced by the micro-organism (as requested in the data requirements). See dedicated chapter below for detailed information on how to report data on secondary metabolites.

Information on **other substances** relevant for the assessment can be reported creating an additional row under the mixture composition document and compiling the relevant newly created dataset, e.g. in case of relevant impurities, co-formulants and killed/deactivated micro-organisms where the toxin is to be assessed (see 'Special cases: submission of dossiers on deactivated/killed micro-organisms' paragraph).

Safeners, synergists and co-formulants can be entered in the FLEXIBLE RECORD.MixtureComposition document (Section 1.4 'Detailed quantitative and qualitative information on the composition of the preparation' – Product dataset) even when they are mixtures (e.g. a co-formulant dissolved in a solvent). Information on the alternative co-formulants should be entered similarly to other co-formulants.

In case of **multiple representative products**, these can be listed in the **product composition section** (1.4.2 'Other representative products' – Product dataset).

Watch video n.2 to see how you can access the different datasets in an IUCLID dossier (Navigating through datasets within a product/mixture).

Note: the dataset in which a study is reported is **dependent on the test material**. All studies should generally be reported only once. The cross-reference function should be used for studies within same dataset to avoid duplicate data entry.

Since it is currently not possible to cross-reference between different datasets, when data provided for the product dataset are needed also for the active substance dataset (or vice-versa), a waiver should be included to indicate where the scientific data can be found. In such cases, reference to the UUID of a IUCLID document can be made in the Reason field of the cross-reference section.

In case of studies including micro-organism and metabolites the following approaches should be used:

- If the test material is the **micro-organism**, studies should be included under the **active substance dataset**;
- If the test material is a **metabolite**, studies should be reported under the **metabolite dataset**;
- If the test material is a **micro-organism and metabolite/s,** studies should be reported under the **active substance dataset**.

As a general principle, IUCLID documents should be fully completed. The required data **must be reported in the relevant IUCLID documents** (Dossier Header, Endpoint summaries, Endpoint study records, Flexible records, Flexible summaries, etc).

Duplication of information should be avoided. Attachments should be provided only as indicated in the instructions provided in this manual.

Where **templates** have been recommended by evaluators and the IUCLID document does **not contain a structured section**, the formatted data should be entered as specified in the templates published in Knowledge Junction and listed in this manual.

When no study is provided for a data requirement/endpoint, a detailed **justification for data waiving** must be completed in the endpoint study record. Only a short description of the justification for data waiving should be reported in the relevant endpoint summary to avoid duplication of information.

Study naming – best practices

Personal data must be avoided, e.g. Endpoint study records should not include author names.

It is recommended to name the study with the shortest name possible and to use the Year of the study, the endpoint and additional relevant context where multiple studies exist for an endpoint.

Examples:

- Analytical methods: 2007_Post-approval control and monitoring purposes_cereal
- Identity, taxonomy and phylogeny: *2021_A.s.name_WGS_analysis*
- Infectivity and pathogenicity: *2018_pathogenicity_rat*
- Toxicity aquatic invertebrates: *2012_pathogenicity_daphnia magna*
- Good agricultural practices (GAP).001: Crop_zone.001, ex. *Apples_NEU.001*

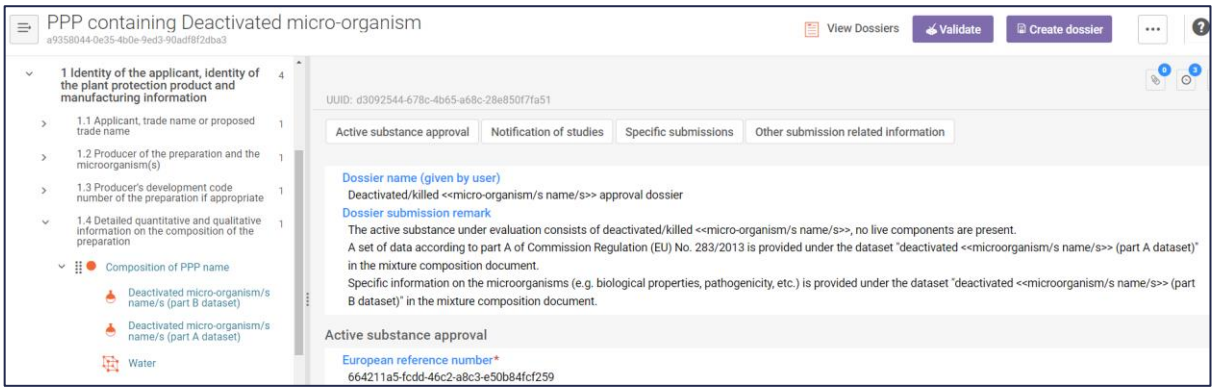
Special cases: 1 - submission of dossiers on deactivated/killed micro-organisms

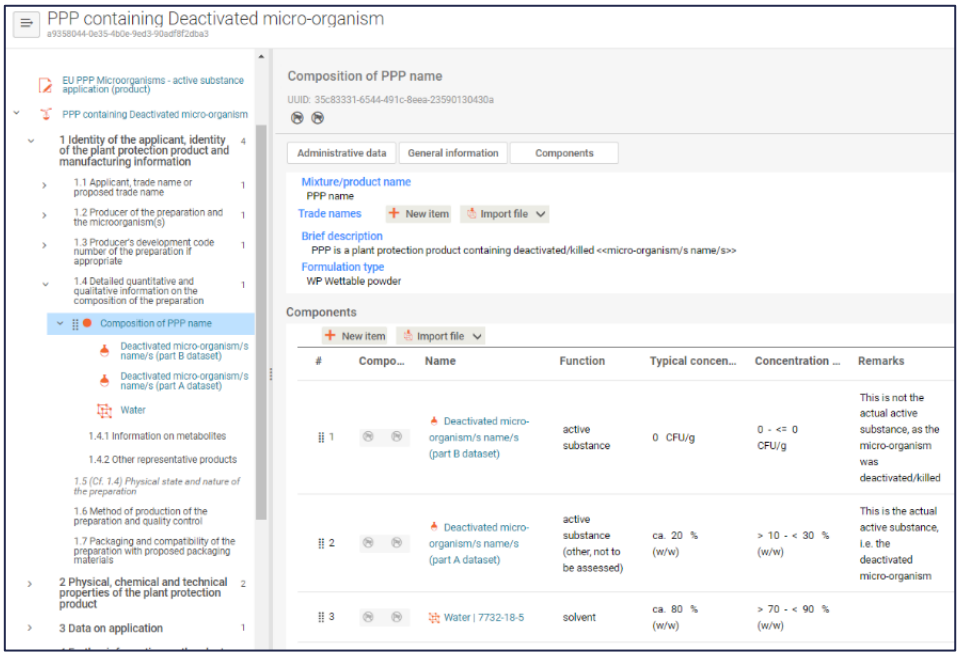
In case the active substance is a deactivated/killed micro-organism, it does not fall under **part B** of Commission Regulations (EU) 283/2013 and 284/2013, as amended by Commission Regulations (EU) 2022/1439 and 2022/1440.

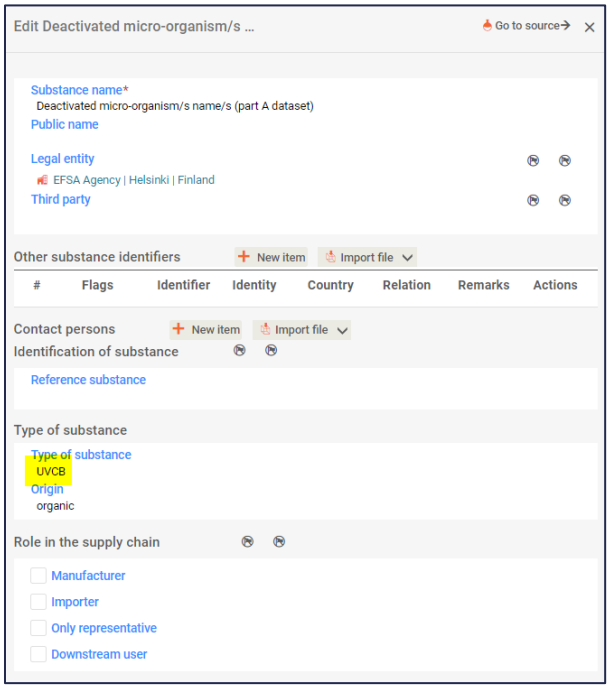
In order to allow reporting of information related to the micro-organism itself (taxonomy, fermentation, whole genome sequencing, etc), the EU PPP Micro-organisms working context should be used, following the instructions given in this paragraph:

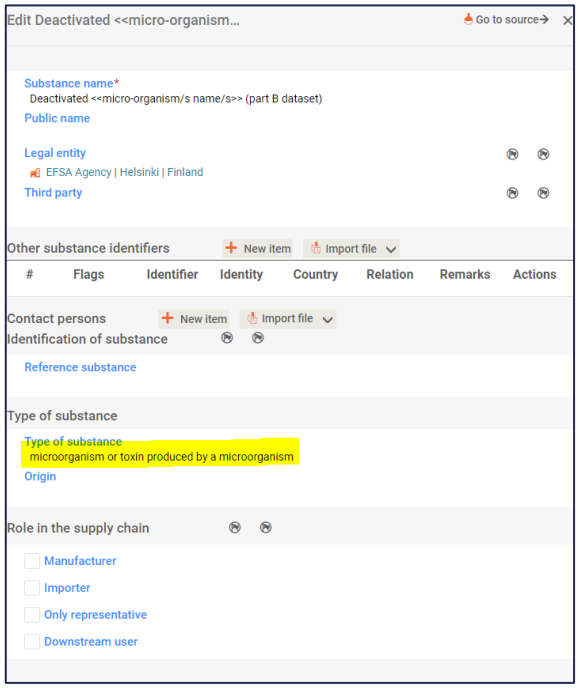
1. Create a product dataset.
2. When completing the **Mixture composition document** to describe the components, create a **substance dataset** for the Micro-organism, set Type of Substance to ***'micro-organism or toxin produced by a micro-organism'*** and assign the function 'active substance' to it. In this way documents such as the biological properties can be completed.
3. Within the same mixture composition document create a **substance dataset** for the 'killed component' but in this case assign the function 'active substance (other not to be assessed)' to it and set Type of Substance to ***'UVCB'***. The attached dataset in this case will follow the Table of Contents of an active substance. In this case all relevant studies can be reported in the relevant dataset.
4. Add a note in the 'Dossier submission remarks' field within the Dossier header highlighting that the active substance under evaluation is not the micro-organism itself but the deactivated/killed micro-organism even if, due to technical constraints, the micro-organism is flagged as the active substance throughout the dossier.
5. To facilitate the correct identification of the active substance under evaluation, the names of the micro-organism and the dossier itself (which are published) should enable evaluators/the public to understand the situation (see screenshots below).
6. The 'active substance (other, not to be assessed)' must not be flagged confidential either at the level of the reference substance or in the mixture composition since this is actually the active substance under evaluation.

Note: Due to the complexity described above, you may receive some validation assistant errors. In this case, export the excel file for the validation assistant report, provide justifications and submit it to the RMS


PPP containing Deactivated micro-organism
View Dossiers
Validate
Create dossier
1 Identity of the applicant, identity of the plant protection product and manufacturing information
1.1 Applicant, trade name or proposed trade name
1.2 Producer of the preparation and the microorganism(s)
1.3 Producer's development code number of the preparation if appropriate
1.4 Detailed quantitative and qualitative information on the composition of the preparation
Composition of PPP name
Deactivated micro-organism/s name/s (part B dataset)
Deactivated micro-organism/s name/s (part A dataset)
Water
Active substance approval
Notification of studies
Specific submissions
Other submission related information
Dossier name (given by user)
Deactivated/killed <<micro-organism/s name/s>> approval dossier
Dossier submission remark
The active substance under evaluation consists of deactivated/killed <<micro-organism/s name/s>>, no live components are present.
A set of data according to part A of Commission Regulation (EU) No. 283/2013 is provided under the dataset "deactivated <<microorganism/s name/s>> (part A dataset)" in the mixture composition document.
Specific information on the microorganisms (e.g. biological properties, pathogenicity, etc.) is provided under the dataset "deactivated <<microorganism/s name/s>> (part B dataset)" in the mixture composition document.
Active substance approval
European reference number*
664211a5-fcdd-46c2-a8c3-e50b84fcf259


PPP containing Deactivated micro-organism
Composition of PPP name
Administrative data
General information
Components
Mixture/product name
PPP name
Trade names
New item
Import file
Brief description
PPP is a plant protection product containing deactivated/killed <<micro-organism/s name/s>>
Formulation type
WP Wettable powder
Components
Compo... Name Function Typical concen... Concentration ... Remarks
1 Deactivated micro-organism/s name/s (part B dataset) active substance 0 CFU/g 0 - <= 0 CFU/g This is not the actual active substance, as the micro-organism was deactivated/killed
2 Deactivated micro-organism/s name/s (part A dataset) active substance (other, not to be assessed) ca. 20 % (w/w) > 10 - < 30 % (w/w) This is the actual active substance, i.e. the deactivated micro-organism
3 Water | 7732-18-5 solvent ca. 80 % (w/w) > 70 - < 90 % (w/w)


Edit Deactivated micro-organism/s ...
Go to source
Substance name*
Deactivated micro-organism/s name/s (part A dataset)
Public name
Legal entity
EFSA Agency | Helsinki | Finland
Third party
Other substance identifiers
New item
Import file
Flags Identifier Identity Country Relation Remarks Actions
Contact persons
Identification of substance
Reference substance
Type of substance
Type of substance
UVCB
Origin
organic
Role in the supply chain
Manufacturer
Importer
Only representative
Downstream user


Edit Deactivated <<micro-organism...
Go to source
Substance name*
Deactivated <<micro-organism/s name/s>> (part B dataset)
Public name
Legal entity
EFSA Agency | Helsinki | Finland
Third party
Other substance identifiers
New item
Import file
Flags Identifier Identity Country Relation Remarks Actions
Contact persons
Identification of substance
Reference substance
Type of substance
Type of substance
microorganism or toxin produced by a microorganism
Origin
Role in the supply chain
Manufacturer
Importer
Only representative
Downstream user

Special cases: 2 - submission of dossiers on micro-organisms whose mode of action is based on secondary metabolites present in the product

In case the metabolite is the actual active substance present in the product, a dossier in accordance with Part A of Reg 283/2013 (i.e. the data requirements for chemical active substances) is required in addition to the dossier for the micro-organism.

Also in this case, the **EU PPP micro-organisms working context** should be used, following the instructions given in this paragraph:

1. Create a product dataset.
2. When completing the **Mixture composition document** to describe the components, create a **substance dataset** for the Micro-organism, set Type of Substance to ***'micro-organism or toxin produced by a micro-organism'*** and assign the function 'active substance' to it. In this way documents such as the biological properties can be completed.
3. Within the same mixture composition document create a **substance dataset** for the metabolite but in this case assign the function 'active substance (other not to be assessed)' to it and set Type of Substance to ***'mono-constituent substance'***. The attached dataset in this case will follow the Table of Contents of an active substance. In this case all relevant studies can be reported in the relevant dataset.
4. The metabolite acting as active substance should also be linked in the section '**List of metabolites**' of the FLEXIBLE SUMMARY.Metabolites document in Section 1.4.1 'Information on metabolites' (product dataset).
5. Add a note in the 'Dossier submission remarks' field within the Dossier header highlighting that the metabolite is the actual active substance present in the product even if, due to technical constraints, it is flagged as 'active substance other, not to be assessed' throughout the dossier.
6. The 'active substance (other, not to be assessed)' must not be flagged confidential either at the level of the reference substance or in the mixture composition since this is actually the active substance under evaluation.

Note: Due to the complexity described above, you may receive some validation assistant errors. In this case, export the excel file for the validation assistant report, provide justifications and submit it to the RMS

How to report information on secondary metabolites

With regards to the 'Guidance on the risk assessment of metabolites produced by micro-organisms used as plant protection active substances'[12]:

If the **principal mode of action** of the active substance is based on the **presence of secondary metabolites** in the formulated plant protection product (i.e. metabolite/s is/are the actual active substance present in the product), then the metabolite/s must be reported in the '**Mixture composition**' document (Section 1.4 – Product dataset) and relevant studies reported in the **linked dataset**.

A **summary** and **conclusion** of the assessment performed by the applicant on the secondary metabolites must be included in the '**Biological properties of the micro-organism**' document in **Section 2** of the active substance dataset, under 'Information on the production of relevant metabolites and toxins', including the **evidence for exclusion of metabolite production**. If **genetic sequencing data** is included as supporting evidence for exclusion, this information should be reported in 1.3 'Identity, taxonomy and phylogeny of the microorganism' in the 'Genomic Characterization Micro-organism' document.

The **metabolites under assessment in accordance with the SANCO/2020/12258** Guidance (including all the **metabolites of potential concern** resulting as the outcome of Stage 2 of the guidance) should be listed in the section '**List of metabolites**' of the FLEXIBLE SUMMARY.Metabolites document in Section 1.4.1 'Information on metabolites' (product dataset). They should be linked as 'Reference substances' unless any studies are

[12] https://ec.europa.eu/food/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf

available and should be reported in the relevant metabolite dataset, in which case they should be linked as 'Substances'. In the case of **metabolites of concern**, these should be linked as 'Substances' and strain-specific **experimental data** should be reported in 'Other substance datasets'. In addition, for the sake of efficiency and harmonisation of the assessment of secondary metabolites, it is highly recommended to use the **template** for the **overview table for secondary metabolites** as provided in **Appendix I** to the 'Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009' (https://food.ec.europa.eu/system/files/2023-10/pesticides_ppp_app-proc_guide_imp-data-req_micro-organisms-ppp_imp-reg-11072009.pdf).

The **overview table** should be uploaded in the 'Reports and administrative information' section of the Flexible_Summary.SummaryEvaluation document (Section 10.2 'Other Reports' - active substance dataset).

Based on Stage 2 in the SANCO/2020/12258 Guidance, 'a first batch of information on the production and/or relevance of metabolites may come from literature'. The main results of this broad range literature search should be reported in the 'Information on the production of relevant metabolites and toxins' section of the '**Biological properties of the micro-organism**' document (Section 2 - active substance dataset). The search process should be documented in the Literature Search document (Section 3.5 'Literature data' - Active substance dataset), taking care of creating literature reference entities for all relevant and reliable studies and linking them in the FlexibleRecord.LiteratureSearch 'link to Relevant Studies' field(s). A link to the Literature Search(es) should be included in the biological properties document, under 'Literature search' field.

The results of **targeted literature searches** for all metabolites of potential concern should be reported in **two additional IUCLID Summary documents** in the **Active Substance dataset**, that should be completed to **conclude on the assessment** of metabolites of concern:

- Section 5.5.1 - Information and toxicity studies on metabolites (Flexible_Summary.InformationToxicityMetabolites)
- Section 8.8 - Information and ecotoxicity of metabolites (FLEXIBLE_SUMMARY.InformationEcotoxicityMetabolites)

In addition, in the same two documents, a further evaluation of the body of knowledge from the scientific literatures presented should be done, based on Step 5 of SANCO/2020/12258, to conclude whether there is sufficient information to conclude on the metabolites of concern.

Components of a IUCLID dossier

Data is entered in IUCLID in **entities** and **documents**.

Entities are data elements that can be re-used and are usually managed in inventories, for example Substance entity, Legal Entity, Literature Reference entity.

Documents gather all relevant data fields for a specific type of information, for example Endpoint study record on acute oral toxicity or Flexible summary on Proposed residue definition.

ENDPOINT STUDY RECORDS

An Endpoint Study Record is a document (template) with predefined fields in which data is entered to describe a study carried out within the subject area defined by the section's title.

IUCLID captures information complying with the reporting requirements of the OECD Test Guidelines, as well as other national/international methods used for chemical studies. The OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) are standard data formats designed to be used in a wide range of regulatory contexts. More information on OHTs can be found on the OECD website[13]. ECHA has recently published a Guidance and Standard Procedure for Drafting Robust Study Summaries which can be consulted for generic guidance on the completion of OHTs.

The endpoint study records usually consist of the following data entry blocks: 'Administrative data', 'Data source', 'Materials and methods', 'Test material', and 'Results and discussion'. There

[13] https://www.oecd.org/ehs/templates/

are also sections for any 'Overall remarks, attachments' and the 'Applicant's summary and conclusion'.

Important note: The main information requested in the data entry boxes of the endpoint study record document (e.g. materials and methods, results and discussion) must always be filled in, also for endpoints which are considered supportive by the applicant and it are based on literature data.

ENDPOINT STUDY SUMMARIES

Endpoint summaries are found in the same Section as the endpoint study records and are used to provide a conclusion from the available studies.

For data requirements where experimental data can be provided, the relevant endpoint study record should be completed for each study which has been notified and is used as evidence of safety in the submitted dossier.

The link/s for the endpoint studies considered to be relevant and reliable should be added in the Endpoint summary. When linking endpoint study records with multiple results make sure to check the relevant checkboxes to identify the **KEY RESULTS**. Provide the scientific conclusion for the endpoint/s reported in the endpoint study records. Information provided in this document will be used to generate lists of endpoints with Report Generator.

Note: None of the fields in ENDPOINT SUMMARIES are subject to the UNLESS_CONF flags, as they are not expected to contain confidential business information ('CBI'). These documents should be completed in a clear and transparent manner as they will be published without redaction as part of the Public Consultation Process foreseen in the Transparency Regulation.

FLEXIBLE/FIXED RECORDS

Similarly to endpoint study records or to endpoint summaries, this name is used for documents in IUCLID where the information stored in the record is not a study and it is not based on an OHT.

- A fixed record is created in a section where there can be only one record.
- A flexible record is created in a section where there can be more than one record.

Attachments

Applicants should provide the following as attachments:

- full study reports (in line with the provisions of the Transparency regulation)

or

- other supporting material (e.g label of packaging) in case they cannot be entered in a specific IUCLID document

Full study reports (including publications and QSAR, QMRF or QPRF reporting forms) must be uploaded as attachments **ONLY to the relevant literature reference entities**. The "Attachments" field of the endpoint study records (when present) **should be not used** to attach the full study reports and duplication of attachments should be avoided. The public version of any attachment **should not be in word/rtf format**, but rather in pdf format.

The literature reference entity allows different types of attachments to be uploaded. Only one attachment with the Attachment type = 'full study report' is permitted.

Other **supporting material** (e.g. excel templates, kinetic fitting reports, MSS/DER composers xml files) can also be added as attachments completing the 'Attachment type' to classify the material.

For attachments other than the full study report, indications are provided below.

