IUCLID Basic Substance application Manual

(IUCLID 6 VERSION 6.X)

European Food Safety Authority (EFSA)

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Introduction

This manual should be read in conjunction with the Working Document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009 (https://ec.europa.eu/food/system/files/2021-06/pesticides_ppp_app-proc_guide_doss_swd-10363-2012.pdf), and EFSA practical arrangements under the Transparency Regulation (https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements).

If you need support you should use the Ask a question web page: https://www.efsa.europa.eu/en/applications/askaquestion

Creating an application

Basic substance applications should be created in **IUCLID cloud services**

https://ecs.echa.europa.eu/cloud/home.html

WHEN PLANNING A DOSSIER SUBMISSION IT IS RECOMMENDED TO CHECK EFSA's APPLICANTS TOOLKIT FOR THE LATEST RESOURCES TO SUPPORT DOSSIER PREPARATION (https://www.efsa.europa.eu/en/applications/toolkit**)**

On this website you will find the link to European Food Safety Authority. (2021, May). EFSA: IUCLID Training for applicants. On the training page you can download either a PDF or a movie explaining how to use IUCLID cloud services

1) The first step is to create a **Legal Entity** for the organization 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'

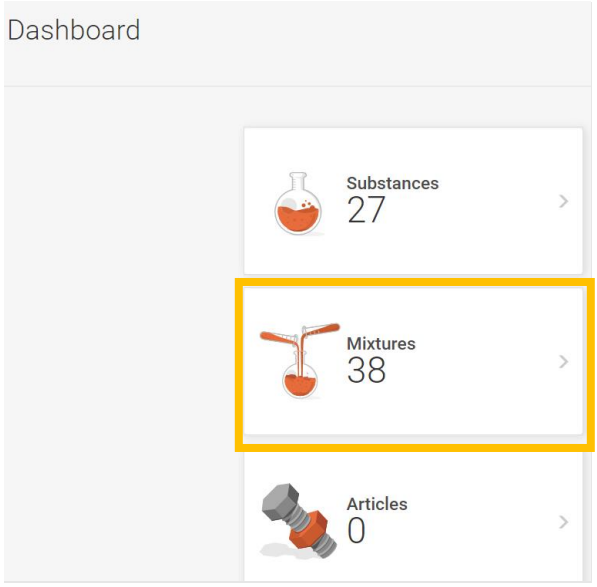
2) The next step is to create a **'Mixture dataset'**[1] and select the **'EU PPP Basic substance application'** working context. See the Overview of IUCLID cloud services and Creating a dossier sections of 'IUCLID Training for applicants'.

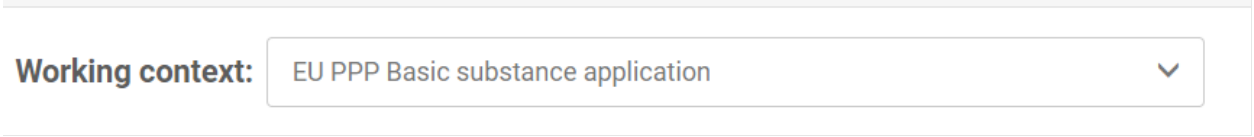
[1] A mixture dataset is a collection of IUCLID documents/forms which are connected via a table of contents based on the data requirements of the application

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 publicly available version should not be in word/rtf format, but rather in pdf format.