Table of contents	Attachment
10.2 Other Reports – active substance dataset	**Overview table for secondary metabolites** as provided in **Appendix I** to the 'Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009' should be uploaded in the Section 'Reports and administrative information' of the Flexible_Summary.SummaryEvaluation document.
1.5.1 Production and quality control – active substance dataset **1.6 Method of production of the preparation and quality control – product dataset**	**Document J** (see dedicated paragraph below) Picture of the manufacturing process/flow chart for the active substance and the plant protection product should be added in the "Attached background material" section in 1.5.1 - active substance dataset and 1.6 – PPP dataset, respectively.
1.7 Packaging, compatibility of the preparation with proposed packaging materials – product dataset	Picture of label of packaging.
12. Summary and evaluation – product dataset	Safety data sheets for the formulants (attached to "Other references" field) Administrative documents such as cover letters (attached to the "Reports and administrative information" field). *Important note*: Such letters do not need to be provided via email or post, but solely attached in the respective IUCLID section.

DOCUMENT J

Note: work is on-going to ensure that all information can be reported in the IUCLID documents and **as from April 2025**, the PDF Document J will no longer be accepted in EU PPP dossiers.

Doc J can be uploaded in the FLEXIBLE_RECORD.Manufacturer_EU_PPP:

- Doc J for plant protection product: in '1.6 Method of production of the preparation and quality control' – Product dataset
- Doc J for active substance: in '1.5.1 Production and quality control' – active substance dataset

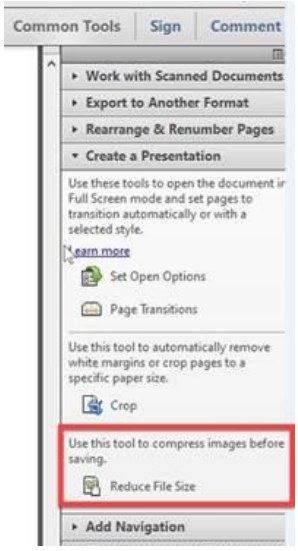
Please note that the information contained in doc J must also be provided in the correct sections of the IUCLID documents. To the extent information typically provided via Document J can already be provided in and flagged confidential via relevant IUCLID records/summaries, applicants should abstain from including the same information in Document J with a view to avoiding duplication of information.

ATTACHMENT SIZE

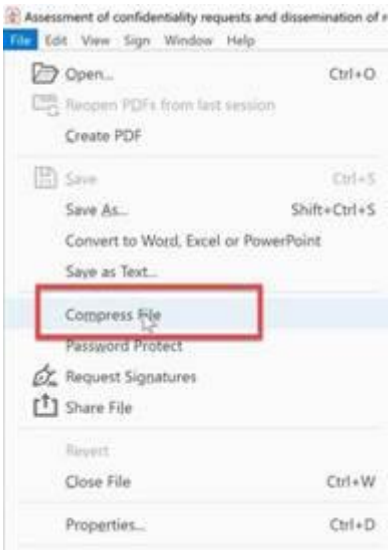
Attachments greater than 100MB will cause issues upon dossier submission. In case of large attachments please follow the instructions below. Reducing the size of attachments in IUCLID documents will result in better performance for dossier processing steps and it is therefore always recommended as best practice.

1. Generate the attachment report for the dossier / dataset to be submitted to get an overview of all the attachments. The most detailed report is shown below and the .ftl files can be downloaded from the IUCLID 6 website. Similar reports for datasets are also available. These attachment reports generate a .csv file (that can be opened in Excel) and list all attachments with their size and type.
2. Identify all the PDF attachments that have an excessive size (e.g. >100MB)

a. Download the large PDF attachments and use Adobe features to reduce the PDF file size:In the past this feature was called *"Reduce File Size"* in Adobe Acrobat Pro



b. In latest version of Adobe Acrobat Pro you can find the following menu item: *"Compress File"*



3. Upload smaller version of the PDF as attachment to the dataset.

This approach can be applied to PDF attachments only, though similar size reduction solution can be applied for other attachment types as well: e.g. extremely large images (with some loss in resolution quality).

When reduction of the size of the attachments is not possible, documents can exceptionally be split. In such cases, please pay special attention in naming the files.

Notification of Studies (NoS)

In accordance with Art. 32(b) of Regulation (EU) 2019/1381, "business operators must, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.

Laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by business operators and carried out by such laboratories or other testing facilities to support an application or a notification, its starting and planned completion dates, as well as the name of the business operator who commissioned such a study".

Pursuant to the EFSA Practical Arrangements on pre-submission phase and public consultation a justification must always be provided in the dossier header of each application in IUCLID for:

- studies notified but not submitted in the application;
- studies notified with delay, i.e., after the study starting date;
- studies notified and later withdrawn;
- studies commissioned or carried out after 27 March 2021, not notified but submitted in the application

IUCLID Report Generator allows applicants and Evaluators to generate a NoS extraction report listing all the studies submitted in the application that were notified, justified and without notification.

Further information on Notification of Studies are available in the User Guide on Notification of studies at the following link: https://www.efsa.europa.eu/sites/default/files/2021-07/user-guide-notification-of-studies.pdf

Validation Assistant

Before submitting a dossier, it is important to run the validation assistant to check the dossier is technically complete. Authorities can run the validation assistant before declaring a dossier admissible. As the rules applied are dependent on the information included in the Dossier Header, make sure this is completed correctly. If the report shows a **business rule failure** (anything starting with BR e.g. BR_PPP_033) this will prevent the applicant from successfully submitting the dossier. If the report shows a **validation warning** (anything starting with QLT e.g. QLT_PPP_001) the applicant will be able to submit the dossier but may encounter problems during the admissibility check.

It is important to resolve all validation assistant warnings, since this will support the 'admissibility check' of the RMS. If Applicants cannot resolve all the warnings re-run validation assistant, it is recommended to download the "Validation assistant Report" in excel format (this excel file replaces document O) and include in this file the justification for not resolving the warning and provide this directly to the RMS. Note that missing studies for a specific data requirement/endpoint should be justified using the data waiver section in the relevant endpoint study record.

In addition to the automated checks, it is important to make sure all the IUCLID documents are well completed and that all the relevant scientific data is provided.

Information on the applicable validation rules is available here:

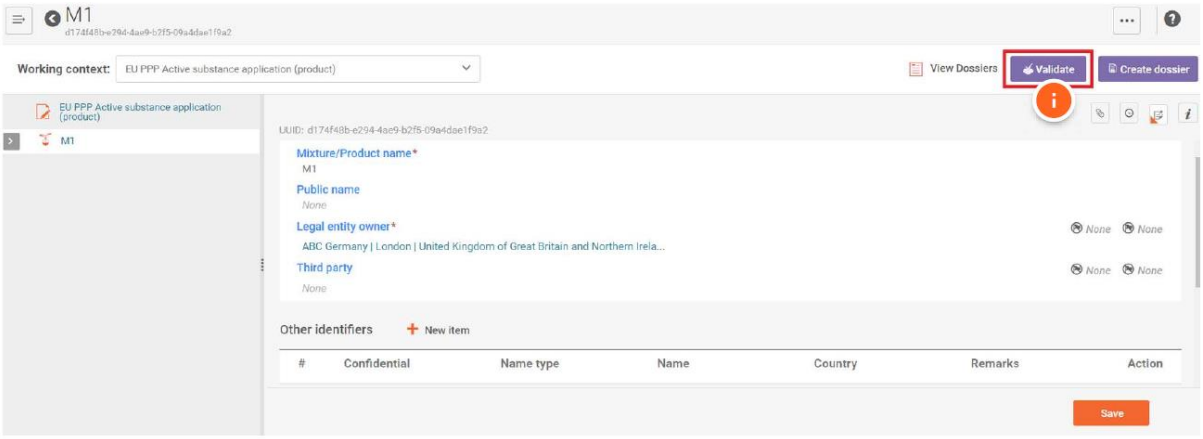
https://doi.org/10.5281/zenodo.5141356

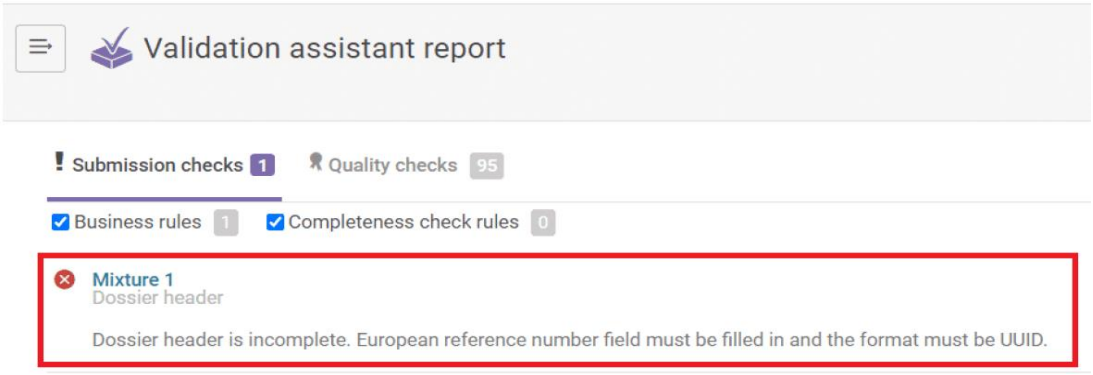
Watch the video on validation assistant:

https://zenodo.org/record/6603483#.YpoTY6hBxD9

Common mistakes training **5. Validation rules**:

https://zenodo.org/record/6603483#.Y1_cZHbMKUm)



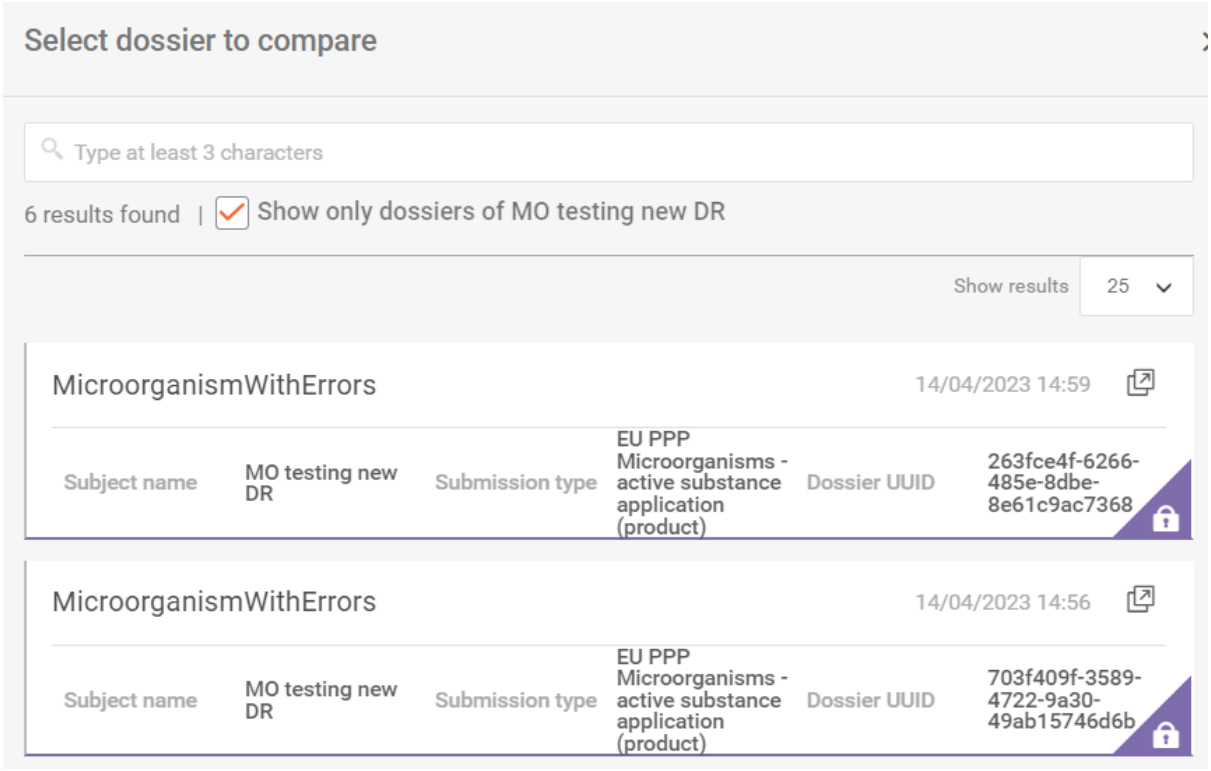


Compare tool

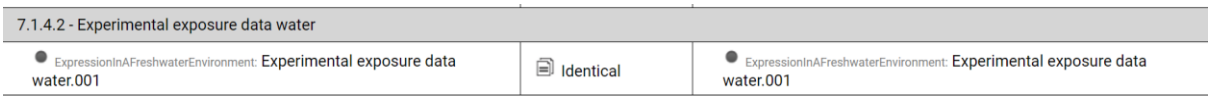
The Compare tool can be used for comparing different versions of a dossier and highlights the differences between the latest submission and any previous versions. It can be used by Applicants before re-submitting a dossier to check which changes were made.

The compare tool can be accessed from the Dossier actions menu (three dots next to the Validation button)

A window will open showing all related dossiers. Select the version of the dossier you want to compare with the current version. An .HTML file is downloaded, open this in a browser application.



If nothing has changed for a specific section/document in a dosser the report indicates 'identical'



If there is a difference in a section/document in the dossier the report indicates 'different'

Clicking on the 'different' link will provide more information on the nature of the changes in the dossier when compared with the selected comparator.

Field	Source	Target
Estimation of concentrations from other routes of exposure > Description of key information	*default* Predicted concentrations in the environment	
PEC other routes Estimation of concentrations from other routes of exposure > PEC from other routes of exposure > PEC other routes	**PEC other routes** Use description • GAP: Data on application (GAP).001 Parent / metabolite parent Substance Microorganism a.s. Genus species Route of exposure *default* Freshwater Method of calculation *default* OECD Calculation method	

In this case a Predicted concentrations document has been completed in the newer dossier. Using compare, deletions can also be checked, in this case the target column would be completed and the source would not.

Watch these Videos on how to use the compare tool:

- Comparison of **Dossiers**: SPC Comparison tool demonstration - YouTube
- Comparison of **Documents**: https://www.youtube.com/watch?v=cUy6ahta3dE

Report Generator

IUCLID provides a feature called "Report Generator" which allows data exraction from single IUCLID dossiers or datasets and generate a readable, user-friendly, customised report of IUCLID information in different output formats, for example, RTF, PDF, CSV and HTML.

Where available, Report generator should be used to compile the reported information into the format required for evaluation.

Many reports are ready to use and made available by default inside IUCLID 6. Templates to create PPP-specific reports are published in Zenodo Knowledge Junction and new versions, including changes and bug fixes, are published regularly and included in the list of "Default IUCLID reports" at each IUCLID release. These templates can also be uploaded in Report Manager as indicated in the IUCLID user manual https://iuclid6.echa.europa.eu/documents/1387205/1809908/iuclid_user_manual_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395?t=1684669746962. After downloading they will appear under the section *"Uploaded IUCLID reports"* of Report Generator.

The list of available reports for PPP can be found on the Applicants toolkit page: Toolkit | EFSA (europa.eu)

Note: report generator and other tasks are now run as 'Background tasks' which can be accessed from the IUCLID dashboard.

Mapping of Appendices of EFSA administrative guidance on submission of dossiers and assessment reports[14] to IUCLID documents

Appendix old name	New name, link and mapping
Appendices C1-C4	Dismissed. Public consultations are managed through the OpenEFSA platform
Appendix D Template for the overview table for analytical methods used for risk assessment	The overview table for analytical methods should be included in the field 'Description of key information' of the ENDPOINT_SUMMARY.AnalyticalMethods document (Section 5 - Product dataset; Section 4 - active substance dataset) based on Template 4.1 - Template for the overview table for analytical methods for risk assessment (available in zenodo: https://doi.org/10.5281/zenodo.4556992)
Appendix I Template for presentation of assessment of endocrine disrupting properties	Dismissed / Not relevant for microbial pesticide active substance
Appendix J Template for presentation the assessment for the equivalence of batches	Template 1.1 The template 1.1 for presentation the assessment for the equivalence of batches is available on EFSA knowledge Junction and replaces the Appendix J of the old EFSA administrative guidance (EFSA, 2019) The filled-in template should be included in the Document J which can be uploaded in the "Production and quality control" document (Sections: 1.5.1 – Active substance dataset; 1.6 – product dataset). The new Analytical profile of batches – Flexible Summary document should also be used (Section 1.4.3 – Active substance dataset). Note: work is on-going to ensure that all information can be reported in the IUCLID documents and as from April 2025, the PDF Document J (and therefore also Template 1.1) will no longer be accepted in EU PPP dossiers.

Inclusion of active substance in Annex IV to Regulation 396/2005 as part of an active substance approval or renewal process

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 summary (Section 6.3) **of the approval/renewal dossier**. There is **no need to submit a separate MRL dossier** in IUCLID.

Joint Submission and sharing of studies

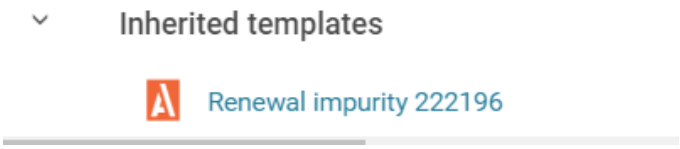
In accordance with Art. 5(2) of Commission Implementing Regulation (EU) No 2020/1740, "where there is more than one applicant requesting the renewal of the approval of the same active substance, those applicants shall take all reasonable steps to submit their dossiers jointly." In light of the above, companies submitting a renewal of approval of the same substance, should reach an agreement on sharing studies and data within a Joint Submission. There are two main types of Joint Submission:

1. joint submission with a third-party representative and a number of member applicants. This third-party representative could be e.g. a consultant;
2. joint submission with a lead applicant and a number of member applicants.

In situation 1), the consultant is expected to submit a renewal dossier with all joint information (including all studies to be evaluated) as well as confidential information of each member of the

[14] EFSA, 2019. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances. https://doi.org/10.2903/sp.efsa.2019.EN-1612

joint submission[15]. To identify the studies contributed by the different parties in the joint submission it is possible to use Inherited templates. Each template has a legal entity, the studies linked to a specific legal entity can be included in a single template and it can also be useful when LoAs to studies not owned by the applicant are to be included in a dossier. Data segregation among applicants is guaranteed provided that a third party is involved and manages the submission as a whole. To include a template, use the inherited templates link at the end of the dataset. More information can be found in the IUCLID User Manual Page Section 7 page 96.



In the case in which one company owns the data for the active substance and different company/ies own the data for the product/s data it is important that the correct legal entity is entered in the substance (SUBSTANCE.OwnerLegalEntity) and mixture dataset (MIXTURE.OwnerLegalEntity). This approach can also be applied to metabolite and other representative product datasets. The 'Third party' information in all datasets must be completed with the legal entity of the consultant preparing the dossier. The consultant can use IUCLID advanced export options to provide separate versions of the dossier to the members of the joint submission once a submission has been made to EFSA Agency IUCLID.

In the situation 2) the lead applicant is expected to submit a renewal dossier which includes joint information submitted by the lead on behalf of all the members including all studies to be evaluated and presented in (robust) study summaries. In addition, the lead applicant would also add his own confidential information in the main lead dossier. Any data which are not to be shared in full with other members of the joint submission can be included in the supplementary renewal dossiers. Lead and member dossiers should not in principle contain and/or refer to the same study reports since it is sufficient for the data to be provided once. The supplementary confidential dossiers should be indicated by selecting 'Joint submission' = yes and 'Lead applicant' = no.

All members of a joint submission or task force must provide the same unique UUID in the EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.ActiveSubstanceApproval.EuJsNumber (Joint submission number) field of the dossier header. All members of a joint submission or task force must use the same reference substance entity for the active substance in all submitted dossiers.

LETTER OF ACCESS

In relation to sharing of studies among companies which own separate data and which give data citation rights (Letter of Access) to each other for active renewal purposes, the approach would be as follows.

To indicate that a Company has a letter of access, follow these instructions in relation to the "Data Source (Literature Reference)" compilation:

- In the reference field: indicate the data is linked to a letter of access
- In the data access field: indicate that data submitter has a letter of access
- In the data protection claimed field: indicate data protection was claimed by the data owner
- In the Attached document field: upload the letter of access in the literature reference entity and set type to 'Letter of access'

Note: Providing a Letter of Access to the data is not sufficient to fulfil the data requirements since all studies supporting the approval/renewal of an active substance must be provided. Applicants must ensure that the studies are either included in their dossier or are provided by

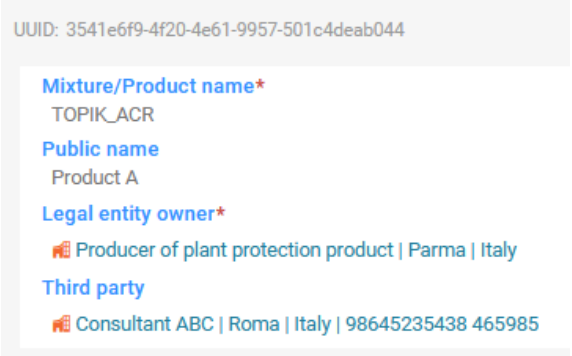
[15] In case the same study report is linked in an IUCLID record/summary of two or member dossiers forming part of the same joint submission, the confidentiality justification as well as the earmarks in the confidential version of the study report and the blackening in the public version of the study report must be consistent in the member dossiers concerned.

the data owner in a linked submission (or in the applicant's submission by means of inherited templates).

The Submission Portal

When preparing a dossier for submission please ensure that your dossier is compliant with the published submission portal rules: European Food Safety Authority. (2021). IUCLID submission rules for PPP dossiers (1.0). Zenodo. https://doi.org/10.5281/zenodo.5141356

Ensure the correct legal entities are assigned in the datasets and in the dossier header. During the submission process the DOSSIER.EU_PPP_ACTIVE_SUBSTANCE_FOR_MIXTURES.subject.legal_entity is checked. The owner of the dossier or the lead applicant in the case of a taskforce must be indicated in the **Mixture document.** If a third-party consultant has prepared the dossier the legal entity of the consultant must also be indicated (see below).



During the processing of dossier submissions in the portal the information on the active substance is taken from the MIXTURE.composition document. It is essential this is filled in before you submit your first dossier. For every submission there is a check that the Legal Entity and the Active Substance are the same for a given European Reference Number.

Ensure that the submitter has the role of Submission Portal Manager: If the submitter is a user of the Legal Entity owner organisation, ask the Legal Entity Manager to give the user the Submission Portal Manager role.

Username	Name	Email	User roles
EFSA_DGSANTE	EFSA Pilot DG SANTE	iuclid6@echa.europa.eu	IUCLID Beta Full Access Submission Portal Manager

If the submitter is a third-party consultant, then they need to ask the Legal Entity Manager of the owner/lead applicant organisation to add the submitter as a foreign user with the role Submission Portal Manager

Please see this short explanatory video for more information on foreign users:

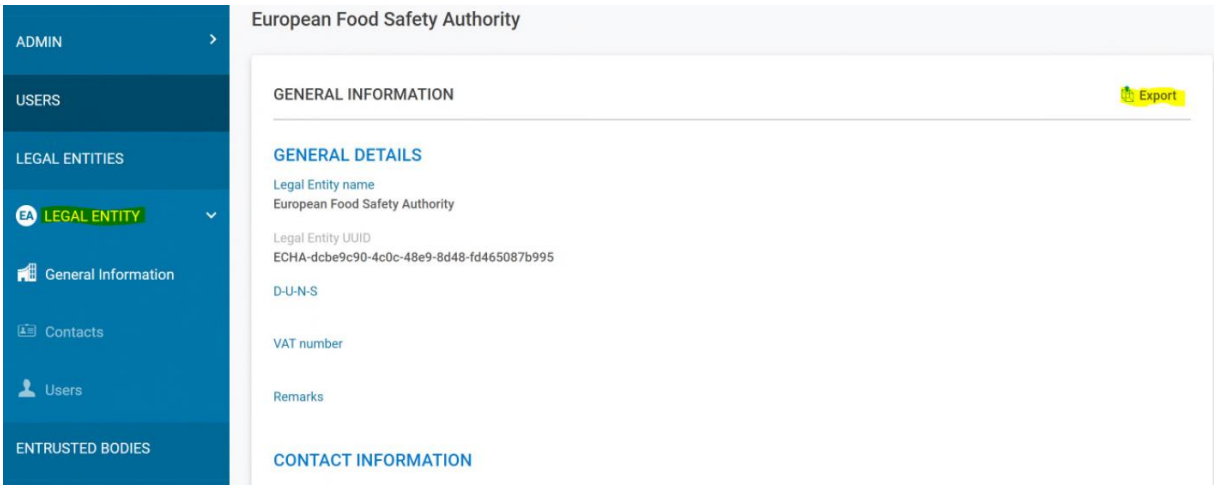
https://www.youtube.com/watch?v=YH5edrjBkxI&list=PLGDvgn1aAEEbL7dMwwWAjoAiK-DgoJmZrY&index=9

If the dossier is being prepared by an organisation other than the Legal entity owner the recommended approach is that the Legal entity owner exports their legal entity details and provides them to the organisation authoring the dossier. This legal entity information can be exported from within ECHA's Identity Management solution (IDM) and not from within IUCLID.

Exporting from IDM ensures alignment with Legal Entity in ECHA IDM when the dossier is submitted.

Note that by submitting the dossier as a foreign user, this person only has access to the submission report in the submission portal and would therefore see the substance name and other basic information. There is no follow-up communication within IUCLID/the submission portal as all subsequent steps are managed by email using the main contact person(s) for the dossier i.e. the third-party consultant. If the submitter should not see equivalent details for other submissions, the Restricted (Submission Portal) role should be applied (see page 9 of the ECHA accounts Manual for Industry Users).

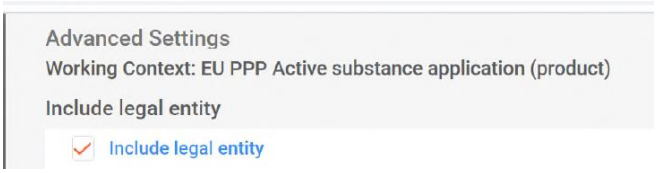
Exporting the Legal Entity: To view the details, please visit: https://ulem.echa.europa.eu/ui/dashboard. Log in with a user account that has the Legal Entity Manager role assigned. Navigate to the Legal Entities tab (on the left) and from the updated central page select the legal entity of the dossier. From the page, find the Export button to export the legal entity details.



The Legal Entity information will be exported as a IUCLID .i6z file which you can then import in IUCLID.

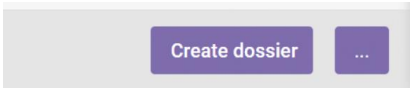
Importing the Legal Entity in IUCLID: The organisation authoring the dossier should add this legal entity to their Legal Entity inventory and use this legal entity in the dossier. The easiest way to import the legal entity details is from the IUCLID dashboard landing page and to import it directly[16], i.e. either by dragging the file onto the import box or by browsing for it.

If the Legal entity owner is not in the dossier header, you will need to recreate the dossier and ensure the 'Include legal entity' is checked from the advanced settings of the 'Create dossier' function.

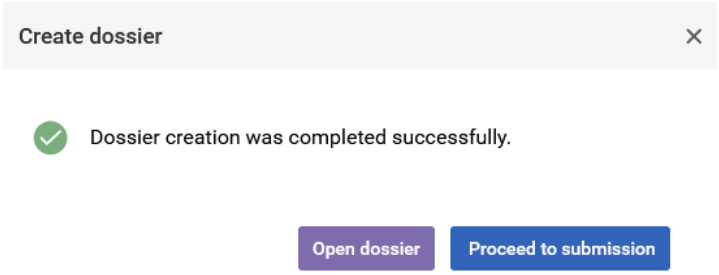


The advanced settings can be accessed from the 'three dots' button.

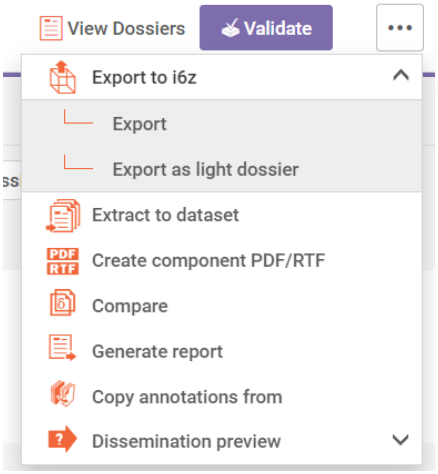
[16] It can also be imported through the Configuration management page ( ) and using the Legal Entity section of Inventory Manager



Proceed to submission: If you are using the IUCLID 6 ECHA Cloud services to author the dossier, simply use 'Create Dossier' and 'Proceed to submission' function. Then follow the submission portal steps listed below



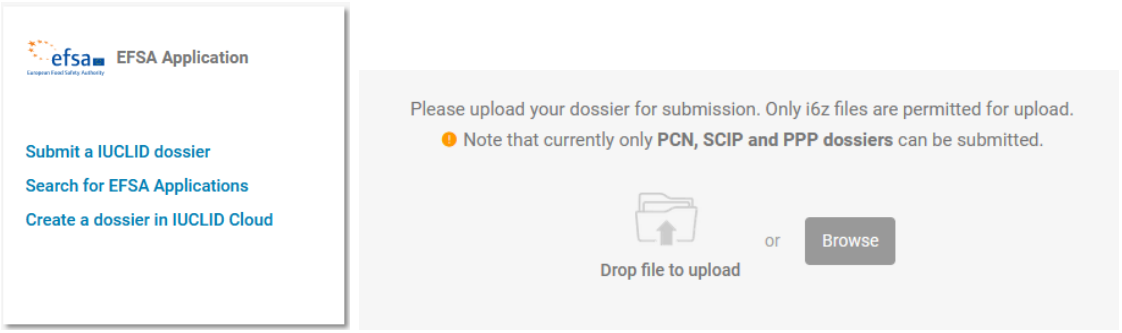
Export dossier: For Client or Server versions of IUCLID the dossier should be exported as an **i6z file** (the ZIP format for IUCLID). The **export** is accessed from the top level of the application window.

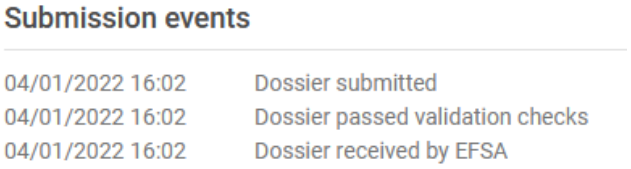


For the first submission of a dossier the standard **'Export'** function should be used.

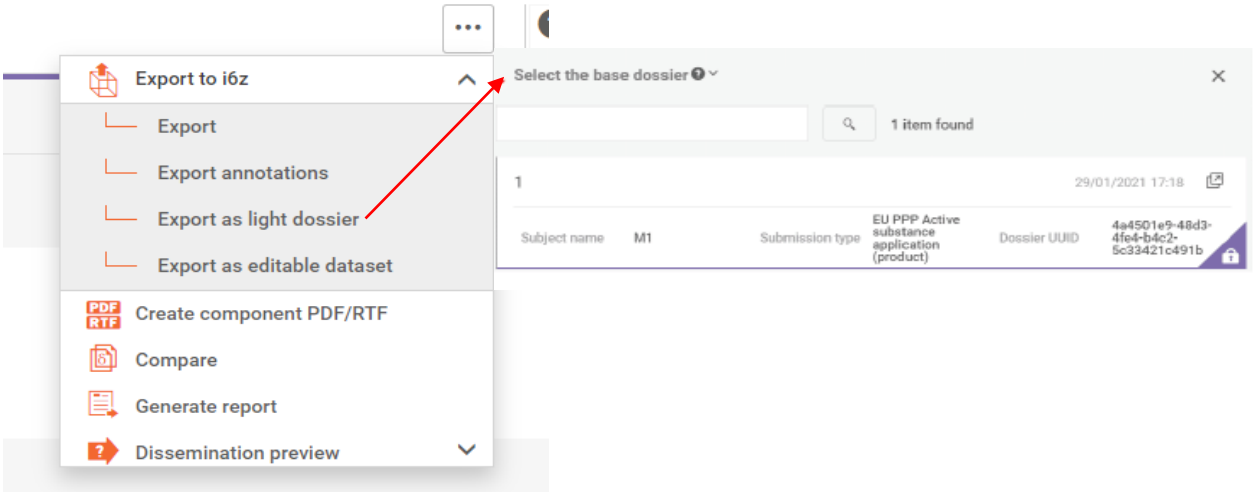
The submission portal: Log in to the submission portal and upload the i6z file. Do not forget to switch legal entity if you are submitting for another organisation. Please note the speed of your submission will be dependent on the size of your dossier and the upload speed of your internet connection. It is important that you check the submission report for your dossier submission. If the Submission event in the report shows "Dossier received by EFSA" then your submission is complete. If the Submission event is 'Dossier failed validation checks' your dossier has been rejected. In this case, 'View Validation report' to identify the issues with your submission, update the dossier and repeat the submission process**.**

Once a valid submission is received EFSA, RMS and EC are informed via an automated e-mail. Additional confirmation of IUCLID submissions via email or letter is NOT necessary unless specifically requested to do so within a certain process. Any cover letters should be added in the 'Summary and Evaluation' section. Dossier submissions via any route other than the Submission Portal will not be accepted for evaluation.





Export as a light dossier (preferred option for resubmissions): This is the preferred option in case of a resubmission since the file that is generated is always smaller than the full dossier. A light dossier includes the full IUCLID dossier with the exception of the attachments that had been provided previously (in the base dossier) and have not been modified.



This option can also be used to sequentially load a large dossier if issues importing a dossier into the submission portal are encountered. The first submission should include as a minimum the Mixture dataset, a completed mixture composition dataset including the active substance component with a completed substance and reference substance document. Once this dossier has 'Dossier received by EFSA' status additional datasets (e.g. metabolites, other representative formulations) can be linked to the main Mixture dataset and exported as 'light dossier' until the full dossier has been submitted.

Resubmission Of Applications

Applications should be prepared in accordance with the relevant legal provisions in place and **all data should be provided as complete as possible already in the initial dossier**. Nevertheless, after submission of an application, applicants **may be required to re-submit the IUCLID dossiers** in the following cases:

1. RE-SUBMISSIONS FOLLOWING REQUEST FROM RELEVANT REGULATORY BODY (RMS/EMS/EC/EFSA).

In the cases foreseen by the legislation, applicants may be required to submit an updated IUCLID dossier upon specific request by the relevant regulatory body.

It is important to highlight that the relevant regulatory body will only consider in their assessments dossier versions resulting from a specific request. With the exception of the cases listed in point 2 below, **versions submitted by applicants without having been requested, will not be taken into consideration in the assessment phase**.

For clear identification of the dossier, in addition to the EU reference number, the UUID of the dossier/s should be stated in each report submitted by the applicant.

Before re-submission, **applicants should always check if a newer IUCLID release is available**, to ensure a valid submission taking into account potential new business rules and validation checks included in the latest IUCLID update.

Any change in the dossier should be limited to addressing specific requests from the relevant regulatory body.

The applicant should respect the confidentiality decisions previously agreed with EFSA and submit new **confidentiality claims limited to the newly provided information only**.

1.1 Request for update during admissibility check

In the context of the admissibility check, the relevant regulatory body must ensure the compliance of the application with the requirements of the applicable regulations.

The admissibility check includes:

1. the **completeness check** against the **data requirements**
2. the check on the **Notification of Studies**
3. a light **check** on the presence of **key elements in confidentiality requests** submitted by the applicant
    a. sanitised personal data
    b. for confidentiality requests submitted, background documents and justification

For each of the checked points, the relevant regulatory body may ask the applicant to provide additional information[17]. It is important to highlight that the relevant regulatory body should judge the importance of the missing data and whether this will have an impact on their admissibility decision (e.g. in case of missing studies), leading to a decision of non-admissibility. The relevant regulatory body should also consider that a first version of the dossier will be published "as is" immediately after the declaration of admissibility.

1.2 Request for update in the context of the confidentiality request assessment/implementation

In the context of the confidentiality check, the applicant may be required to submit an updated version of the IUCLID dossier i) in response to a request for clarification regarding the confidentiality requests or ii) following the decision taken on confidentiality claims submitted with a view to implementing that decision in the IUCLID dossier.

1.3 Request for update during application evaluation

Once an application has been declared admissible, in the context of the application evaluation, the relevant regulatory body may ask the applicant to provide additional information[18]. This additional information must be submitted in the form of an updated dossier in IUCLID.

[17] According to Art 9 of Reg 1107/200, for new active substance applications and request for amendment of approval conditions:
According to Art 8 of Reg 1740/2020 for renewal application
According to SANCO Guidance on MRL setting procedure (SANTE/2015/10595 Rev. 6.1, for MRL applications
According to Article 32b (2) and (3)[17] of Regulation (EC) No 178/2002 and EFSA practical arrangements for all applications
[18] According to Art 11 of Reg 1107/2009 for new active substance applications

1.4 Request for update during EFSA peer-review

During the peer-review process, EFSA may request the applicant to submit additional information[19]. When responding to EFSA's request for additional information, the applicant must upload the additional information using the IUCLID format and the central submission system through which the additional information is made available to EFSA, to the RMS, all Member States and the European Commission.

2. SPONTANEOUS RE-SUBMISSIONS

Note: Spontaneous re-submissions should be limited to the cases foreseen by the current legislation as detailed in the paragraph below.

2.1 Re-submission following changes in administrative information for renewal applications

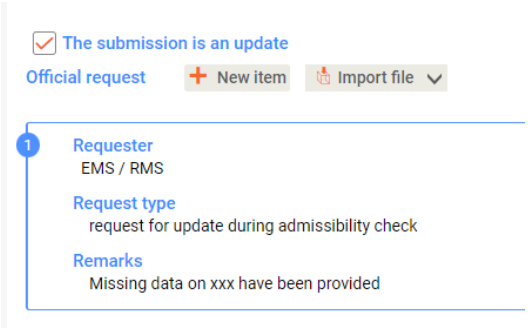
In case of changes in the administrative information of applications, the applicant should inform the relevant regulatory body via email and update the IUCLID dossier (update limited to specific administrative change)[20].

2.2 Re-submission following identification of potentially harmful or unacceptable effects

In case new information is available on potential harmful or unacceptable effects of the active substance, in accordance with Art. 56 of Reg 1007/2009, "*the holder of an authorisation for a plant protection product shall immediately notify the Member States that granted an authorisation of any new information concerning that plant protection product, the active substance, its metabolites, a safener, synergist or co-formulant contained in the plant protection product, which suggests that the plant protection product no longer complies with the criteria set out in Articles 29 and 4 respectively".*

When making a resubmission make sure the reason for resubmission is reported in the **"Specific submissions" section at the bottom of the dossier header**. Flag that the submission is an update and then provide additional details on whether:

a) the update is due to an official request, in which case you are asked to provide details on the requester and the reason for the request or a spontanous update followed by details on the reason

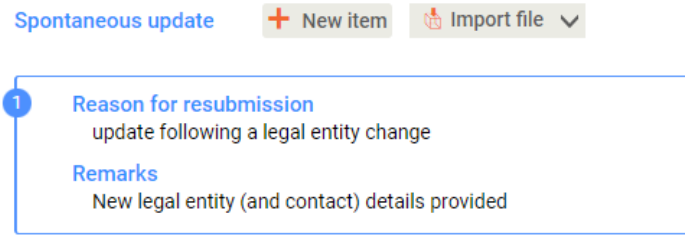


b) the update is spontanous, followed by details on the reason

According to art 11 of the Reg 1740/2020 for renewal application
According to SANCO Guidance on MRL setting procedure (SANTE/2015/10595 Rev. 6.1) for MRL applications
According to Article 32b (2) and (3)18 of Regulation (EC) No 178/2002 and EFSA practical arrangements for all applications

[19] According to Article 12(3) of Regulation (EC) No 1107/2009, or according to Article 13(2) of Commission Implementing Regulation (EU) 2020/1740 in case of renewal of approval

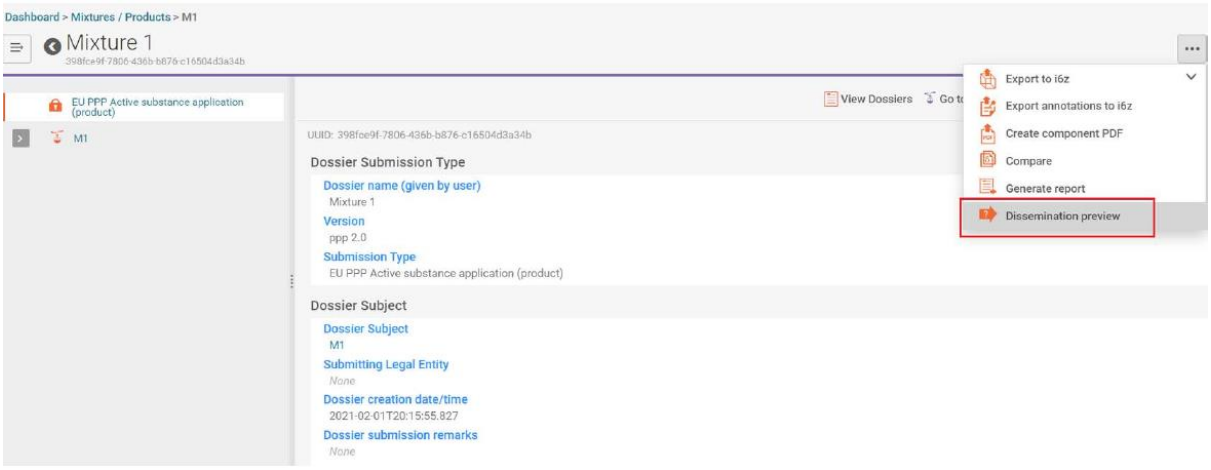
[20] According to Art 15 of Regulation 1740/2020



Dossier publication

Information not meant to be published is removed from the dossier, in accordance with the published version of the filtering rules. The public version of the dossier is then made available via the OpenEFSA Portal (https://open.efsa.europa.eu/). Dossier filtering is an automated process.

Prior to submitting a dossier, the 'View report and create filtered dossier' function under 'Dissemination Preview' can be used to create a filtered dossier.



Although a visual check of the filtered dossier can be useful to check how the published dossier will look, it is recommended to also use the dissemination preview excel file to filter for sensitive documents and check the publication status of each completed field in that document. All fields with the outcome = Published will be visible in the dossier available on the OpenEFSA portal. Dossier filtering is an automated process.

Pay attention to remark fields in open and closed picklists as currently these are not published if a corresponding confidentiality flag has been set in the relevant IUCLID record/summary.

	A	B	C	D	E	F	G	H
1	entity	sectionName	documentName	field	outcome	sourceDocumentKey	referencedDocumentKey	path
2	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dt		DOSSIER/EU_PPP_BASIC_SUBSTANCE.NA
3	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dt		DOSSIER/EU_PPP_BASIC_SUBSTANCE.LE
4	Dossier		Efsa basic	EU PPP Basic substance	Not published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dt		DOSSIER/EU_PPP_BASIC_SUBSTANCE.RE
5	Dossier		Efsa basic	EU PPP Basic substance / Basic substance a	Published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dt		DOSSIER/EU_PPP_BASIC_SUBSTANCE.Ba
6	Dossier		Efsa basic	EU PPP Basic substance / Basic substance a	Published	de84bbd8-7acf-42db-b09a-c3735c1f94b5/de84bbd8-7acf-42dt		DOSSIER/EU_PPP_BASIC_SUBSTANCE.Ba
7	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Mixture/Product name	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.MixtureName
8	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Legal entity owner	Published	69295a37-e087-4416-aa8e	ECHA-fc3c9382-ed4a-4990-bdf2-70(	MIXTURE.OwnerLegalEntity
9	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Contact persons / 1	Not published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.ContactPersons[0]
10	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Contact persons / 2	Not published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.ContactPersons[1]
11	Mixture/Product	1 Identity and applicant	efsa test basic 1	Mixture / Role in the supply chain / Manufac	Published	69295a37-e087-4416-aa8e-8f840b506c95/de84bbd8-7acf-42d		MIXTURE.RoleInSupplyChain.Manufact
12	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Na	Published	3fe10c84-2eb8-4c8c-961c-8340efb6-efea-4086-9cb6-4667854		FLEXIBLE_RECORD/MixtureComposition
13	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Fu	Published	3fe10c84-2eb8-4c8c-961c-dabd08febd14/de84bbd8-7acf-42db		FLEXIBLE_RECORD/MixtureComposition
14	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 1 / Ty	Published	3fe10c84-2eb8-4c8c-961c-dabd08febd14/de84bbd8-7acf-42db		FLEXIBLE_RECORD/MixtureComposition
15	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 2 / Na	Published	3fe10c84-2eb8-4c8c-961c-4094f25d-7eb4-412d-af25-767d92b		FLEXIBLE_RECORD/MixtureComposition
16	Flexible Record	2 Preparation of the substance for use	Mixture composition.001	Composition (mixture) / Components / 2 / Fu	Published	3fe10c84-2eb8-4c8c-961c-dabd08febd14/de84bbd8-7acf-42db		FLEXIBLE_RECORD/MixtureComposition
17	Flexible Summary	4 Application template, studies, bibliograp	Application template, studies, bibliography and confidentiality requests.001		Not published	523fb0ff-59c3-438e-bfce-b8fe32da782b/de84bbd8-7acf-42db-l		FLEXIBLE_SUMMARY/SummaryEvaluatic
18	Legal entity		Breaking Bad	Legal entity / General information / Legal ent	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.LegalEntityNa
19	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
20	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
21	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
22	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
23	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
24	Legal entity		Breaking Bad	Legal entity / General information / Address	Published	ECHA-fc3c9382-ed4a-4990-bdf2-70041a08dd23/de84bbd8-7ac		LEGAL_ENTITY.GeneralInfo.ContactAddr
25	Reference substance		Water	Reference substance / Reference substance r	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.ReferenceSubst
26	Reference substance		Water	Reference substance / IUPAC name	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.IupacName
27	Reference substance		Water	Reference substance / Inventory / CAS numbe	Published	8340efb6-efea-4086-9cb6-4667854d269b/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.Inventory.CASN
28	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Reference substance r	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.ReferenceSubst
29	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / IUPAC name	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.IupacName
30	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Inventory / Inventory	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.Inventory.Inven
31	Reference substance		Bis(2-(2-methoxyethoxy)ethyl) etl	Reference substance / Inventory / CAS numbe	Published	4094f25d-7eb4-412d-af25-767d92b5cee0/de84bbd8-7acf-42dt		REFERENCE_SUBSTANCE.Inventory.CASN
32	Contact		kon; Breaking Bad		Not published	d4e869be-babf-45dd-bba7-4b2a074a6eb2/de84bbd8-7acf-42d		CONTACT
33	Contact		tds; Breaking bad		Not published	dbc9040f-57c4-471d-af76-1760772e417f/de84bbd8-7acf-42db		CONTACT

Note: The Dissemination preview works on **dossiers** and **not datasets.**

If report generator is being used to prepare reports for inclusion in the dossier, a sanitised version of the report can be created by running report generator on the filtered dossier.