Note: a substance dataset is not required for a Basic substance application

Note: there are no Endpoint Study Records in a Basic substance application





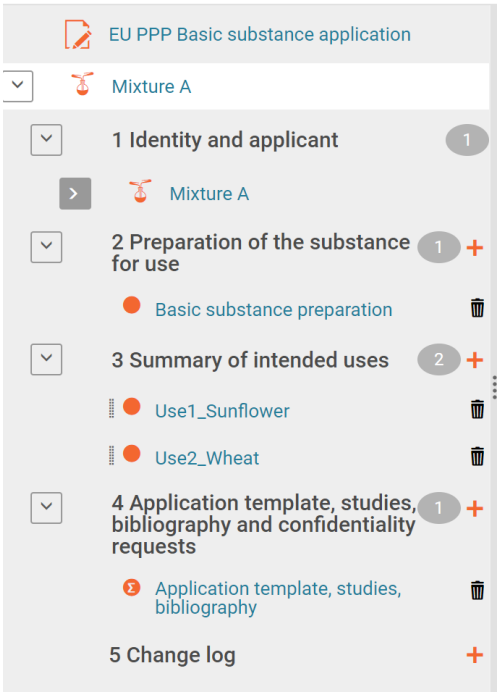
3) For a Basic substance application the following must be completed:

A MIXTURE DATASET with the following IUCLID documents must be completed

- The dossier header containing the administrative data
- Section 1 Identity and applicant, including the Legal entity and details for the contact person
- Section 2 Preparation of the substance for use, including a description of the composition of the preparation for use
- Section 3 Summary of intended uses, including one or more document/s describing each of the intended uses
- Section 4 Application template, studies, bibliography and confidentiality requests, upload the Application template document

The relevant entities[2] in the IUCLID documents must also be completed

- literature reference
- reference substance
- legal entity
- contact persons.



To add a document to a dataset, click on the red crosses (see above).

Detailed instructions on completing the IUCLID documents and entities are provided in the sections below.

4) Before submitting a dossier, it is important to run **validation assistant** to check the dossier is technically complete. The rules applied are dependent on the information included in the Dossier Header, make sure this is completed correctly.

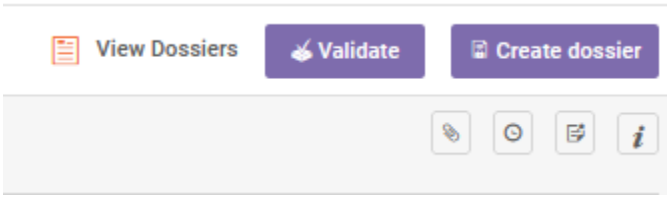
   If the report shows a **business rule failure** (anything starting with BR, e.g. BR_PPP_033) this will prevent the dossier from being successfully submitted. If the report shows a **validation warning** (anything starting with QLT, e.g. QLT_PPP_001) the dossier can be submitted but might not pass the validity check. If you cannot resolve all the warnings re-run validation assistant,

[2] IUCLID entities are documents which cover a specific topic e.g. contact details or substance identity. Entities are reused in other IUCLID documents to reduce typing the same information in multiple places. Entities can be managed in the Inventory Manager.

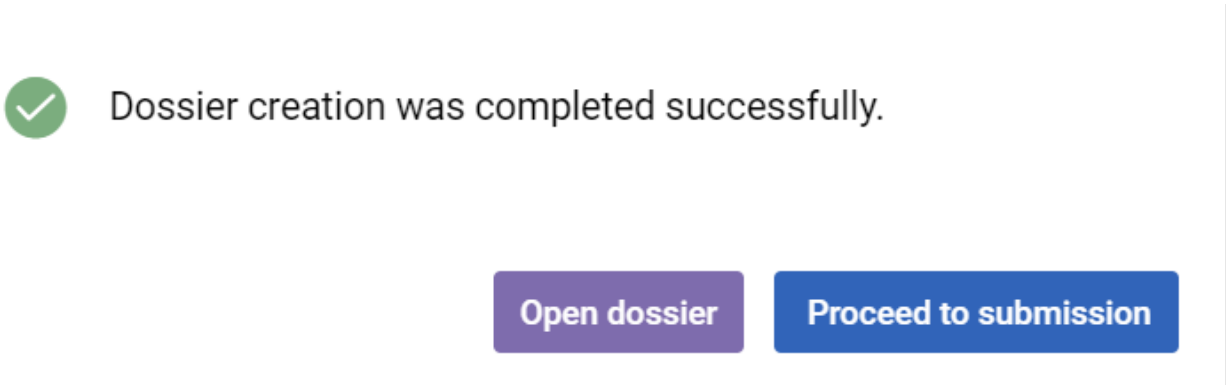
download the excel file and include in this file the justification for not resolving the warning and provide this directly to the EC.