Confidentiality of dossiers submitted via IUCLID

For guidelines on requesting confidentiality in IUCLID dossiers, please refer to the "User Guide on confidentiality" available on the EFSA toolkit page: https://www.efsa.europa.eu/en/applications/toolkit

Validation rules

IUCLID submission rules for PPP dossiers currently applicable in the Submission portal are available in a separate document at the following link: IUCLID Validation Assistant rules for PPP dossiers

Filtering rules

IUCLID filtering rules for PPP dossiers currently applicable are available in a separate document at the following link: IUCLID for PPP Filter rules | Zenodo

ANNEX 1 – NEW AND AMENDED DOCUMENTS

This section includes instructions on how to compile new/amended documents introduced to make the micro-organisms working context fit for purpose so as to accommodate the submission of data in accordance with the new regulatory framework. For the remaining documents, please refer to the micro-organisms manual: https://doi.org/10.5281/zenodo.4773526

EU PPP MICRO-ORGANISMS - ACTIVE SUBSTANCE APPLICATION WORKING CONTEXT – ACTIVE SUBSTANCE DATASET

Genomic characterisation of the micro-organism – Endpoint Study Record

Section 1.3 - Identity, taxonomy and phylogeny of the microorganism

Purpose

Record for reporting micro-organism identity, including the possibility to submit Whole Genome Sequencing (WGS) information and FASTQ files.

In the area of plant protection products, Commission Regulation (EU) No 283/2013, as amended by Commission Regulation (EU) 1439/2022, also recommends the most appropriate molecular analytical methods to be used to characterize the micro-organism. The WGS-based data analysis can provide information to unequivocally assign taxonomic identification of the strains, as well as on the characterization of their potential functional traits of concern (e.g. virulence factors, resistance to antimicrobials of clinical relevance for humans and animals, production of known toxic metabolites).

ENDPOINT_STUDY_RECORD.GenomicCharacterisationMicroorganism		
Name	**Instructions**	**Data type**
Administrative data	Administrative data – common block https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Header 1
Data source	Data source – common block	Header 1
Background		Header 1
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. Example: This field can be used for summarising the pipeline followed to characterise the micro-organism using genomic methods, e.g. WGS.	Text (2,000 char.) Display: Basic
Materials and methods	Material and methods – common block	Header 1
Test material	Test material – common block	Header 2
Sample preparation		Header 2

Culture conditions	Describe the type of culture and culture conditions for the microorganism prior to the extraction of genetic material, if applicable (e.g. pure culture, monosporic culture).	Text (2,000 char.) Display: Detailed
Genetic material extraction procedure	Describe the protocol / method used to extract DNA (with chromosomal and extra-chromosomal elements) or RNA (e.g. for viruses).	Text (2,000 char.) Display: Detailed
Library preparation	Describe the library construction method for sequencing, e.g. DNA fragmentation method and selection of fragments, addition of adapters… Specify the manufacturer's instructions followed, including version number, and describe any deviations from that method.	Text (2,000 char.) Display: Detailed
Sequencing and Quality Control		Header 2
Sequencing platform / instrument	Indicate the sequencing platform / instrument used for sequencing, including the technology used (e.g. Sequencing by Synthesis, Pyrosequencing, Nanopore…), the company and the device. Further details about the method can be provided in field 'Details on sequencing method'	Text (255 char.) Display: Basic
Read type	Select the type of reads generated by the instrument.	List sup. (picklist with remarks) Display: Basic
Details on sequencing method	Provide any further details about the sequencing strategy and any base-calling method, where applicable.	Text (2,000 char.) Display: Detailed
Trimming, adapter removal, and filtering strategy	Describe the strategy followed for trimming, removing adapters and filtering, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Quality control method	Describe the method for quality control, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Assembly		Header 2
Type	Indicate the method used for the assembly.	List sup. (picklist with remarks) Display: Basic

De-novo assembly (if applicable)		Header 3
Assembly strategy	Describe the strategy followed for the assembly, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Post-assembly strategy	If post-assembly processing is carried out, describe the approach followed, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Genome annotation	If genome annotation is carried out, describe the approach followed, including software, version and parameters used. Database(s), version (where applicable) and/or date of accession should be indicated.	Text (2,000 char.) Display: Detailed
Reference-based mapping (if applicable)		Header 3
Reference genome	Indicate the reference genome(s) / database(s) used for the mapping and justify this choice.	Text (2,000 char.) Display: Detailed
Mapping strategy	Describe the approach followed for mapping to the reference genome, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Taxonomic identification		Header 2
Taxonomic identification strategy	Describe the strategy followed for the taxonomic identification of the microorganism, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Detection of contamination		Header 2
Contamination detection strategy	Describe the strategy followed for detection of contamination, including software, version and parameters used.	Text (2,000 char.) Display: Detailed
Identification of traits of concern		Header 2
Genetic modifications	Describe the methodology (e.g. alignment strategy) and sequences used for the detection of genetic modifications, including reference genome used, alignment software and parameters.	Text (2,000 char.)

		Display: Detailed
AMR genes	Described the strategy followed to identify genes related to antimicrobial resistance, including databases, software, version and/or accession date.	Text (2,000 char.) Display: Detailed
Toxigenicity and pathogenicity	Described the strategy followed to identify genes related to toxigenicity and pathogenicity (e.g. production of toxins, invasion and adhesion factors, participation in metabolic pathways involved toxigenicity, etc), including databases, software, version and/or accession date.	Text (2,000 char.) Display: Detailed
Any other information on materials and methods incl. tables		Header 2
	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.	Text (rich-text area) Display: Basic
Results and discussion		Header 1
Sequencing and quality control		Header 2
Raw sequencing data	Attach here the files containing raw sequencing data. Accepted formats are: - **fastq** (*.fastq.gz; *.fq.gz) - for assembled genomes: **fasta** (*.fasta; *.fna; *.fa; *.fasta.gz; *.fna.gz; *.fa.gz)	Attachment (multiple) Display: Basic
Raw reads quality control (before filtering and trimming)	Include data on the raw reads (before filtering and trimming).	Header 3
Total reads		Numeric (integer) Display: Basic
Average read length		Numeric (decimal)

		Display: Basic
% bases Q≥ 20		Numeric (decimal) Display: Basic
% bases Q≥ 30		Numeric (decimal) Display: Basic
% GC		Numeric (decimal) Display: Basic
Remarks		Text (2,000 char.) Display: Detailed
Processed reads quality control (after filtering and trimming)	Include data on the processed reads (after filtering and trimming).	Header 3
Total reads		Numeric (integer) Display: Basic
Average read length		Numeric (decimal) Display: Basic
% bases Q≥ 20		Numeric (decimal) Display: Basic
% bases Q≥ 30		Numeric (decimal) Display: Basic
% GC		Numeric (decimal) Display: Basic
Remarks		Text (2,000 char.) Display: Detailed
Assembly		Header 2
Genome size	Indicate the genome size from the assembly.	Numeric (integer)

		Display: Basic
Coverage	For de-novo assembly, indicate the % of reference genome covered by the assembly. For reference-based mapping, indicate the coverage at >5x depth.	Numeric (decimal) Display: Basic
Gene annotations		Block of fields (repeatable) Start
Type of genes / elements		List (picklist) Display: Basic
Total number		Numeric (integer) Display: Basic
Remarks		Text (2,000 char.) Display: Detailed
Gene annotations		Block of fields (repeatable) End
Additional details on assembly and gene annotation		Text (2,000 char.) Display: Detailed
De-novo assembly (if applicable)		Header 3
Number of contigs		Numeric (integer) Display: Basic
Total contig length		Numeric (integer) Display: Basic
N50		Numeric (integer) Display: Basic
Longest contig length		Numeric (integer) Display: Basic
Mean contig length		Numeric (integer)

		Display: Basic
Remarks	E.g. if size not +/- expected length	Text (2,000 char.) Display: Detailed
Reference-based mapping (if applicable)		Header 3
% reads mapped		Numeric (decimal) Display: Basic
Median read depth		Numeric (decimal) Display: Basic
Taxonomic identification		Header 2
Organism type		List (picklist) Display: Basic
Species		Text (255 char.) Display: Detailed
Strain		Text (255 char.) Display: Detailed
TaxID	Indicate NCBI's Tax ID for the organism.	Numeric (integer) Display: Detailed
Identity to reference genome	Indicate ANI for bacteria, ANI or % identity for fungi	Numeric (decimal including unit) Display: Basic
Phylogenetic tree	Attach here the phylogenetic tree	Image upload Display: Basic
Additional details on taxonomic identification		Text (2,000 char.) Display: Detailed

Contamination		Header 2
% contamination		Numeric (decimal) Display: Basic
Organism identified		Block of fields (repeatable) Start
Organism		Text (2,000 char.) Display: Detailed
% total reads		Numeric (decimal) Display: Basic
Remarks		Text (2,000 char.) Display: Detailed
Organism identified		Block of fields (repeatable) End
Additional details on contamination		Text (2,000 char.) Display: Detailed
Traits of concern		Header 2
Genetic modifications		Header 3
Genetic modifications detected		List (picklist) Display: Basic
List of genetic modifications		Block of fields (repeatable) Start
Type	Select the type of genetic modification	List (picklist) Display: Detailed
Start	Indicate the start position of the genetic modification	Numeric (integer) Display: Basic
End	Indicate the end position of the genetic modification	Numeric (integer) Display: Basic

Strand	Indicate the strand	List (picklist) Display: Basic
Genetic element type	Select the type of genetic element(s) or feature(s) (e.g. gene, CDS, regulatory element…) affected by the genetic modification. Picklist values are based on the feature key definitions of the International Nucleotide Sequence Database Collaboration (INSDC) https://www.insdc.org/submitting-standards/feature-table/.. If none of the key features is applicable, please select "other" and indicate the genetic element. You can provide further information in the remarks field.	List sup. (picklist with remarks) Display: Detailed
Genetic element name	Indicate the name of the genetic element (e.g. gene name) affected by the genetic modification, if applicable	Text (255 char.) Display: Detailed
Remarks	Indicate any additional information or annotations regarding the genetic modification or the genetic element affected	Text (2,000 char.) Display: Detailed
List of genetic modifications		Block of fields (repeatable) End
Graphical description		Image upload Display: Basic
Additional details on genetic modifications		Text (2,000 char.) Display: Detailed
AMR genes		Header 3
AMR genes detected		List (picklist) Display: Basic
List of genes		Block of fields (repeatable) Start
Gene name		Text (255 char.) Display: Detailed
Accession number		Text (255 char.) Display: Detailed
Database		Text (255 char.)

		Display: Detailed
Function		Text (255 char.) Display: Detailed
% identity		Numeric (decimal) Display: Basic
% length covered		Numeric (decimal) Display: Basic
Gene mobile	Indicate if there is a correlation with mobile genetic elements and provide a justification in the remarks field.	List sup. (picklist with remarks) Display: Basic
List of genes		Block of fields (repeatable) End
Dendrogram	Link here a dendrogram with related species or strains for which the presence of AMR is known.	Image upload Display: Basic
Additional details on AMR genes		Text (2,000 char.) Display: Detailed
Toxigenicity and pathogenicity		Header 3
Genes linked to toxigenicity and pathogenicity detected		List (picklist) Display: Basic
List of genes		Block of fields (repeatable) Start
Gene cluster	Indicate if the gene belongs to any specific cluster, group of category e.g. for secondary metabolites	Text (255 char.) Display: Detailed
Gene name		Text (255 char.) Display: Detailed

Accession number		Text (255 char.) Display: Detailed
Database		Text (255 char.) Display: Detailed
Function		Text (255 char.) Display: Detailed
% identity		Numeric (decimal) Display: Basic
% length covered		Numeric (decimal) Display: Basic
List of genes		Block of fields (repeatable) End
Dendrogram	Link here a dendrogram with related species or strains for which the toxigenicity and pathogenicity are known.	Image upload Display: Basic
Additional details on genes linked toxigenicity and pathogenicity		Text (2,000 char.) Display: Detailed
Any other information on results incl. tables	Any other information on results incl. tables – common block	Header 2
Overall remarks, attachments	Overall remarks, attachments – common block The form in Appendix A of EFSA, 2021 (https://doi.org/10.2903/j.efsa.2021.6506) should be duly completed and signed by the applicants at the time of submission, and attached to this document.	Header 1
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Header 1

Link to Supporting material:

European Food Safety Authority (EFSA), 2021. EFSA statement on the requirements for whole genome sequence analysis of micro-organisms intentionally used in the food chain https://doi.org/10.2903/j.efsa.2021.6506

Analytical profile of batches – Flexible Summary

Section 1.4.3 – Analytical profile of batches

Purpose

At least five representative batches from recent and current production of the micro-organism shall be analysed. All of the representative batches shall bear a date within the last five years of manufacture. Manufacturing dates of the representative batches and batch size shall be reported. Where the active substance is produced in different manufacturing plants, the information required under this point shall be provided for each of the plants separately. Where the information provided relates to a pilot manufacturing plant production system, the information required 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.

FLEXIBLE_SUMMARY.AnalyticalProfileOfBatches		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
5-batch Analysis	Use this repeatable block to provide the 5-batch analysis report and select the 5 substance composition records which describe the batches. If 5-batch data are provided for more than one manufacturing plants (sources) create a row for each manufacturing plant (source) clearly indicating its name.	Block of fields (repeatable) Start
Manufacturing site	Link here the site entity corresponding to the manufacturing site where the 5-batch analysis and QC has been performed.	Link to entity (single) Display: Basic
Reference	Data source (Literature Reference) – common block	Link to lit. reference (multiple) Display: Basic
Data access		List sup. (picklist with remarks) Display: Basic
Data protection claimed		List sup. (picklist with remarks) Display: Basic
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 either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for	Block of fields (repeatable)

	selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field. Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references.	
Reason / purpose for cross-reference	Select the appropriate reason of the cross-reference, i.e.: - adverse outcome pathway (AOP) (in case the 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) - data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver) - defined approach for combining with results from another methods (*in vitro*, *in chimico*, *in silico*) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver) - read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.) - read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary) - (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.) - reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay) - reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified).	List sup. (picklist with remarks) Display: Basic
Related information	As appropriate, select the record containing the related information, thus creating a link.	Link to endpoint (single) Display: Basic
Remarks	This field can be used for including any remarks.	Text (32,768 char.) Display: Basic

Substance composition analysis	Select the 5 substance composition documents that contain the batch data described in the report.	Link to endpoint (multiple) Display: Basic
Quality control		Block of fields (repeatable)
Number of batches	Indicate the number of batches analysed for quality control.	Numeric (integer) Display: Basic
Date		Date Display: Basic
Units	Indicate the units in which QC data are reported in the table below.	List (picklist) Display: Basic
QC data		Block of fields (repeatable)
	Set confidentiality and regulatory programme flags.	Confidentiality Display: Basic
Component	Assign here the reference substance that identifies the component.	Link to entity (single) Display: Basic
Avg	Indicate the average concentration of the component in the batches analysed. The units should be consistent for all components in the block, and correspond to the selection in the "Units" field above.	Numeric (decimal) Display: Basic
Min	Indicate the minimum concentration of the component in the batches analysed. The units should be consistent for all components in the block, and correspond to the selection in the "Units" field above.	Numeric (decimal) Display: Basic
Max	Indicate the maximum concentration of the component in the batches analysed. The units should be consistent for all components in the block, and correspond to the selection in the "Units" field above.	Numeric (decimal) Display: Basic
SD	Indicate the standard deviation for the concentration of the component in the batches analysed. The units should be consistent for all components in the block, and correspond to the selection in the "Units" field above.	Numeric (decimal) Display: Basic
Remarks	As appropriate, include remarks, e.g. a short description of the batch analysis included in this table, quality control, dates when analysis were performed.	Text (255 char.) Display: Basic

Description of key information		Header 1
Description of key information	Report the minimum purity (using of the active substance as manufactured based on the results for the 5 – batch analysis and indicate if supporting data were provided to further justify the technical specification. 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 (published). NB. For micro-organisms the content shall be expressed in appropriate microbial unit that most accurately reflects plant protection action, such as number of active units, colony forming units, or international units per volume or weight or any other manner that is relevant to the risk assessment on the micro-organism.	Text (rich-text area) Display: Basic
Description of key information (confidential)	Summarise the results for the analysis of batches and indicate if supporting data were provided to further justify the technical specification. If the active substance is manufactured as technical concentrate (TK), a summary of the results should be provided for the TK and for the theoretical dry weight material (not published).	Text (rich-text area) Display: Basic
Technical specification		Link to endpoint (single) Display: Basic
Additional information	Additional information – common block	Header 1

Biological properties of the micro-organism – Flexible Record

Section 2 – Biological properties of the micro-organism

Purpose

Use this document to provide information on:

- Origin and isolation source
- Occurrence
- History of use
- Ecology and life cycle of the micro-organism
- Mode of action on the target organism and host range (see Section 3.1 Function and target organism)
- Growth requirements
- Infectivity to the target organism
- Relationship to known human pathogens and to pathogens to non-target organisms
- Genetic stability and factors affecting it
- Information on metabolites of concern
- Presence of transferable antimicrobial resistance genes

FLEXIBLE_RECORD.BioPropertiesMicro		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Confidentiality Display: Basic
Biological properties of the micro-organism		Header 1
General information on the micro-organism		Header 2
	Familiarity (availability of relevant knowledge) of the microorganism not covered by the sections below. If the micro-organism is genetically modified, the type of modification should be provided.	Text template Display: Basic
Type of micro-organisms		List (picklist) Display: Basic
Strain characteristics		List multi. (multi-select list with remarks) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Historical background	Not relevant for PPP dossiers – see next section History of uses	Header 3
	Historical background of the wild type. Provide information at the most relevant taxonomic level (e.g. strain, species, genus).	Text template Display: Basic
Taxonomic level	Select the taxonomic level of the information provided above and provide a justification of the choice of taxonomic level in the remarks field.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic

Historical uses		Header 3
	2.1.3 History of use Previous and current known uses of the micro-organism (e.g. research, commercial, uses evaluated for recommending the Qualified Presumption of Safety status). Include both plant protection and other uses (e.g. uses and/or assessments under other regulatory frameworks, bioremediation, uses in food and feed). Provide information at the most relevant taxonomic level (e.g. strain, species, genus), and according to the valid and accepted taxonomic criteria applicable at the time of the submission of the application.	Text template Display: Basic
Taxonomic level	Select the taxonomic level of the information provided above and provide a justification of the choice of taxonomic level in the remarks field	List sup. (picklist with remarks - 2,000 char.) Display: Basic
QPS status	Select the Qualified Presumption of Safety Status https://doi.org/10.5281/zenodo.1146566. Qualifications from in the QPS list can be reported in the remarks	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Origin, natural occurrence and geographical distribution		Header 3
	2.1.1 Origin and isolation source 2.1.2 Occurrence The geographical location and environmental compartment (e.g. substrate, host organisms), from which the micro-organism was isolated, shall be stated. The method of isolation and the selection procedure of the microorganism shall be reported. The geographical distribution of the micro-organism shall be described. The environmental compartment(s) where the micro-organism is already expected to occur shall be described (e.g. soil, water, rhizosphere, phyllosphere, host organism). When relevant, food or feed commodities where the micro-organism is already expected to occur shall be described.	Text template Display: Basic

	The information referred to in this point shall be provided at the most relevant highest taxonomic level (e.g. strain,species, genus), and the choice of the relevant highest taxonomic level shall be justified.	
Occurrence in water	Indicate the occurrence in water selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Occurrence in soil	Indicate the occurrence in soil selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Occurrence in rhizosphere	Indicate the occurrence in rhizosphere selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Occurrence in phyllosphere	Indicate the occurrence in phyllosphere selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Occurrence in host organisms	Indicate the occurrence in host organisms selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Occurrence in food or feed	Indicate the occurrence in food or feed selecting the appropriate value from the picklist: - In strain under evaluation - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks) Display: Basic
Food or feed matrix	When relevant, food or feed commodities where the micro-organism is already expected to occur shall be described.	List multi. (multi-select list with remarks) Display: Basic
Reference	Data source (Literature reference) – common block	Link to lit. reference (multiple)

	Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Display: Basic
Development stages / life cycle of the microorganism		Header 2
	2.2 Ecology and life cycle of the micro-organism The known life cycle(s) of the micro-organism, its lifestyle(s) (e.g. parasitic, saprophytic, endophytic, pathogenic) and its ecological niche(s) shall be described, along with all forms that may occur and the type of reproduction. For **bacteriophages**, information shall be provided on, if applicable, lysogenic and lytic properties. For **fungi** and **bacteria**, information shall be provided, if applicable, on: - external conditions for resting stages, information on resistance of spores against adverse environmental conditions, survival time of the spores and conditions for germination, and/or - formation of biofilm.	Text template Display: Basic
Life cycle		List multi. (multi-select list with remarks) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Relationships to known plant or animal or human pathogens		Header 2
	2.6 Relationship to known human pathogens and to pathogens to non-target organisms Where the microorganism is closely related to any known pathogens to humans, animals, crops or other non- target species, the applicant shall: - list the pathogens and the type of known diseases caused, - describe the known virulence factors belonging to the pathogens, - describe the known virulence factors belonging to the micro-organism, which is the active substance,	Text template Display: Basic

	- describe the phylogenetic relationship between the micro-organism and the related pathogens identified, - describe the way or means to distinguish the active micro-organism from pathogenic species.	
Related to known pathogens	Indicate relationship to known plant or human or animal pathogens selecting the appropriate value from the picklist: - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Phylogenic tree	Upload a picture of the phylogenetic tree of the microorganism. The scale of the phylogenetic tree shall be selected to include relevant strains and species (e.g. in case of use of read-across among related strains or species to address data requirements). Superseded names of included micro-organisms or taxonomic groupings may be indicated in the phylogenetic tree.	Image upload Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Genetic stability and factors affecting it		Header 2
	2.7. Genetic stability and factors affecting it Where the micro-organism is a non-virulent variant of a plant pathogen virus, the likelihood of regaining virulence through mutation after application under the proposed conditions of use shall be reported, including the information on measures that can be taken to reduce the likelihood of this occurrence and the effectiveness of such measures.	Text template Display: Basic
Non-virulent virus variant	[Relevant for viruses only] Select yes if the micro-organism is a non-virulent variant of a plant pathogen. If yes is selected, the likelihood of regaining virulence through mutation after application under the proposed conditions of use shall be reported, including the information on measures that can be taken to reduce the likelihood of this occurrence and the effectiveness of such measures in the remarks field.	List sup. (picklist with remarks - 32,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic

Information on the production of relevant metabolites and toxins	Instructions on how to report information on metabolites of (potential) concern are reported in the introduction of this manual, subsection '**Information on secondary metabolites**'.	Header 2
	2.8 Information on metabolites of concern A summary and conclusion of the assessment performed by the applicant on the secondary metabolites must be included in this field. The applicant shall identify under this point the **metabolites of concern** produced by the micro-organism, including a summary of the information submitted under data requirements points 5.5.1, 8.8.1, 6.1, 7.2.1 and 7.2.2 used to identify or to exclude metabolites as being of concern. All metabolites of potential concern should be listed in the Flexible Summary Metabolites in the in the Section 1.4.1 of the product dataset. The evidence for exclusion of metabolite production should be reported in this field.	Text template Display: Basic
Absence of genes for secondary metabolite production	Indicate (Y/N) the absence of gene(s) required for the production of the identified metabolite(s) of potential concern. Where genomic sequence data is available this should be reported in Section '1.3 Identity, taxonomy and phylogeny of the microorganism' of the active substance dataset	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Metabolites of potential concern identified	Indicate whether metabolites of potential concern were identified selecting the appropriate entry from the picklist: - in strain under evaluation - in closely related species - in organisms of the same genus - no	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Production and resistance to antibiotics and other antimicrobial agents		Header 2
	2.9 Presence of transferable antimicrobial resistance genes Where the micro-organism is a bacterium, information on any resistance to relevant antimicrobial agents shall be reported at strain level.	Text template Display: Basic

	Information on whether the antimicrobial resistance genes are acquired, transferable and functional shall be reported. Where genomic sequence data is available this should be reported in section 1.3 Identity, taxonomy and phylogeny of the micro-organism	
Presence of antimicrobial resistance genes		List sup. (picklist with remarks - 2,000 char.) Display: Basic
Presence of transferrable antimicrobial resistance genes	The information provided shall be sufficient to perform an evaluation as to the risks for human and animal health due to a possible transfer of relevant antimicrobial resistance genes.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Robustness to environmental factors		Header 2
	2.4 Growth requirements The conditions required for growth and proliferation of the micro-organism shall be described (e.g. host, nutrients, pH, osmotic potential, humidity).	Text template Display: Basic
Temperature range for growth (°C)	The minimum, optimum and maximum temperature required for growth and proliferation shall be reported.	Numeric range (decimal) Display: Basic
Generation time	Report the generation time under favourable growth conditions	Numeric range (decimal with picklist) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Further information on the microorganism		Header 2

	Any further relevant information.	Text template Display: Basic
Taxonomic level	Select the taxonomic level of the information provided above and provide a justification of the choice of taxonomic level in the remarks field	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Effectiveness against target organisms	Not relevant for PPP dossiers – This information should be reported in section 3.1 Function and target organism	Header 1
Infectiveness, dispersal and colonisation ability	Not relevant for PPP dossiers	Header 2
		Text template Display: Basic
Infectivity to the target organism	2.5 Infectivity to the target organism In case any pathogenic mode(s) of action on the target organism is described in **Section 3.1** [*Mode of action on the target organism and host range*], virulence factors and (if applicable) environmental factors affecting them shall be indicated and described. The results of any relevant experimental studies and/or data/information from the existing literature at the relevant taxonomic level shall be reported.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Methods to prevent loss of virulence of seed stock of the microorganism	Not relevant for PPP dossiers	Header 2
		Text (rich-text area) Display: Basic
Reference	Data source (Literature reference) – common block	Link to lit. reference

	Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	(multiple) Display: Basic
Measures necessary to protect humans, animals and the environment	Not relevant for PPP dossiers Information on Precautions and Methods in case of accidents should be reported in Section 4.1 Procedures doe cleaning and decontaminating of application equipment	Header 1
Monitoring plan to be used for the active microorganism including handling, storage, transport and use	Not relevant for PPP dossiers	Header 2
		Text (rich-text area) Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Classification & Labelling of the micro-organism (for biocidal products)	Not relevant for PPP dossiers	Header 1
Relevant risk group specified in Article 2 of Directive 2000/54/EC		Header 2
		List (picklist) Display: Basic
Biological properties of the micro-organism in the biocidal product	Not relevant for PPP dossiers	Header 1

		Text template Display: Basic
Reference	Data source (Literature reference) – common block Link to relevant Literature Reference entities to support the descriptions of the biological properties reported above. See also Literature search at the end of the table.	Link to lit. reference (multiple) Display: Basic
Supporting literature searches **(if relevant)**		Block of fields (repeatable) Start
Literature search	When collecting evidence for specific biological properties the method for searching, retrieving, and assessing studies for relevance and reliability should be presented. **Note:** For each biological properties section a literature search document should be completed, the literature search document should be named according to the section where the literature references where cited	Link to endpoint (single) Display: Basic
Remarks	Provide any additional remarks on the literature search, i.e. which section(s) of biological properties is addressed by the literature search	Text (2,000 char.) Display: Basic
Supporting literature searches **(if relevant)**		Block of fields (repeatable) End

Links to supporting material:

Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) http://data.europa.eu/eli/dir/2000/54/2020-06-24

Guidance on the Risk Assessment Of Metabolites Produced by Microorganisms Used As Plant Protection Active Substances. SANCO/2020/12258
https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf

Application of systematic review methodology to food and feed safety assessments to support decision making https://www.efsa.europa.eu/en/efsajournal/pub/1637

EFSA Qualified presumption of safety (QPS)
https://www.efsa.europa.eu/en/topics/topic/qualified-presumption-safety-qps

Literature Search – Flexible Record

Section 3.5 – Literature data

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.

In accordance with Art 8(5) of Regulation (EC) No 1107/2009, the summary dossier shall include "Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier" (both in case of chemical and microbial active substance).

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 should be included in the field "Link to relevant studies". An appropriate Endpoint Study Record should be completed for each relevant study and the literature reference included in the data source section).

FLEXIBLE_RECORD.LiteratureSearch		
Name	**Instructions**	**Data Type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality
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
Literature reference(s)		Literature reference list
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 plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species	Rich text area
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
Search strategy	Indicate how the literature search was carried out.	Header 1

Bibliographic databases used in the literature review and search results	A description each of the search strategies used in the literature review	
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
Date of search	Provide the date when the search was performed using the database.	Date
Time window of the literature search	The period covered in the literature search e.g. 2010 to 2020	Text
Search string(s) used	The search strings used to retrieve the records e.g. 1. ts= (Beauveria bassiana OR B. bassiana) 2. ts=(Beauveria bassiana OR B. bassiana) AND (secondary metabolite* OR toxin*) 3. ts=(Beauveria bassiana OR B. bassiana) AND (Antimicrobial resist*)	Multi-line text
Filters	Indicate if filters were applied in the search. If yes is selected the filters applied must be described	Closed list with remarks
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
Number of hits	The number of hits for the search in each database/source	Integer
Number of hits after refinement	The number of hits after refinement, if applicable	Integer
Number of hits after duplicate removal	The number of hits after duplicate removal	Integer
Bibliographic databases used in the literature review and search results		
Evaluation of the review		Header 1
Records retrieved	The number of records retrieved when the results for the searches above where combined	Integer
Records after removal of duplicates	Total number of summary records retrieved after removing duplicates from all database searches	Integer

Records after rapid assessment	Report the number of records retained after title/abstract screening	Integer
Records after detailed assessment	Report the number of records retained after full text screening	Integer
Reliable studies	Report the number of records retained after the reliability assessment	Integer
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
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	
Literature reference	Link a reference to the excluded publication.	Literature reference list
Exclusion reason	Reason for not including publication in dossier (based on relevance and reliability criteria).	Multi-line text
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	
Additional information		**Header 1**
Additional information	Any other information needed to interpret the results for the literature research	Rich text area
Attached background material	Upload supporting files e.g. bibliographic metadata	
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
Remarks	Indicate the source of the contents of the file and the format type.	Text
Attached background material		

Link to supporting 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

Additional considerations:

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA.

Assessment on potential infectivity and pathogenicity of the microorganism to human – Flexible summary

Section 5.2 - Assessment on potential infectivity and pathogenicity of the microorganism to humans

Purpose

Summary to conclude on the absence of infectivity and pathogenicity of the microorganism to humans, including links to relevant toxicological studies and literature search and using weight of evidence (WoE) approach as described in EFSA Scientific Committee, 2017.

FLEXIBLE_SUMMARY.PathogenicityInfectivityHumans		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Assessment of potential infectivity and pathogenicity of the microorganism to humans	Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S, Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017 EFSA Journal 2017;15(8):4971, 69 pp. First published: 03 August 2017 https://doi.org/10.2903/j.efsa.2017.4971	Header 1

	Conclude on potential infectivity and pathogenicity based on the lines of evidence presented below.	Text (rich-text area) Display: Basic
Assembling evidence	Link to any literature searches for evidence on pathogenicity of infectivity.	Link to endpoint (multiple) Display: Basic
Weighing evidence		Block of fields (repeatable) Start
Description of key conclusion for the study	Include consideration of the relevance and reliability of the study	Text (32,768 char.) Display: Basic
Identified uncertainties		Text (32,768 char.) Display: Basic
Link to relevant study record	Link to the endpoint study describing the supporting evidence.	Link to endpoint (single) Display: Basic
Weighing evidence		Block of fields (repeatable) End
Integrating evidence		Header 2
Opportunistic infection	Indicate whether there is evidence of opportunistic infection in immunocompromised persons	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Absence of infectivity		List sup. (picklist with remarks - 2,000 char.) Display: Basic

Absence of pathogenicity		List sup. (picklist with remarks - 2,000 char.) Display: Basic
Additional information	Additional information – common block	Header 1

Links to supporting material:

EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S, Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017. Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. https://doi.org/10.2903/j.efsa.2017.4971

Information on metabolites of toxicological concern – Flexible Summary

Section 5.5.1 - Information and toxicity of metabolites

Purpose

Summary to conclude on the toxicity of metabolites based on literature search in order to identify metabolites of concern for human and animal health and/or to conclude on exclusion of metabolites as being of concern.

All the metabolites of potential concern should be listed, providing further information to demonstrate whether they are of concern of not.

Identified metabolites of concern to be reported in *Flexible_Summary.Metabolites & Other Substance for Assessment* dataset (see instructions above).

FLEXIBLE.SUMMARY_InformationToxicityMetabolites		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Description of key information	This document is for Metabolites of Concern for Human Health See SANCO/2020/12258 Guidance on the risk assessment of metabolites produced by micro-organisms used as plant protection active substances. Stage 1 and Stage 2 the collection of basic information from literature should be reported in the Biological	Header 1

	Properties document (Section 2 of the active substance dataset). This document should be used to report the results of targeted literature searches for all metabolites of potential concern in order to identify 'Metabolites of Concern'. If the identity is known, a complete list of metabolites of potential concern should be listed in the 'Information on Metabolites' document and for the metabolites of concern the experimental data should be provided in the linked datasets. Provide additional information from the metabolite specific literature searches which cannot be reported in the repeatable block below.	
		Text (rich-text area) Display: Basic
Metabolites		Block of fields (repeatable) Start
Link to metabolite		Link to entity (single) Display: Basic
Link to Literature Search		Link to endpoint (single) Display: Basic
Hazardous effect observed in toxicological studies	If the picklist value 'no' is selected provide the justification in the remarks field. No further information is required in this table. If the picklist value 'yes' is selected complete all the information required in the table.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Conditions	Describe the conditions under which the microorganism produces the metabolite.	Text (2,000 char.) Display: Basic
LOQ of method	Any available information about the LOQ of the method used to determine/quantify the metabolite.	Numeric range (decimal with picklist)

		Display: Basic
Expected quantities	4.1 Any available information about the expected quantities.	Numeric range (decimal with picklist) Display: Basic
Regulation mechanism	Any available information on the mechanism by which the microorganism regulates the production of the metabolite shall be provided.	Text (2,000 char.) Display: Basic
Mode of action	Any available information on the influence of the produced metabolites on the micro-organism's mode of action against the target organism(s) shall be provided.	Text (2,000 char.) Display: Basic
Sufficient body of knowledge	Is there enough published literature to assume that a literature search would provide sufficient information on metabolite production? Make reference to the literature search included in the 'Link to Literature Search' in the table when justifying the selection of 'yes' or 'no' in the remarks field.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Remarks	Provide any other information to support the classification of this metabolite as 'of concern'.	Text (2,000 char.) Display: Basic
Metabolites		Block of fields (repeatable) End
Step 5: Is the genus of the strain under evaluation well studied?	Literature data. Is the microorganism well studied? (see step 5.1 of SANCO/2020/12258) Provide a further an evaluation of the body of knowledge from the scientific literatures presented above. Is there sufficient information to conclude on the metabolites of concern? As a matter of principle, it is highly recommended to the applicant to conduct the search beyond the normally requested period of 10 years before the application, in order to gather all the possible relevant scientific literature to support the risk assessment.	Header 2
	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	Text (rich-text area) Display: Basic

	- 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.	
Additional information	Additional information – common block	Header 1

Link to supporting material:

Guidance on the risk assessment of metabolites produced by micro-organisms used as plant protection active substances. SANCO/2020/12258 https://food.ec.europa.eu/system/files/2023-06/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern.pdf

Environment Qualitative Exposure Assessment – Flexible Summary

Section 7.1.3 - Qualitative exposure assessment of the microorganism

Purpose

Summary to record environmental qualitative exposure assessment, including links to relevant environmental and ecotoxicological studies and using weight of evidence (WoE) approach as described in EFSA Scientific Committee, 2017.

FLEXIBLE_SUMMARY.EnvironmentQualitativeExposureAssessment		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Qualitative exposure assessment of the microorganism	Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S, Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017 EFSA Journal 2017; 15(8):4971, 69 pp.	Header 1

	First published: 03 August 2017 https://doi.org/10.2903/j.efsa.2017.4971	
	Conclude on environmental exposure based on the lines of evidence presented below.	Text (rich-text area) Display: Basic
Assembling evidence	Link to any literature searches for evidence to support the qualitative exposure assessment in the environment.	Link to endpoint (multiple) Display: Basic
Weighing evidence		Block of fields (repeatable) Start
Description of key conclusion for the study	Include consideration of the relevance and reliability of the study	Text (32,768 char.) Display: Basic
Identified uncertainties		Text (32,768 char.) Display: Basic
Link to relevant study record	Link to the endpoint study describing the supporting evidence.	Link to endpoint (single) Display: Basic
Weighing evidence		Block of fields (repeatable) End
Integrating evidence		Header 2
Potential risk identified for non-target organisms	Indicate whether there is evidence of risk for non-target organisms	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Non-target organisms	Where effects on non-target organisms are observed indicate the species group	List multi. (multi-select list) Display: Basic
Additional information	Additional information – common block	Header 1

Links to supporting material:

EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S, Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017. Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. https://doi.org/10.2903/j.efsa.2017.4971

Expression in Soil – Endpoint Summary

Section 7.1.4.1 Experimental exposure data soil

Purpose

Summarise experimental data on density of micro-organisms in the soil.

If under consideration of the information provided under points 7.1.1, 7.1.2, 7.1.3 and 7.2 of Commission Regulation (EU) 1439/2022 a potential risk is identified for humans or non-target organism(s) or information is not sufficient to conclude about it, the population density of the microorganism shall be determined in relevant environmental compartment(s) (e.g. soil, water, plant surfaces).

ENDPOINT_SUMMARY.ExpressionInSoil		
Name	**Instructions**	**Data type**
Administrative data	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.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint (multiple) Display: Basic
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration	Text (rich-text area) Display: Basic

	- other contextual information on the origin of the key value	
Additional information	Additional information – common block	Header 1

Expression in a Terrestrial Environment – Endpoint Study Record

Section 7.1.4.1 Experimental exposure data soil

Purpose

Report experimental data on density of micro-organisms in the soil.

If under consideration of the information provided under points 7.1.1, 7.1.2, 7.1.3 and 7.2 of Commission Regulation (EU) 1439/2022 a potential risk is identified for humans or non-target organism(s) or information is not sufficient to conclude about it, the population density of the microorganism shall be determined in relevant environmental compartment(s) (e.g. soil, water, plant surfaces).

ENDPOINT_STUDY_RECORD.ExpressionInATerrestrialEnvironment		
Name	**Instructions**	**Data type**
Administrative data	Administrative data – common block https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Header 1
Data source	Data source – common block	Header 1
Materials and methods	Material and methods – common block	Header 1
Test material	Test material – common block	Header 2
Study design		Header 2
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.	Block of fields (repeatable) Start
Soil no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
Soil type	Select from drop-down list.	List (picklist) Display: Basic
% 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.	Numeric range (decimal) Display: Basic
% 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.	Numeric range (decimal) Display: Basic
% Sand	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second	Numeric range (decimal)

	numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable.	Display: Basic
% 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 both numeric fields together with the appropriate qualifier(s) if applicable.	Numeric range (decimal) Display: Basic
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.	Numeric range (decimal) Display: Basic
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.	Numeric range (decimal with picklist) Display: Basic
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.	Numeric range (decimal) Display: Basic
% 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.	Numeric range (decimal) Display: Basic
Soil properties		Block of fields (repeatable) End
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.	Block of fields (repeatable) Start
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
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.	Numeric range (decimal with picklist) Display: Basic
Duration of test (contact time)		Block of fields (repeatable) End
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	Block of fields (repeatable) Start

	different parameters, the initial concentration is based on (e.g. COD and test substance).	
Soil No.	Select a consecutive soil number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
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.	Numeric range (decimal with picklist) Display: Basic
Based on	From drop-down list, select the parameter on which the initial concentration is based.	List sup. (picklist with remarks) Display: Basic
Initial test substance concentration		Block of fields (repeatable) End
Any other information on materials and methods incl. tables		Header 2
	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.	Text (rich-text area) Display: Basic
Results and discussion		Header 1
Detection of microorganism	For each soil/sediment type, indicate the microorganism detection levels for each time point.	Block of fields (repeatable) Start
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, Pesticides NAFTA or EU REACH) on how to use this field.	Check box Display: Basic
Test system no.	Select a consecutive soil/sediment number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic

Sampling date		Date Display: Basic
Microorganism detected		List (picklist) Display: Basic
Quantification	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.	Numeric range (decimal) Display: Basic
St. dev.	Enter numeric value.	Numeric (decimal) Display: Basic
Sampling time	Enter numeric value.	Numeric (decimal including unit) Display: Basic
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:'	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Detection of microorganism		Block of fields (repeatable) End
Any other information on results incl. tables	Any other information on results incl. tables – common block	Header 2
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Header 1

Expression in Water – Endpoint Summary

Section 7.1.4.2 Experimental exposure data water

Purpose

Summarise the experimental data on density of micro-organisms in water.

If under consideration of the information provided under points 7.1.1, 7.1.2, 7.1.3 and 7.2 of Part B of the Annex to Reg 283/2013 a potential risk is identified for humans or non-target

organism(s) or information is not sufficient to conclude about it, the population density of the microorganism shall be determined in relevant environmental compartment(s) (e.g. soil, water, plant surfaces).

ENDPOINT_SUMMARY.ExpressionInWater		
Name	**Instructions**	**Data type**
Administrative data	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.	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Link to endpoint (multiple) Display: Basic
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Text (rich-text area) Display: Basic
Additional information	Additional information – common block	Header 1

Expression in a Freshwater Environment – Endpoint Study Record

Section 7.1.4.2 Experimental exposure data water

Purpose

Report experimental data on density of micro-organisms in water.

If under consideration of the information provided under points 7.1.1, 7.1.2, 7.1.3 and 7.2 of Part B of the Annex to Reg 283/2013 a potential risk is identified for humans or non-target organism(s) or information is not sufficient to conclude about it, the population density of the microorganism shall be determined in relevant environmental compartment(s) (e.g. soil, water, plant surfaces).

ENDPOINT_STUDY_RECORD.ExpressionInAFreshwaterEnvironment		
Name	**Instructions**	**Data type**
Administrative data	Administrative data – common block https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Header 1
Data source	Data source – common block	Header 1
Materials and methods	Material and methods – common block	Header 1
Test material	Test material – common block	Header 2
Study design		Header 2
Test system properties	Repeat this block of fields for each different water/sediment used as indicated by the water/sediment sample number. Enter water/sediment type as cited in the study report and the respective water/sediment properties.	Block of fields (repeatable) Start
Test system no.	Select a consecutive water/sediment sample number from drop-down list if more than one water/sediment types were used.	List (picklist) Display: Basic
Test system	Select from drop-down list.	List (picklist) Display: Basic
Temperature (°C)	Report the temperature in degrees Centigrade. 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.	Numeric range (decimal) Display: Basic
Oxygen conditions	Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate.	List sup. (picklist with remarks) Display: Basic
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.	Numeric range (decimal) Display: Basic

Nutrients	Indicate any nutrients detected or added to the water / sediment.	Text (2,000 char.) Display: Basic
Sunlight	Indicate if the test system was exposed to sunlight.	List (picklist) Display: Basic
Hardness	Report the hardness to the water in the test system.	Numeric range (decimal) Display: Basic
Test system properties		Block of fields (repeatable) End
Duration of test (contact time)	Specify duration of test in terms of contact time. Repeat block for each water/sediment type. If different test runs have different durations, enter lower and upper value in respective subfields.	Block of fields (repeatable) Start
Test system no.	Select a consecutive water/sediment number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
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.	Numeric range (decimal with picklist) Display: Basic
Duration of test (contact time)		Block of fields (repeatable) End
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).	Block of fields (repeatable) Start
Test system no.	Select a consecutive soil number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
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.	Numeric range (decimal with picklist) Display: Basic
Based on	From drop-down list, select the parameter on which the initial concentration is based.	List sup. (picklist with remarks)

		Display: Basic
Initial test substance concentration		Block of fields (repeatable) End
Any other information on materials and methods incl. tables		Header 2
	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.	Text (rich-text area) Display: Basic
Results and discussion		Header 1
Detection of microorganism	For each water/sediment type, indicate the microorganism detection levels for each time point.	Block of fields (repeatable) Start
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) on how to use this field.	Check box Display: Basic
Test system no.	Select a consecutive water/sediment number from drop-down list if more than one soil types were used.	List (picklist) Display: Basic
Sampling date		Date Display: Basic
Microorganism detected		List (picklist) Display: Basic
Quantification	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.	Numeric (decimal including unit) Display: Basic
St. dev.	Enter numeric value.	Numeric (decimal) Display: Basic

Sampling time	Enter numeric value.	Numeric (decimal including unit) Display: Basic
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'	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Detection of microorganism		Block of fields (repeatable) End
Any other information on results incl. tables	Any other information on results incl. tables – common block	Header 2
Overall remarks, attachments	Overall remarks, attachments – common block	Header 1
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Header 1

Information on metabolites of ecotoxicological concern – Flexible Summary

Section 8.8 – Information and ecotoxicity of metabolites

Purpose

Summary to conclude on the toxicity of metabolites based on literature search in order to identify metabolites of concern for non-target organisms and conclude on exclusion of metabolites as being of concern.

All the metabolites of potential concern should be listed, providing further information to demonstrate whether they are of concern of not.

Identified metabolites of concern to be reported in *Flexible_Summary.Metabolites & Other Substance for Assessment* dataset (see instructions above).

FLEXIBLE.SUMMARY_InformationEcotoxicityMetabolites		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s).	Confidentiality Display: Basic

	For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	
Description of key information	This document is for Metabolites of Concern for Non-Target Organisms See SANCO/2020/12258 Guidance on the risk assessment of metabolites produced by micro-organisms used as plant protection active substances. Stage 1 and Stage 2 the collection of basic information from literature should be reported in the Biological Properties document. This document should be used to report the results of targeted literature searches for all metabolites of potential concern in order to identify 'Metabolites of Concern'. If the identity is known, complete list of metabolites of potential concern should be listed in the 'Information on Metabolites' document and for the metabolites of concern the experimental data should be provided in the linked datasets. Provide additional information from the metabolite specific literature searches which cannot be reported in the repeatable block below.	Header 1
		Text (rich-text area) Display: Basic
Metabolites		Block of fields (repeatable) Start
Link to metabolite		Link to entity (single) Display: Basic
Link to Literature Search		Link to endpoint (single) Display: Basic
Hazardous effect observed in ecotoxicology studies	If the picklist value 'no' is selected provide the justification in the remarks field. No further information is required in this table. If the picklist value 'yes' is selected complete all the information required in the table.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Non-target organisms	Where effects on non- target organisms are observed indicate the species group.	List multi. (multi-select list) Display: Basic
Conditions	Describe the conditions under which the microorganism produces the metabolite.	Text (2,000 char.) Display: Basic

LOQ of method	Any available information about the LOQ of the method used to determine/quantify the metabolite.	Numeric range (decimal with picklist) Display: Basic
Expected quantities	Any available information about the expected quantities.	Numeric range (decimal with picklist) Display: Basic
Regulation mechanism	Any available information on the mechanism by which the microorganism regulates the production of the metabolite shall be provided.	Text (2,000 char.) Display: Basic
Mode of action	Any available information on the influence of the produced metabolites on the micro-organism's mode of action against the target organism(s) shall be provided.	Text (2,000 char.) Display: Basic
Sufficient body of knowledge	Is there enough published literature to assume that a literature search would provide sufficient information on metabolite production? Make reference to the literature search included in the 'Link to Literature Search' in the table when justifying the selection of 'yes' or 'no' in the remarks field.	List sup. (picklist with remarks - 2,000 char.) Display: Basic
Remarks	Provide any other information to support the classification of this metabolite as 'of concern'.	Text (2,000 char.) Display: Basic
Metabolites		Block of fields (repeatable) End
Step 5: Is the genus of the strain under evaluation well studied?	Literature data. Is the microorganism well studied? (see step 5.1 of SANCO/2020/12258) Provide a further evaluation of the body of knowledge that includes the history of safe use, the ecology of a micro-organism in the agro-food chain or in other sectors, the scientific literature, clinical observations and reports (e.g. like infections in immunocompromised people where the microorganism has been isolated), industrial and/or medicinal applications, and other factors as considered appropriate. As a matter of principle, it is highly recommended to the applicant to conduct the search beyond the normally requested period of 10 years before the application, in order to gather all the possible relevant scientific literature to support the risk assessment.	Header 2
	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	Text (rich-text area) Display: Basic

	- 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.	
Additional information	Additional information – common block	Header 1

Links to supporting material:

https://food.ec.europa.eu/system/files/2023-06/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern.pdf

EU PPP MICROORGANISMS - ACTIVE SUBSTANCE APPLICATION WORKING CONTEXT – PRODUCT DATASET

Information on metabolites – Flexible summary

Section 1.4.1 - Information on metabolites

Purpose

This document should be used to compile the list required for Stage 2: Collecting a basic set of information on metabolites, resulting in a list of metabolites of potential concern.

Any information on potentially harmful effects of metabolites on human and animal health, the environment or on groundwater shall be included in the dossier.

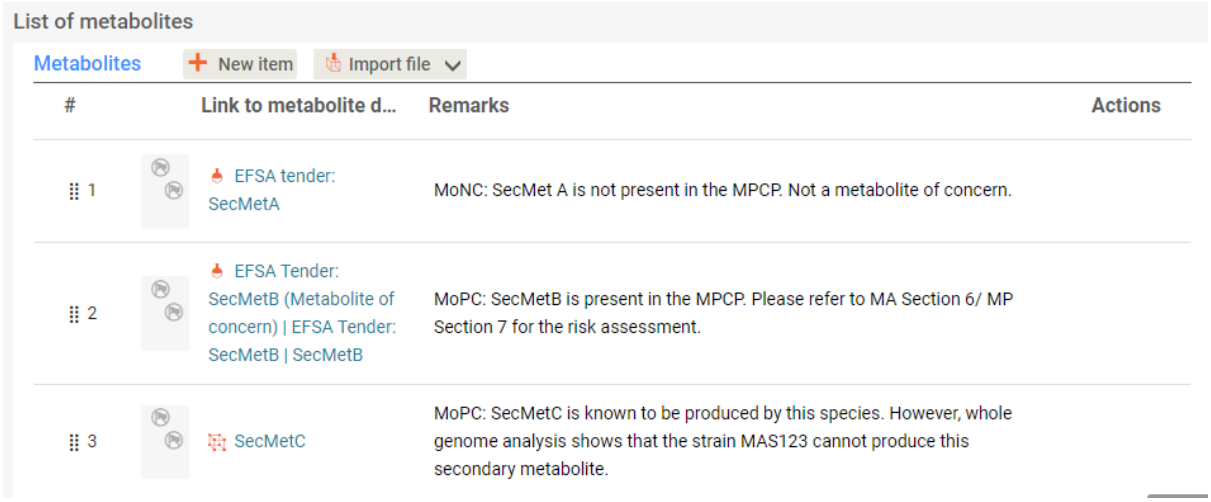
Chemical name in accordance with IUPAC and CA nomenclature, CAS-number, EC number, molecular and structural formula, molar mass should be reported.

FLEXIBLE_SUMMARY.Metabolites		
Name	**Instructions**	**Data type**
Metabolites information		Header 1
Metabolites information overview	Description of the metabolites included in the dossier.	Rich text area
Parent of metabolites	Not applicable to micro-organisms	Entity reference field
List of metabolites		Header 1
Metabolites		
	https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Confidentiality
Link to metabolite dataset	A metabolite dataset is required where further studies have been performed using a metabolite as the test material. The link must be made using a substance to create a dataset. In the dataset linked to the substance endpoint	Entity reference field

	study records and endpoint summaries can be completed in the relevant sections e.g. Toxicological and metabolism studies, Fate and behavior in the environment, Ecotoxicological studies. The Table of Contents for a metabolite is the 'Other substance' dataset. Where a metabolite is detected and reported in an endpoint study record and the test material is the active substance only a link to a reference substance is required. In both cases the IUPAC and CA nomenclature, CAS-number EC number, molecular and structural formula, molar mass should be reported in the reference substance document. SMILES and InChi are recommended.	
Remarks	Use this field to report the wording: • 'MoC', in case of metabolites identified as being of concern. • 'MoPC', in case of metabolites identified as being of potential concern. • 'MoNC', in case of metabolites identified as being of no concern	Multi-line text
Metabolites		
Additional information	Additional information – common block	Header 1

Links to supporting material:

Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances in accordance with article 77 of Regulation (EC) No 1107/2009. SANCO/2020/12258 https://food.ec.europa.eu/system/files/2023-06/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern.pdf



Efficacy Data - Endpoint Study Record

Section 6 - Efficacy data

Purpose

Information to evaluate the nature and extent of benefits that accrue following use of the plant protection product, in comparison to an untreated control and where they exist in comparison to suitable reference products and damage thresholds, and to define its conditions of use.

Sufficient data shall be submitted to confirm that patterns of use of the plant protection product tested are representative of the regions and the range of conditions likely to be encountered in the regions concerned, for which its use is intended.

The performance of the active substance against target organisms, representative for the proposed uses at the proposed dose, as well as observations on undesirable or unintended side-effects and information on the development of resistance should be presented by the applicant in the dossier, as part of study summaries for all field trials, and where appropriate, in tabular format.

Description of **Compatibility in plant protection programmes**, as requested in point 6.7 of Commission Regulation (EU) 2022/1440.

ENDPOINT_STUDY_RECORD.EfficacyData		
Field name	**Instructions**	**Data type**
Administrative data	Administrative data – common block https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf	Header 1
Data source	Data source – common block	Header 1
Materials and methods	Material and methods – common block	Header 1
Test material	Test material – common block	Header 2
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.	Display: Basic
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'. 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. 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.	List sup. (picklist with remarks)

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.	
Compliance with quality standards	**Indicate whether the efficacy data were generated according to GEP (Good Experimental Practice)** or by an officially recognised organisation. If this is not the case, enter 'no', 'no data' or 'not required' as applicable. Refer to programme-specific guidance as to the required adherence to official recognition, GEP or other quality assurance standards. In the supplementary remarks field, you can add explanations as appropriate, e.g. provide a certificate number. If required, attach any (signed and dated) certificate or quality assurance statement in field 'Attached background material'.	Display: Basic
Test material	Test material – common block	List sup. (picklist with remarks)
Formulation type	Indicate the type of formulation used in the study. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field, for instance any code for the formulation type, if required, according to programme-specific guidance.	
Analytical monitoring	Indicate whether the active substance was monitored during the test.	Display: Basic
Details on sampling and analytical methods	If the amount of test material exposed to the organisms was monitored, provide details on sampling and analytical methods used.	List (picklist)
Pest / target organisms to be controlled		
Test / target organisms	Specify the test / target organism(s) used in the study. Repeat this block of fields for specifying all organisms covered by this record. Due to the great number of possible test 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. If this template is used to summarise several efficacy studies (e.g. by attaching summary tables as described in the instructions for field 'Background information'), this block of fields can be left empty. However, if the number of different species is reasonable, you should also specify them here in addition to the summary tables. This will allow searching.	Display: Basic

Scientific name	Select appropriate scientific name from picklist. If not listed, select 'other' and specify. The EPPO database can be consulted to retrieve the scientific names of target organisms. 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 so according to programme-specific guidance.	Check box
Common name	Select appropriate common name from picklist. If not listed, select 'other' and specify; if necessary, consult the EPPO database. 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.	
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.	Display: Basic
Developmental stage of target plant	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. 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 used in analogy for the target plants.	Check box
Details on test / target organisms	Freetext template: Option 1 For single species test - Strain: - Source: - Wild type: [yes/no] - Any selection pressure (sensitivity, resistance): - Pre-conditioning / rearing conditions: - Weight at study initiation: - Age (of the stadium) at study initiation: [mixed age population / ....] - Numbers used in the test: - Sex of those used in the test (where appropriate): - Other (specify): Option 2 For test with microbial population / inoculum - Nature: - Origin: - Collection / storage of samples:	

	- Preparation of inoculum for exposure: - Pretreatment: - Initial biomass / density / numbers in test system: - Other (specify):	
Products (materials), organisms or objects to be protected / under study		Display: Basic
Organisms (to be protected) or treated materials	If applicable, describe and specify the organism(s) or materials(s) / object(s) to be protected as addressed by these efficacy data.	Check box
Study design		
Total exposure duration (contact time)	If applicable, 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.	Display: Basic
Remarks	Enter any remarks related to the total exposure duration.	Date
Mode of efficacy assessment	Freetext template: - Effects investigated: - Method for recording / scoring effects: - Intervals of examination: - Post monitoring of test organisms Describe the parameter(s) measured for assessing efficacy and the intervals of measurements, together with the scoring or assessment system used. Where appropriate, describe the duration of post monitoring of test organisms. Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary.	
Method of application	Indicate the method of application. If not listed, select 'other' and specify. Any remarks can be entered in the supplementary remarks field.	Display: Basic
Details on study design	Option 1 Optional items for laboratory studies FURTHER DETAILS ON APPLICATION - Application/dosage and dilution rates (incl. dose justification): - Adjuvans/vehicle/carrier: - Presence of interfering substances:	Date

	- Other (specify) MONITORING OF TEST SUBSTANCE - Monitoring of active substance concentration: - Method of analysis: TEST CHAMBER / DEVICE - Type and design of test chamber / device: - Other (specify) SURFACE TYPES - Type: [porous, non-porous] TEST CONDITIONS - Temperature: - Rel. humidity: - Aeration: - Light cycles during test: - pH: - Water hardness: - Soil type: - Nutrient supply conditions: - Any additions or alterations to the test environment during the study: - Other (specify) INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS - Initial density / numbers in test system: - Frequency or level of infestation / infection: REPLICATES - Number of replicates: CONTROLS - Untreated controls: - Positive controls (reference substance): OTHER (specify): Option 2 Optional items for field and use tests APPLICATION - Type/method of application: - Code of application type (if any): - Application rates: More than one application rate can be needed. Number and timing of applications have to be stated. The water volume/ha should also be stated. - Application/dosage and dilution rates (incl. dose justification):	

	- Adjuvans/vehicle/carrier: - Other (specify) EXPERIMENTAL DESIGN - GEOGRAPHICAL LOCATION - For efficacy evaluation the EPPO climatic zones should be mentioned TEST CONDITIONS / METEOROLOGICAL INFORMATION INITIAL DENSITY/NUMBERS OF TARGET ORGANISMS - Initial density / numbers in test system: - Frequency or level of infestation / infection: REPLICATES - Number of replicates: CONTROLS - Untreated controls: - Positive controls (reference substance): OTHER (specify):	
Any other information on materials and methods 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, 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.	
Results and discussion		Display: Basic
Efficacy / performance assessment	If possible, indicate the percentage of efficacy in terms of control, reduction, damage of target organisms or reduction of disease caused by pest organisms. Copy this field block for entering more than one efficacy level (e.g. based on other exposure duration, dose or endpoint) if necessary. Note: It may be appropriate to record, in this block of fields, only the mean level of effect or control. If the effect level relates to several test runs (i.e. test conditions), give ranges.	Text (255 char.)
Efficacy parameter	Indicate the efficacy / performance parameter (e.g. % kill/cidal activity) to which the index entered in the next field refers to.	
Efficacy (in %)	Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'.	Display: Basic

	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.	
Time to produce effect	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.	List (picklist)
Treatment	If efficacy results are recorded for different treatment conditions (by repeating this block of fields), briefly indicate the type of treatment/application the results refer to. Specify dose, application rate, duration, etc.	
Interfering substances	Indicate if interfering substances were present. If 'yes' is selected, briefly specify in the supplementary remarks field.	Display: Basic
Remarks on result	- not determinable - not determinable because of methodological limitations - not measured/tested - other: 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:'.	List sup. (picklist with remarks - 32,000 char.)
Minimum effective dose	If determined, provide the minimum effective dose, i.e. the dose or concentration considered the minimum necessary to achieve sufficient efficacy against the target organism(s) studied under the treatment conditions indicated. Copy this field block for recording values based on different treatment conditions if necessary	
Minimum effective dose	Enter minimum effective dose.	Display: Basic
Time to produce effect	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.	List (picklist)
Treatment	If efficacy results are recorded for different treatment conditions (by repeating this block of fields), briefly indicate the type of treatment/application the results refer to. Specify dose, application rate, duration, etc.	
Interfering substances	Indicate if interfering substances were present. If 'yes' is selected, briefly specify in the supplementary remarks field.	Display: Basic

Remarks on result	- not determinable - not determinable because of methodological limitations - not measured/tested - other: 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:'.	List multi. (multi-select list with remarks - 32,000 char.)
Details on results	RESULTS - Effects observed: - Dose/concentration dependence of effects: - Begin and duration of effectiveness: - Observed effects in post-monitoring phase: - Reinvasion/reinfestation: - Existence of threshold concentration: - Other: REPORTED STATISTICS: REFERENCE SUBSTANCE - Results with reference substance: - Results with reference substance valid Summarise any relevant results. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report, upload predefined table(s) in the rich text field 'Any other information on results incl. tables' or attach graphs in field 'Attached background material'. Note: Observed limitations on efficacy in terms of resistance, undesirable or unintended side effects, or other limitations should be described in the corresponding fields below.	
Observed limitations on efficacy		Display: Basic
Indication of resistance	Indicate whether any development of resistance was observed or not. In below field 'Details on development of resistance', give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Text template

Details on development of resistance	Provide details on the development of resistance as observed in the efficacy study(ies), including any evidence of cross-resistance.	
Undesirable or unintended side effects	Indicate whether any undesirable or unintended side effects were observed or not. In below field 'Details on undesirable or unintended side effects', give details or provide any further explanation, e.g. stating that effects were observed, but considered negligible. Select 'not examined' or 'no data' as applicable.	Display: Basic
Details on undesirable or unintended side effects	Provide details on undesirable or unintended side effects as observed in the efficacy study(ies). Where appropriate or required by the relevant legislation, insert subheadings, e.g.: -Adverse effects on plants - Adverse effects on health of host animals - Adverse effects on site of application (e.g. discoloration, corrosion, etc.) - Adverse effects on beneficial and other non-target organisms - Adverse effects on objects to be protected:	Block of fields (repeatable) Start
Other limitations observed	Where there is evidence of other possible limitations as derived from the study results, describe the relevant factors that can possibly reduce the efficacy, e.g. certain climatic or edaphic conditions.	Attachment (single)
Compatibility in plant protection programmes	Where the use conditions include other plant protection products in tank mix, spray sequences or other relevant types of applications - Indicate potential effects on the activity of the product after mixing, spraying in sequence - Possible loss of efficacy due to interaction in tank mix, spray sequences - Intervals between applications to avoid negative effects - Potential adverse effects on natural enemies, non-target arthropods, conservation biological control.	Text
Relevance of study results	For laboratory studies, provide arguments for performing such studies instead of a field test. If a study was conducted in a reduced scale, the dimension should be given as compared to the actual scale of the product (e.g. 'Test was reduced to a scale of 1:100'). If the study or studies summarised in this record were conducted with another formulation type or application method, provide a justification for this read-across through either the provision of a	Display: Basic

	reasoned case based on data or through bridging arguments. Use freetext template and delete/add elements as appropriate.	
Any other information on results incl. tables	Any other information on results incl. tables – common block	List sup. (picklist with remarks)
Overall remarks, attachments	Overall remarks, attachments – common block	
Applicant's summary and conclusion	Applicant's summary and conclusion – common block	Display: Basic

Links to supporting materials:

https://www.julius-kuehn.de/en/jki-publication-series/bbch-scale/

EPPO standard series PP1: Efficacy evaluation of plant protection products https://pp1.eppo.int/

EPPO global database: Scientific names and EPPO codes for target organisms https://gd.eppo.int/taxon/

Assessment of potential toxicity – Flexible summary

Section 7.2 - Assessment of potential toxicity of the plant protection product

Purpose

Summary to conclude on the absence of toxicity of the plant protection product to humans, including links to relevant toxicological studies and literature search and using weight of evidence (WoE) approach as described in EFSA Scientific Committee, 2017.

FLEXIBLE_SUMMARY.AssessmentOfPotentialToxicity		
Name	**Instructions**	**Data type**
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page.	Confidentiality Display: Basic
Assessment of potential toxicity	Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S,	Header 1

	Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017 EFSA Journal 2017;15(8):4971, 69 pp. First published: 03 August 2017 https://doi.org/10.2903/j.efsa.2017.4971	
	Conclude on potential toxicity of the plant protection product based on the lines of evidence presented below.	Text (rich-text area) Display: Basic
Assembling evidence	Link to any literature searches for evidence on toxicity.	Link to endpoint (multiple) Display: Basic
Weighing evidence		Block of fields (repeatable) Start
Description of key conclusion for the study	Include consideration of the relevance and reliability of the study.	Text (32,768 char.) Display: Basic
Identified uncertainties		Text (32,768 char.) Display: Basic
Link to relevant study record	Link to the endpoint study describing the supporting evidence.	Link to endpoint (single) Display: Basic
Weighing evidence		Block of fields (repeatable) End
Integrating evidence		Header 2
Sufficient information to classify the product	Based on the evidence presented above conclude on whether or not sufficient information is available to classify the plant protection product in accordance with Regulation (EC) No 1272/2008 with regard to toxicity to humans and whether or not acute toxicity studies on animals are needed.	List sup. (picklist with remarks) Display: Basic
Additional information	Additional information – common block	Header 1

Links to supporting material:

EFSA Scientific Committee, Hardy, A, Benford, D, Halldorsson, T, Jeger, MJ, Knutsen, HK, More, S, Naegeli, H, Noteborn, H, Ockleford, C, Ricci, A, Rychen, G, Schlatter, JR, Silano, V, Solecki, R, Turck, D, Benfenati, E, Chaudhry, QM, Craig, P, Frampton, G, Greiner, M, Hart, A, Hogstrand, C, Lambre, C, Luttik, R, Makowski, D, Siani, A, Wahlstroem, H, Aguilera, J, Dorne, J-L, Fernandez Dumont, A, Hempen, M, Valtueña Martínez, S, Martino, L, Smeraldi, C, Terron, A, Georgiadis, N and Younes, M, 2017. Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. https://doi.org/10.2903/j.efsa.2017.4971

Literature Search – Flexible record

Section 13 - Literature Data

See instructions above in the **active substance dataset**.

REFERENCED ENTITIES AND COMMON BLOCKS

Reference substance

Purpose

A 'Reference substance' entity enables you to store identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc.), identity codes (EC number, CAS number), molecular and structural information.

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	Data Type
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant". **Important:** Setting this flag ensures that substance identity is not published in any IUCLID document where a link to the reference substance is used. This should be used for confidential substances included mixture or substance composition documents.	Confidentiality
Reference substance name	Indicate 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
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 **micro-organisms** the scientific name (species and strain) should be reported in this field.	Multi-line text

Description	Specify any additional information relevant for the description of the reference substance in this field For **micro-organisms** 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	Text template
Inventory		Header 1
Inventory number	This field can be used to select existing substances with pre-assigned EC numbers.	Entity reference list
No inventory information available - Justification	Not relevant for EU PPP	Open list with remarks
CAS number	Indicate CAS Registry Number	Text
CAS name	Indicate CAS name	Multi-line text
CIPAC number	Indicate CIPAC number	
Synonyms		Header 1
Synonyms	Provide in this table synonym identifiers of the reference substance, as appropriate. 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.	
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
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
Identity	Enter here the identity (name, number, code) corresponding to the identifier type selected.	Text area
Remarks	Provide additional information if relevant	Text

Molecular and structural information		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
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 bottom of the section)	Multi-line text
Molecular weight	Molecular weight should be reported as a single numeric value	Range (Decimal)
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
InChI	The IUPAC international chemical identifier https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	Multi-line text
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image
Remarks	Provide additional information if relevant. Such information may for example include an explanation to why molecular and structural information could not be provided due to the nature of the substance.	Text area
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	
Structure file	Select file to be attached	Single file attachment
Remarks on structure file	Provide additional information if relevant.	Text
Related substances	Not relevant for EU PPP	Header 1
Identifier	Not relevant for EU PPP	Open list
Identity	Not relevant for EU PPP	Text area
Remarks	Not relevant for EU PPP	Text
Relation	Not relevant for EU PPP	Open list
Group / category information	Insert information about chemical groups and categories the substance belongs to.	Multi-line text

Links to supporting material:

CIPAC number: https://cipac.org/index.php/code-numbers/navigate-code-numbers

https://www.cas.org/support/documentation/chemical-substances

http://doi. paramCode - European Food Safety Authority. (2020). Harmonized terminology for scientific research [Data set]. Zenodo. 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/

https://iuclid6.echa.europa.eu/inventories-iuclid

Legal entity

Purpose

Submissions require a Legal entity which must 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.

A legal entity should identify in an unambiguous manner a company or organisation with a role in the submission of dossiers. The submissions attributed to a specific company/applicant should all have the same legal entity. The same applies to third party consultants, they should also maintain a unique legal entity that can be included in the 'Third Party' field.

Information provided in the Legal entity should be similar to that provided in a publicly accessible company register. It should contain the address and contact details, including fax and phone number as well as e-mail address, of the legal person.

Note: information provided in the Legal Entity is published. Hence, no personal information relating to natural persons should be provided under these fields.

Note that information regarding the Contact person is to be managed in the Contact entity manager. The information provided in the Contact entity is by default not published.

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.

Name	Instructions	Data Type
General information		Tab
Legal Entity name	Indicate name of the legal entity i.e. Company name	Text
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	List (picklist)
Remarks	Add any additional information on the legal entity, if relevant	Text
Other names		Block of fields

		(repeatable)
Name	Other names can be specified and if needed these names can be marked as confidential	
Address		Header 1
	See Confidentiality Requests	Confidentiality
Address 1	Street address of the legal entity	Text
Address 2	Secondary address, if relevant	Text
Postal Code	Postal code of the legal entity	Text
Town	Town of the legal entity	Text
Region/State	Region/State of the legal entity	Text
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.	List (picklist)
Phone	Phone number of the legal entity (this field must not contain personal data, therefore e.g. the number of a switchboard should be provided)	Text
Fax	Fax number of the legal entity (this field must not contain personal data)	Text
Email	Email address of the legal entity (this field must not contain personal data, therefore e.g. the email address of a functional mailbox should be provided)	Text
Website	Legal entity website	Text
Legal entity 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 Confidentiality Requests.	Tab
Contact information	See instructions reported below under "Contact entity" common block	Tab

Links to supporting 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

Contact entity

Note: contact entities must never be claimed confidential (using the confidentiality flags in the documents where they are referenced) because they are not published by default.

Name	Instructions	Data Type
General information		Header 1
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
Last name	Last name of the contact person. Note that this field is mandatory	Text
First name	First name of the contact person.	Text
Organisation	Name of the Organisation. Note that this field is mandatory	Text
Department	e.g. scientific department.	Text
Title	Title of the contact person (e.g. Mr.).	Text
Phone	Phone number of the contact person.	Text
Mobile	Mobile phone number of the contact person.	Text
Fax	Fax number of the contact person.	Text
Email	Email address of the contact person.	Text
Address 1	Street address of the contact person.	Text
Address 2	Secondary address, if relevant	Text
Postal code	Postal code of the street address of the contact person.	Text
Town	Town of the contact person.	Text
Region / state	Region/State of the contact person.	Text
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
Remarks	Any additional information, if relevant.	Text area

Literature reference

Purpose

The literature Reference entity should be used for storage of bibliographic metadata with attached documents including full study reports and published scientific papers and for linking studies to the Notification of Studies Database.

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).The literature Reference entity should always be linked in the "data source" section of Endpoint Study Records.

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 in the relevant section of this manual. 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 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.

Name	Instructions	Data Type
General information		Header 1
Reference Type	Select 'study report' for a full study report used as a data source for an endpoint study record. Select 'publication' for relevant studies identified from a literature search to address data requirements. Select 'other company data' to characterise any unpublished information from a company other than a study report. For any other select 'other:' and specify. **Only** in case of a publication already available to the public (studies published in scientific journals or similar publications) but subject to access restrictions (e.g. upon payment of a fee) for which the applicant does not have or cannot obtain IPRs for the purposes of the proactive public disclosure requirements, select 'publication (copyright not owned for reproduction)'.	Open list
Title	Report title of the study report, publication or other report type	Text
Author	Report author names for the study. These will be redacted from the published dossier for unpublished toxicology studies.	Multi-line text
Year	The year the report must be reported (this is used for sorting and filtering)	Integer
Bibliographic source	For published studies information on the journal and edition should be completed. This should include the DOI (Digital Object Identifier)	Text
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
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
Report number	Specify the report number allocated by the testing laboratory. This information will not be published for studies involving tests on vertebrate animals.	Text
Study sponsor	Information on the source of funding of the study can be provided	Text

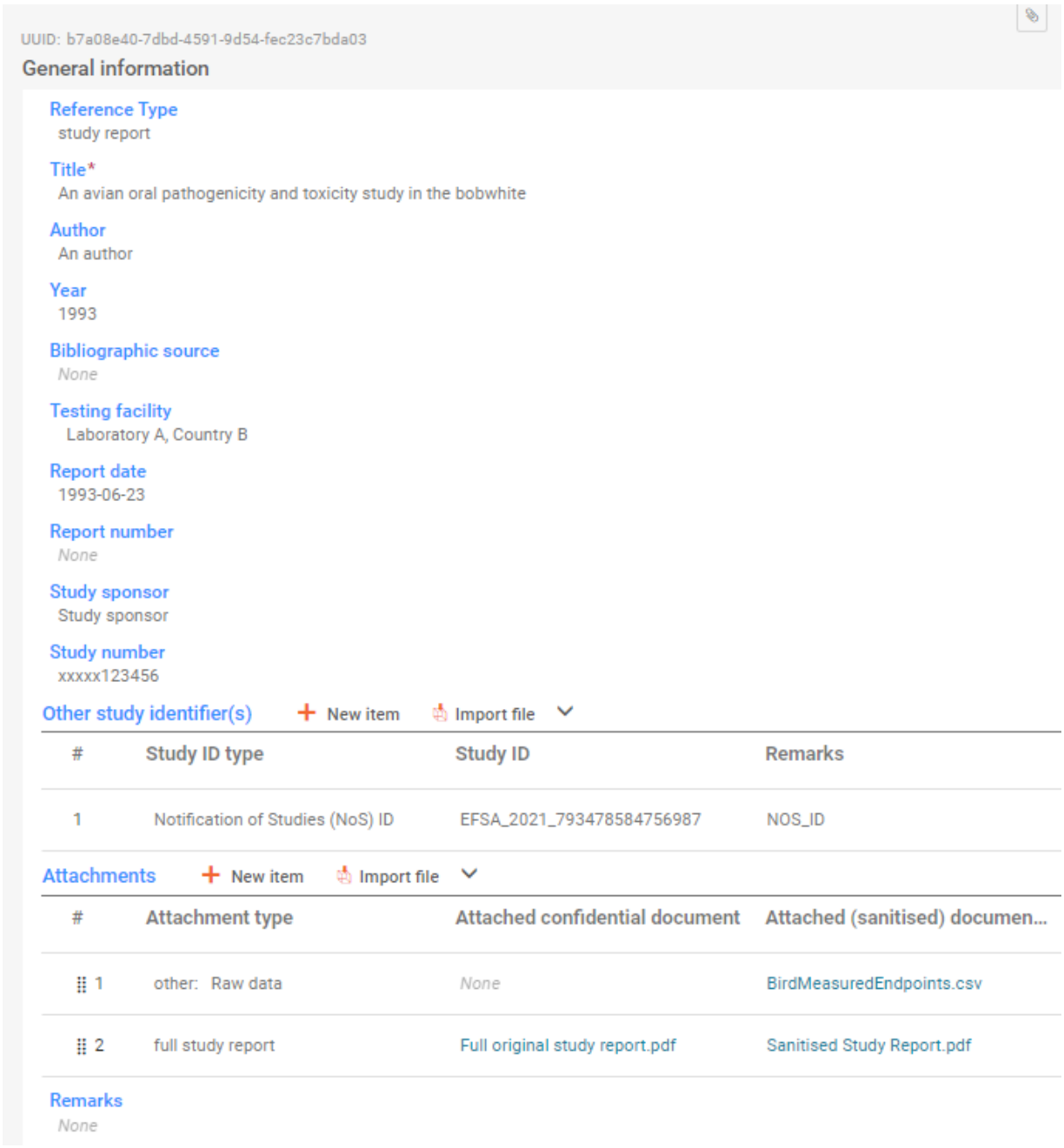
Study number	Report the company identifier, if it differs from the laboratory report number	Text
Other study identifier(s)	Applies to study reports. When other study identifiers are available e.g. NOS number or MAP number, click on 'New item' and compile relevant fields accordingly.	
Study ID type	For all studies carried out or commissioned after March 2021 for which the study notification requirement applies: - Select 'Notification of studies (NoS) ID and report the NoS ID in the 'Study ID' field below. For studies carried out or commissioned before March 2021 Select 'Notification of studies (NoS) ID and provide a justification for not providing a NoS ID in the 'Remarks' field e.g. "Study was commissioned before 27 March 2021". For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is already available in the existing collections of maps (and therefore is not attached to the dossier), select 'other' and specify "Unique Individual MetaPath File Number (MAP-number/card number)" in the free text field. Optionally, if a Master Record Identification (MRID) is available for the existing MSS/DER composer file, create an additional item and select "Master Record Identification (MRID)". - If a MSS/DER composer file is not available in the collection of maps and is submitted within the dossier, leave this field empty.	Open list
Study ID	Report the relevant identification number (e.g. the NoS ID generated from the NoS database).	Text
Remarks	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'.	Text area
Attachments		Header 1
Attachment type	Select 'full study report' to identify the original study report. Only one set of attachments (original and sanitised) can be set to 'full study report'.	Open list

	Use 'other' to indicate the type of content of the other sets of attachments e.g. addendum. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for this dossier (because it was not available in the existing collections of maps),.select "other" and specify "MSS composer file" or "DER composer file". - if a MSS/DER composer file is already available in the existing collections of maps, only the reference to the Individual MetaPath File Number (MAP-number) is required (cf. above instructions in "Other study identifier(s)").	
Attached confidential document	If the applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType", a full copy of the relevant publication in PDF format needs to be provided under the field "Attached confidential document". For the purposes of proactive publication, it is sufficient to provide the following bibliographic metadata in the literature reference entry enabling the retrieval of the published literature online: title, author, year and bibliographic source . No public version of the published literature must be provided. If the applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType",the original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field, (a) confidentiality claim(s) must be submitted for each part of the file considered confidential via the related endpoint record and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for the dossier (because it was not available in the existing collections of maps) the newly created MSS/DER composer file should be attached here. - if a MSS/DER composer file is already available in the existing collections of maps it is not required to be attached here.	Single file attachment

Attached (sanitised) document for publication	The applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType": Only a citation including the abstract of the relevant publication should be uploaded in this field. The uploaded attachment will be included in the published dossier. The applicant has not selected the option "publication (copyright not owned for reproduction)" from the drop-down list pertaining to the field "GeneralInfo.ReferenceType": any document uploaded here must be uploaded in their public (non-confidential) version. The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here. Other supporting documentation e.g. addendum can be uploaded. For rat/plant/livestock metabolism studies: - if a MSS/DER composer file is newly created for the dossier (because it was not available in the existing collections of maps) and confidentiality requests are made on the MSS.xml /DER.xml file (regarding confidential business information (CBI) or personal data (PD), a sanitised pdf version of the word report generated from the MSS/DER render function, where the items for which a confidentiality request has been submitted are blackened, must be attached here (in case no confidentiality requests are submitted with regard to the MSS.xml /DER.xml file a pdf version without blackening for proactive publication must be attached here). - if a MSS/DER composer file is already available in the existing collections of maps it is not required to be attached it here.	Single file attachment
Remarks	Additional remarks on the uploaded literature reference content can be added here. **Note**: if an applicant provides a sanitised/public attachment which contains personal data (and this is not an issue because the document is already publicly available), this should be mentioned in the Remarks field to avoid misunderstanding.	Text

Links to supporting material:

Practical arrangement for Notification of studies: https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation



UUID: b7a08e40-7dbd-4591-9d54-fec23c7bda03

General information

Reference Type
study report

Title*
An avian oral pathogenicity and toxicity study in the bobwhite

Author
An author

Year
1993

Bibliographic source
None

Testing facility
Laboratory A, Country B

Report date
1993-06-23

Report number
None

Study sponsor
Study sponsor

Study number
xxxxx123456

Other study identifier(s) + New item Import file

#	Study ID type	Study ID	Remarks
1	Notification of Studies (NoS) ID	EFSA_2021_793478584756987	NOS_ID

Attachments + New item Import file

#	Attachment type	Attached confidential document	Attached (sanitised) documen...
1	other: Raw data	None	BirdMeasuredEndpoints.csv
2	full study report	Full original study report.pdf	Sanitised Study Report.pdf

Remarks
None

Test material

Purpose

For the **product**: A detailed description of the composition used shall be provided.

Chemicals: 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.

In case of renewals, 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.

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)

Micro-organisms: Where studies are conducted using micro-organisms produced in the laboratory or in a pilot plant production system, the studies must be repeated using micro-organisms as manufactured, unless it can be demonstrated that the test material used is essentially the same for the purposes of the testing and assessment

Name	Instructions	Data Type
Name	Indicate number of the batch	Multi-line text
Composition		Header 1
Type	Indicate for each component if it is a constituent, impurity or additive.	Closed list
Reference substance	Link to the reference substance for the component.	Entity reference field
Concentration	Indicate concentration of the component. For the chemical active substance and impurities this should be in g/kg.	Range with open list (Decimal)
Remarks	Specific remarks related to the concentration of the component can be reported in this field.	Multi-line text
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
Other characteristics		Header 2
Test material form	Select the form of the test material.	Open list with remarks (2000)
Details on test material	Provide the expiry date. Differences between non-radio labelled and radio labelled can be indicated in this field.	Text template

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

Links to supporting material:

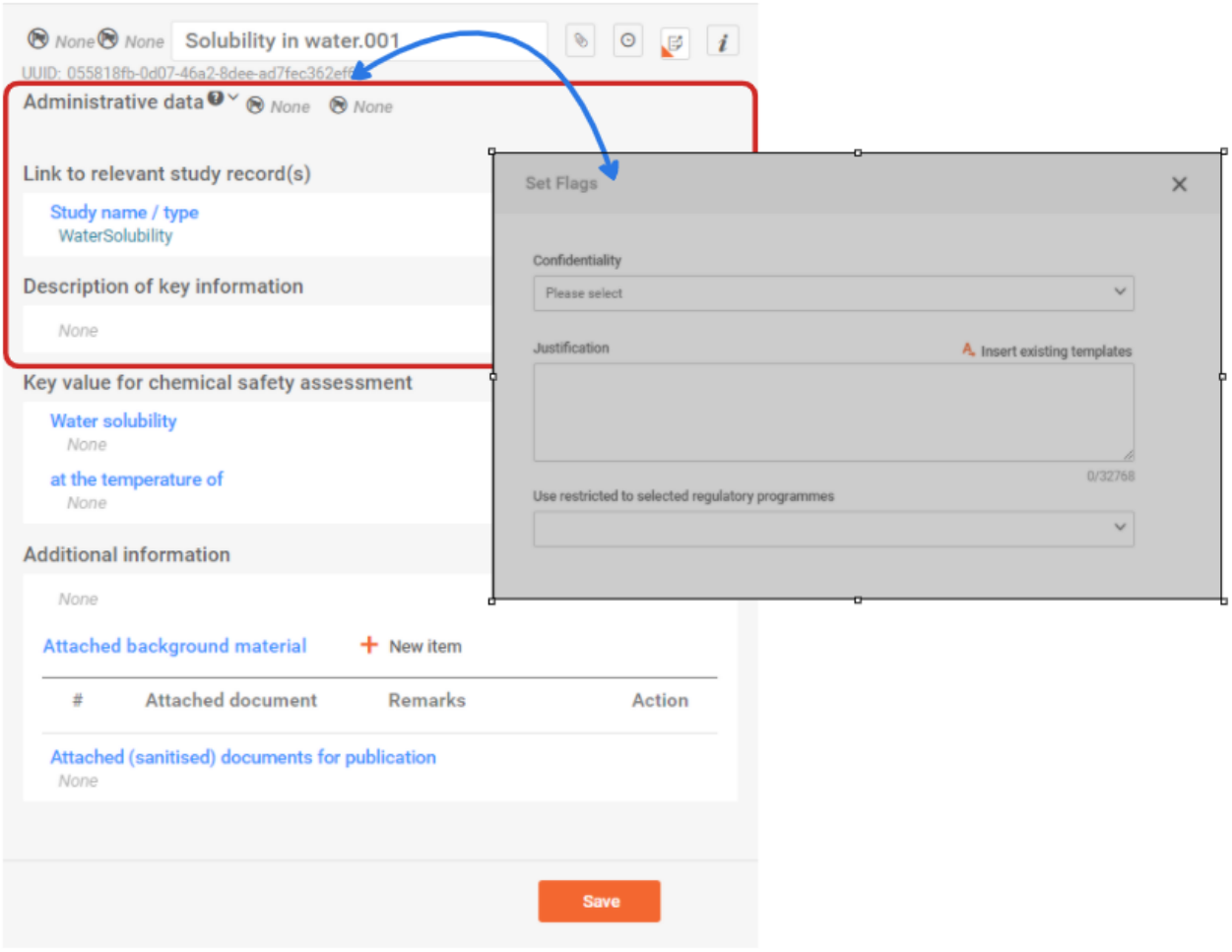
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_guidance_equivalence-chem-substances_en.pdf

Template 1.1– Template for presentation the assessment for the equivalence of batches (https://doi.org/10.5281/zenodo.4557366)

Endpoint Summaries – Common blocks

Administrative data

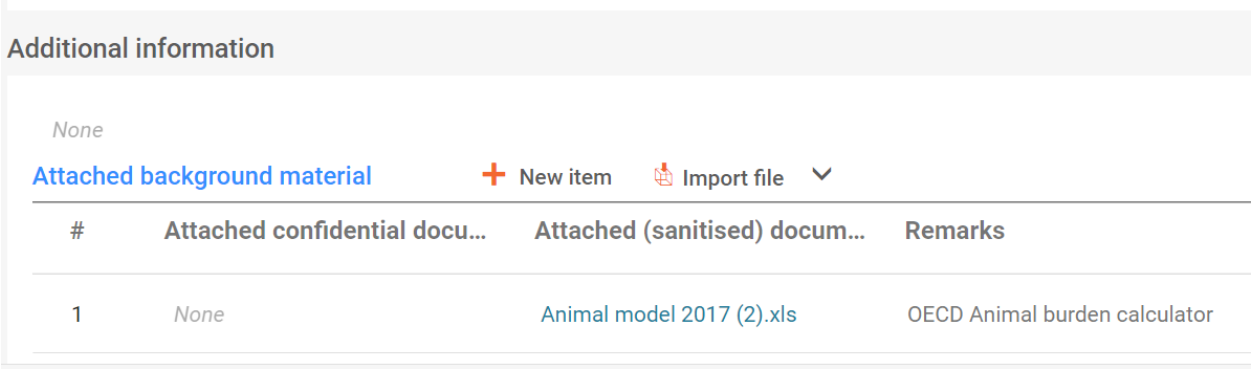
Name	Instructions	Data Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see: "User Guide: submission of confidentiality requests" available under the IUCLID software section of the Toolkit page"	Confidentiality
Link to relevant study record(s)		Header 1
Link to relevant study record(s)	Provide here the link(s) to the study record(s) supporting the choice of the key value for assessment. The study(ies) giving rise to the highest concern should be chosen. The following factors, among others, should be taken into account when the study record is selected: quality of the study (e.g. Klimisch score), type of study (e.g. duration, experimental design, observed effects), whether or not the study is GLP. Please provide your rationale for the selection of the relevant study record in the field "Additional information".	Cross-reference: ENDPOINT_STUDY_RECORD.AnalyticalMethods
Description of key information		Header 1
	If all key information is provided in the linked study records, this field can be left empty. In case there is no linked study record, or in case you want to point to specific information in the linked study record, provide a summary of the key information related to the studies here. The summary could include, for example: - the test type - the test guideline used (and any deviations from it) - the test organism - the exposure duration - other contextual information on the origin of the key value	Rich text area



Additional information

Name	Instructions	Data Type
Additional information		Header 1
	Provide information related to the assessment of the endpoint, for example: - any endpoint specific information relevant for the interpretation of the results - the rationale for the choice of the key study(ies) and the choice for the key value that characterises the endpoint - information on the potential data gaps and the quality of the whole database for this endpoint - relevance of the results for the risk assessment (e.g. in case no effects have been observed at the limit dose) - the rationale for any user-derived values for the key result for assessment (for example, if a corrected value or a geometric mean is reported) - any additional information such as epidemiological data or higher tier testing	Rich text area

	(e.g. mesocosm studies or field studies) when relevant If there is no additional information to be reported, this field may be left empty.	
Attached background material		
Attached confidential document	Provide any additional documents relevant for the assessment of the endpoint, for example, a scientific publication. Provide the original version of any document that contains confidential material.	Single file attachment
Attached (sanitised) documents for publication	If required, public (non-confidential) versions of other relevant documents can be attached. These attachments should be sanitised, if needed.	Single File Attachment
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
Attached background material		



Endpoint studies – Common blocks

Administrative data

Name	Instructions	Data Type
Administrative data		Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). For further information see "Confidentiality of dossiers submitted via IUCLID - practical instructions for applicant".	Confidentiality
Endpoint	From the picklist select the relevant endpoint addressed by this study summary. An endpoint must always be selected when entering data into an Endpoint Study Record. In some cases, there is only one endpoint title, which may be entered automatically depending on the software application. If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>, other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT). Please note: For (Q)SAR studies, if an 'in silico' option does not exist, the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint. Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study.	Closed list with remarks
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

Adequacy of study	Indicate the purpose of the record selecting the adequacy in terms of usefulness for fulfilling the information requirements for the 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.	Closed list
Robust study summary	Set this flag if relevant for the respective regulatory programme. It is used 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.	Check box
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. Not relevant for micro-organisms since they do not fall under the CLP Regulation.	Check box
Used for SDS	Not relevant for EU-PPP	Check box
Study period: start date	Indicate the start date of the study. Note: for 'Notified' studies this should be after the date of notification.	Text
End date	Indicate the end date of the study	Text
Remark	Add remarks if relevant	Text
Reliability	The term reliability defines the inherent quality of a test report or publication. In field Reliability, enter a reliability score as judged at your discretion, i.e. 1 (reliable without	Open list

	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. 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. The deviations from the guideline should be described in 'Test guideline' section but the impact of these deviations should be considered in the rationale for reliability. When assessing an older study against the current guideline, the current guideline can be specified in this field. 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)
Data waiving	If no 'key study' or 'weight of evidence' study is provided for a data requirement, then data waiving must always 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
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 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'.	Multi select open list with remarks (32000)

	If you select the option 'Other' you need to indicate the type of data waiving you are submitting 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
Attached justification		Header 2
Attached justification	A document can be uploaded to support data waiving, but it is recommended to complete in full the data waiving fields. Upload file by clicking the upload icon.	Single file attachment
Reason / purpose	Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify.	Closed list with remarks
Cross-reference	In case the study has been reported for another data requirement use cross reference to link to the study to this section. The creation of duplicate versions of endpoint studies should be avoided. Cross reference should be used to link to an 'Analytical Methods' document when a specific method is used in a study. This allows an overview of methods used in different studies e.g. toxicology and ecotoxicology.	
Reason / purpose for cross-reference	Select the appropriate reason of the cross-reference, i.e. - adverse outcome pathway (AOP) (in case the 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) - data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver) - defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver) - read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)	Open list with remarks

	- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary) - (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.) - reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay) - reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified).	
Related information	As appropriate, select the record containing the related information, thus creating a link.	Endpoint reference field
Remarks	If relevant, add remarks	Text area

Links to supporting material:

Appendix to: EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092. 49 pp. doi:10.2903/j.efsa.2011.2092

https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf

Administrative data None EU: PPP

Endpoint
stability of residues in stored commodities

Type of information
experimental study

Adequacy of study
key study

☑ **Robust study summary**

☐ **Used for classification**

☐ **Used for SDS**

Study period
6. April 1993 - 27. April 1995

Reliability
1 (reliable without restriction)

Rationale for reliability incl. deficiencies
guideline study

Data waiving
None

Justification for data waiving
None

Justification for type of information
None

Reason / purpose for cross-reference
reference to other study
Validation data for the analytical method(s) used in the present study

Related information
AnalyticalMethods (Endpoint Study Record) | 4.1.1 NEW_Adolph S. (2013)

Remarks
None

Data waiving
other justification

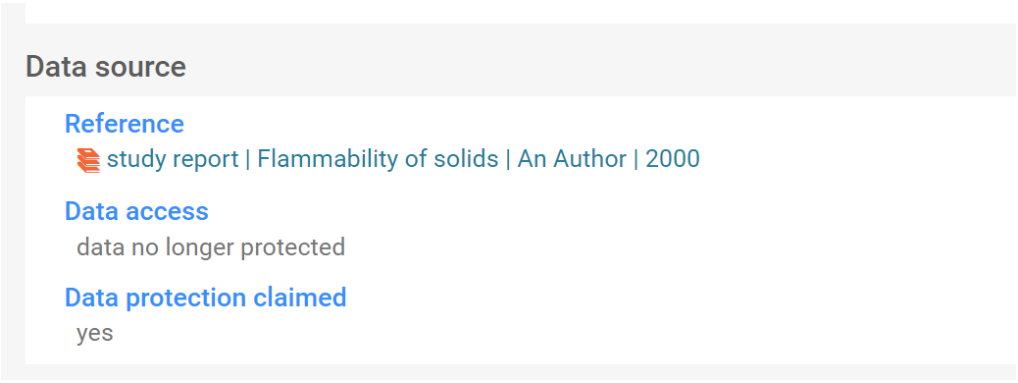
Justification for data waiving
✓ other: Study not needed due to the use described in the GAP document

Data source

Name	Instructions	Type
Data source		Header 1
Reference	Link to **Literature reference** Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as the Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc. as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there is more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of the publication(s) in addition to the reference of the original study.	Literature reference list
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.	Open list with remarks
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 refer to a document attached that provides justification (e.g. 'for justification see attached document X') Note that this field is always published so do not put any confidential data in it.	Closed list with remarks

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 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.



Material and methods

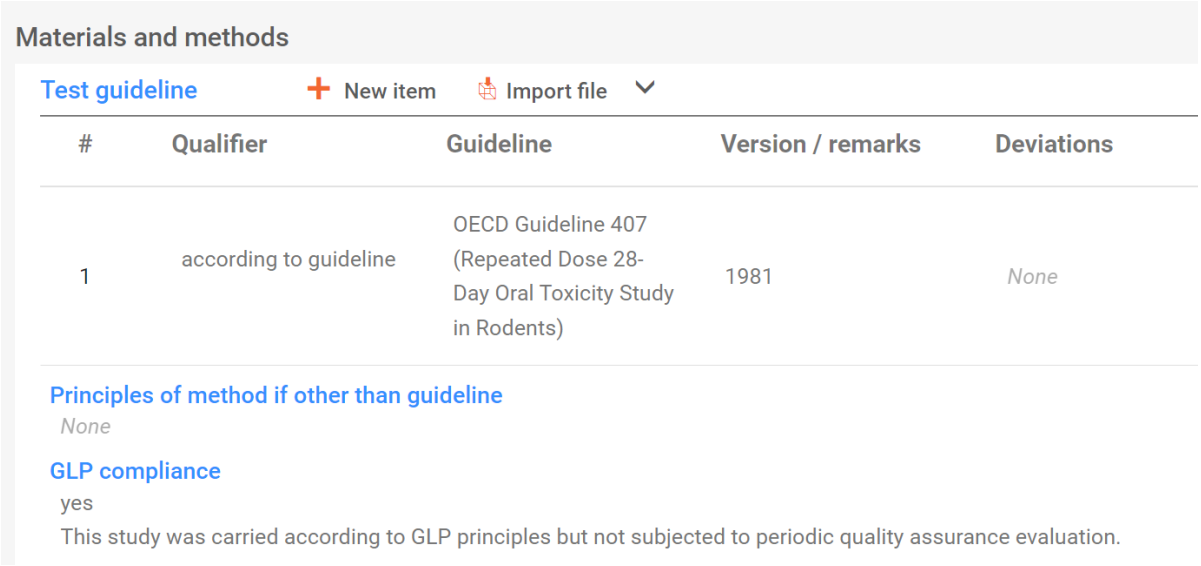
Name	Instructions	Type
Test guideline	Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'. Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline).	Header
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	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	Open list

	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'.	
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.	Multi-line text
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.	Closed list with remarks
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. 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
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
Other quality assurance	Indicate any non-GLP quality assurance system adhered to, if any.	Open list with remarks

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

Links to supporting material:

GEP https://www.eppo.int/ACTIVITIES/plant_protection_products/gep



Test material

Name	Instructions
Test material	All Test Material batches should be entered in the TM entity manager and then the appropriate TM should be selected.
Test material information	Select the appropriate Test material
Additional test material information	Select additional Test material i entities if relevant. For example, in long term studies where more than one batch of test material has been applied or there may be differences between the labelled and unlabelled test materials.
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. The determination shall also include quantities of unknown materials, if any, to account for 100% of the sample 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., 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 - 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 characterizing 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 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., 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 - 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 characterizing the tested material.

Test animals

Name	Instructions
Test animals	
Species	Select species as appropriate. If not available from picklist, select 'other' and specify.
Strain	Select strain as appropriate. If not available from picklist, select 'other' and specify.
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.
Sex	Select as appropriate. If females were used, indicate in field "Details on test animals and environmental conditions" whether nulliparous and non-pregnant.
Details on test animals or test system	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

and environmental conditions	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).

Test animals

Species
rat

Strain
other: Tif RAIf

Sex
male/female

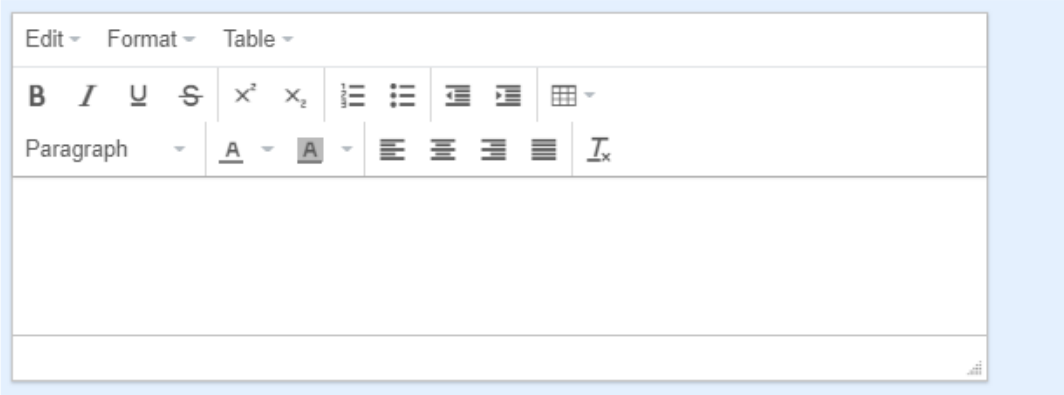
Details on test animals or test system and environmental conditions
Weight at study initiation: 166-227 g
Source: xxx
Initial age: 7-8 weeks
Husbandry: Caging in Macrolon cages type 4 (5 animals per cage) with standardized soft wood bedding. The animal room was air conditioned:
Temperature: 22+/-3°C
Relative humidity: 55+/-15%
12 hours light/day, approximately 15 air changes/h
Acclimatization period: at least 5 days

Any other information on materials and methods incl. tables

Name	Instructions	Type
Any other information on materials and methods incl. tables		Header
	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	Rich text field

	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.	

Any other information on materials and methods incl. tables



Results of examinations

Name	Instructions	Type
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
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
Dermal irritation (field available only for 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
Description (incidence and severity) **(field available only for dermal study)**	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	Text area

	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	Indicate whether mortality was observed and whether it was treatment-related or not.	Closed list
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
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
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
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
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
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

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
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
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
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
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
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

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
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
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
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
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
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
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	Text area

	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.	
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
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
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
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
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

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
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
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
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
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
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

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
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
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
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
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
Details on results	Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters.	Text area

Results and discussion

Results of examinations

Clinical signs
effects observed, treatment-related

Description (incidence and severity)
Beginning with day 5 of treatment all male animals of group 4 (200 mg/kg) showed symptoms like apathia, ruffled fur, hunched posture, altered locomotion, ptosis, muscular weakness and in some cases salivation, ventral body position and bluish discoloration of the tail. No clinical symptoms were noted in all other treated male groups. Only one female (group 4, 200 mg/kg) showed similar symptoms like apathia, ruffled fur and hunched body position prior to death. Female number 60 (group 2, 5 mg/kg) died following misapplication by gavage.

Mortality
mortality observed, treatment-related

Description (incidence)
All treated males of group 4 (200 mg/kg bw.) died between day 7 and 10 of the treatment, while only one treatment-related death occurred in female group 4 (200 mg/kg). Female number 60 (group 2, 5 mg/kg bw.) died from causes unrelated to the treatment (misapplication) and female number 47 (control) died following blood withdrawal at scheduled sacrifice. No other deaths were registered during the course of the study.

Body weight and weight changes
effects observed, treatment-related

Description (incidence and severity)
The mean body weight of treated male group 4 (200 mg/kg) was depressed at week 1 prior to death of the animals. Further, the mean body weight of treated male group 3 (40 mg/kg) was slightly and that of female group 4 (200 mg/kg) was significantly depressed. The mean body weight of all other treated male and female groups was comparable to that of the respective controls (see Table 1)

Food consumption and compound intake (if feeding study)
effects observed, treatment-related

Description (incidence and severity)
The mean food consumption of male group 4 (200 mg/kg) was markedly reduced during the first week. Further, the mean food consumption in male group 3 (40 mg/kg) and in female group 4 (200 mg/kg) was depressed. The mean feed consumption in all other treated male and female groups was similar to that of the respective control groups during the whole experiment. No statistical analysis was performed.

Effect levels

Name	Instructions	Type
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, Pesticides NAFTA or EU REACH) on how to use this field.	Check box
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	Closed list with 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. The following units should only be used in the case of microbial active substances: - cells - CFU (colony-forming unit) - ITU (International Toxic Unit) - IU (International Unit) - OB (occlusion bodies) - spores	Range with closed list (Decimal)
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
Sex	Select from drop-down list.	Closed list
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)
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)

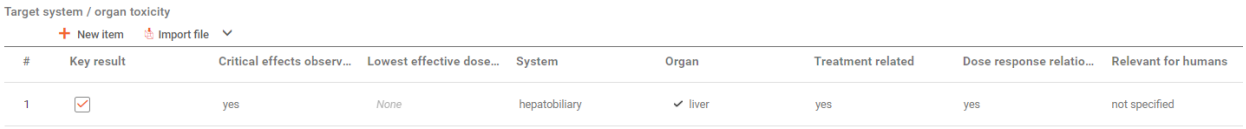
Target system/organ toxicity

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.

Name	Instructions	Type
Key result	Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.	Check box

	Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.	
Critical effects observed	Flag to indicate if critical effects were observed in the study within specific organs or systems.	Closed list
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 Closed List (Decimal)
System	Select any specific system where toxicity was observed that is considered of biological relevance.	Open list
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
Treatment related	Flag to indicate if the effects in systems and/or organs are treatment related.	Closed list
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
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

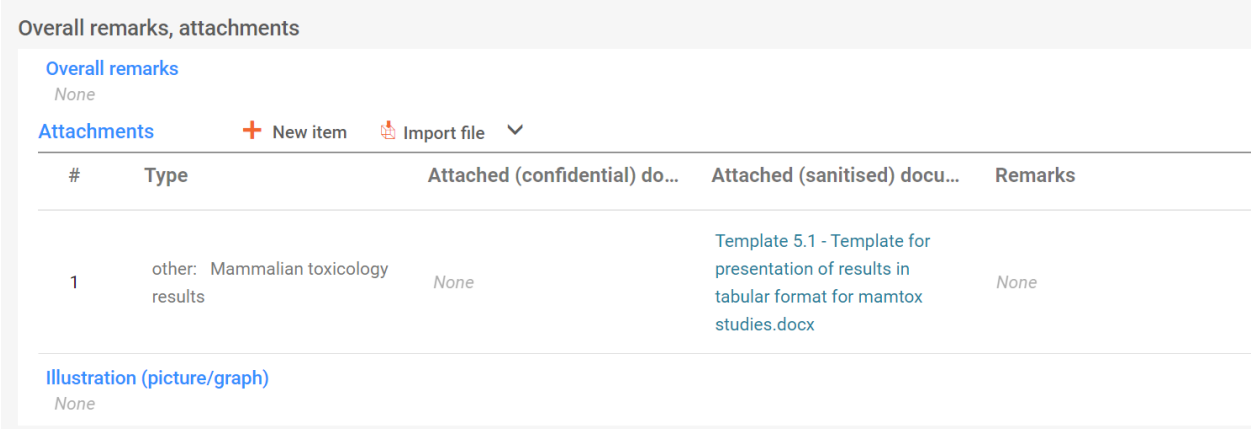


Overall remarks, attachments

Name	Instructions	Type
Overall remarks, attachments		Header 1
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 document. Use this field only if strictly necessary i.e. when no other specific fields such as repeatable blocks exist in the document to enter the data of interest. Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS	Rich text area

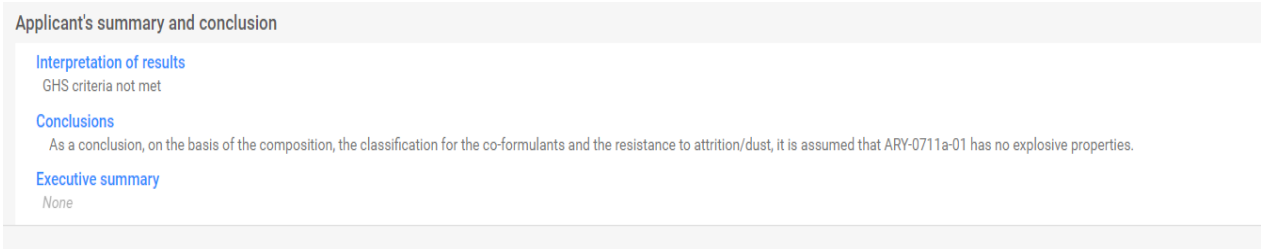
	section. In addition, the fields 'Overall remarks' and 'Executive summary' allow rich text entry.	
Attachments	Attach any background document that cannot be inserted in any rich text editor field, particularly image files. Copy this block of fields for attaching more than one file.	
Type	Classify the type of attachment uploaded e.g 'Appendix F mammalian toxicology result' Full study reports should be uploaded in the Literature reference entity	Open list
Attached (confidential) document	The original file only needs to be attached here if the non-confidential file uploaded under "Attached (sanitised) documents for publication" contains redactions. If a file is uploaded under this field (a) confidentiality claim(s) must be submitted for each part of the file considered confidential and the information claimed confidential must be clearly boxed or earmarked consistently with the redactions applied in the corresponding non-confidential file. This file will not be published.	Single file attachment
Attached (sanitised) documents for publication	Provide any additional documents relevant for the submission, not already provided under the literature reference entity. 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. See IUCLID templates for PPP Risk Assessment Templates on EFSA Knowledge Junction (zenodo). Any additional background documents uploaded here must be uploaded in their public (non-confidential) version . The public version will be published once the dossier has been considered valid/admissible. All elements therein claimed confidential should be sanitised. Save for the elements blackened, if applicable, content and layout-wise the public version must be fully identical with the confidential version. Upon conclusion of the confidentiality assessment, if applicable, a revised public version removing the redactions relating to confidentiality requests that were rejected in part or in full must be uploaded here. Any document uploaded here must be uploaded in their public (non-confidential) version. The public version will be published once the dossier has been	Single File Attachment

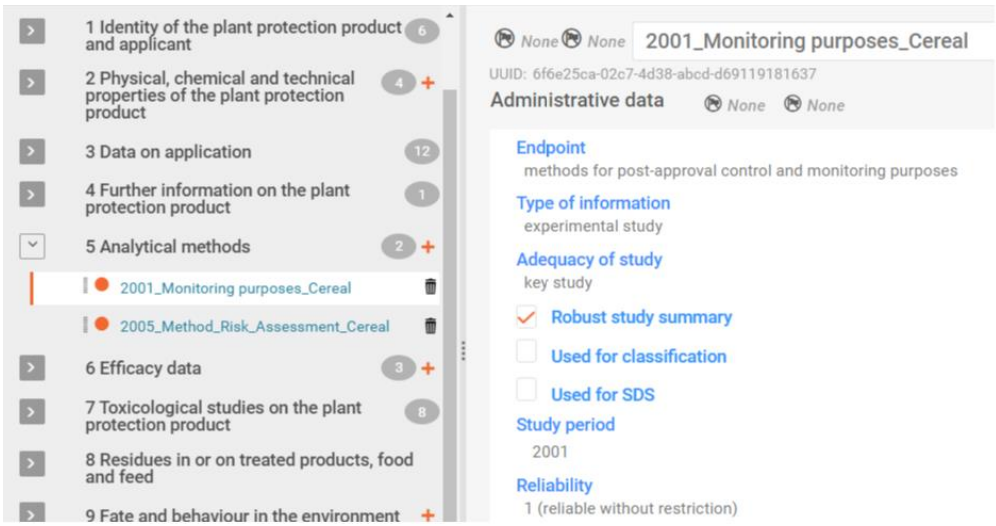
	considered valid/admissible. All elements therein claimed confidential should be sanitised.	
Remarks	As appropriate, include remarks, e.g., a short description of the content of the attached document if the file name is not self-explanatory.	Text



Applicant's summary and conclusion

Name	Instructions	Type
Applicant's summary and conclusion		Header 1
Interpretation of results	This field is present ONLY in document 6.3 Magnitude of resdiues in plants" (OHT 85-5): Indicate overall interpretation of test results with regard to expected residues in crop commodities as given in the study report or as concluded by the submitter. You can give an explanation in the supplementary remarks field, e.g. for indicating at what plant back interval residues are taken up by rotational crop, i.e. in which crop fractions and at what levels, or for indicating if conclusions originally reported were changed by submitter. For more detailed discussion of test results, use field 'Conclusions'.	Closed list with remarks (2000)
Conclusions	This field should be used to summarize the conclusions by the applicant and will be used in study summaries produced using report generator.	Text area
Executive summary	If relevant for the respective regulatory programme, briefly summarize 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.	Rich text area


Applicant's summary and conclusion
Interpretation of results
GHS criteria not met
Conclusions
As a conclusion, on the basis of the composition, the classification for the co-formulants and the resistance to attrition/dust, it is assumed that ARY-0711a-01 has no explosive properties.
Executive summary
None


1 Identity of the plant protection product and applicant 6
2 Physical, chemical and technical properties of the plant protection product 4
3 Data on application 12
4 Further information on the plant protection product 1
5 Analytical methods 2
2001_Monitoring purposes_Cereal
2005_Method_Risk_Assessment_Cereal
6 Efficacy data 3
7 Toxicological studies on the plant protection product 8
8 Residues in or on treated products, food and feed
9 Fate and behaviour in the environment
None None 2001_Monitoring purposes_Cereal
UUID: 6f6e25ca-02c7-4d38-abcd-d69119181637
Administrative data None None
Endpoint
methods for post-approval control and monitoring purposes
Type of information
experimental study
Adequacy of study
key study
Robust study summary
Used for classification
Used for SDS
Study period
2001
Reliability
1 (reliable without restriction)

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