To run validation assistant click on the 'Validate' button

5) Once the dataset is complete you need to create a dossier[3] and then submit it to EFSA via the 'Submission portal'. See the How to create a dossier section of 'IUCLID Training for applicants'



Once the dossier is created the message below will be shown. Click on the 'Proceed to submission' button and the dossier will be sent to EFSA via the Submission Portal.



Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants

CATEGORIES OF IUCLID FIELDS AND ASSOCIATED FILTER RULES

The information contained in IUCLID fields is automatically disclosed by EFSA, in accordance with the published filtering rules, once the application has been deemed valid. Confidentiality requests submitted by applicants are assessed either by **EFSA** (applications for renewal of approval of an active substance, basic substance and MRL dossiers).

Even though experience to date has shown that applications for the approval of basic substances rarely contain information that can be considered confidential, the applicant may include a request for certain information to be treated as confidential.

[3] A dossier has the same content as a dataset but it cannot be edited.

It should be noted that the concept of basic substances implies that no commercial interest is involved in the approval as a basic substance, since this substance should already be placed on the market for purpose(s) other than for plant protection. Therefore, it is in generally expected that applications for approval of basic substances contain very limited information that could be considered as compliant with Article 63 of Regulation EC No 1107/2009 and EFSA's Practical Arrangements concerning Transparency and Confidentiality. Article 63 of Regulation EC No 1107/2009 identifies the closed positive lists of the items for which confidentiality requests may be introduced.

Confidentiality requests are permitted only with regard to fields that correspond to the items listed in Article 63 of Regulation EC No 1107/2009 (*see* also Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009, SANCO/10363/2012).

EFSA will assess each confidentiality request, by performing an individual examination of the information claimed as being confidential by the applicant and of the relevant justification provided. Confidentiality requests are processed by EFSA in accordance with EFSA's EFSA's Practical Arrangements concerning transparency and confidentiality. Where EFSA adopts a confidentiality decision rejecting partially or entirely the confidentiality requests, a second version of the dossier is to be published after the completion of the confidentiality assessment and in accordance with the confidentiality decision.

Each IUCLID field has been assigned a **filter rule** (*see* column C in the "*Filter rules*" sheet of the filtering excel file).

There are three main rule types:

- "***PUBLISHED***": information provided under fields subject to this filter rule are published by default (for example, information provided in "*Attached(Sanitised)DocumentsForPublication*" and "*LegalEntity*" (hence, **no personal information should be provided in "LegalEntity"** – more details are available here)).
- "NOT_***PUBLISHED***": information provided under fields subject to this filter rule are NOT published by default (for example, information provided under "*AttachedConfidentialDocument*"[4] and "*AttachedStudyReport*" and personal contact details).
- "***UNLESS_CONF***": if the CBI flag has been set to request confidentiality in an entity, document, section, row or field, the field(s) with the "***UNLESS_CONF***" rule will be redacted during the filtering and publication process. In general, "***UNLESS_CONF***" applies to endpoint study records / flexible records and is rarely used in endpoint/flexible summaries. The underlying rationale is that endpoint summaries contain information that is key to the safety assessment and should not include confidential information. Please note that fields subject to the "***UNLESS_CONF***" rule will be published on the OpenEFSA Portal, unless a confidentiality request has been submitted by the

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

applicant and accepted by EFSA. Information on additional specific rules applied to a limited set of fields (e.g. redaction of author names) is available in the published filter rule excel file.

Before submitting a confidentiality request, always verify whether the relevant field(s) you intend to claim confidential can be subject to a confidentiality request, by consulting the filter rules for plant protection product IUCLID dossiers. Any confidentiality request submitted in relation to fields not governed by the filter rule 'UNLESS_CONF' will, in principle, be automatically rejected as inadmissible.

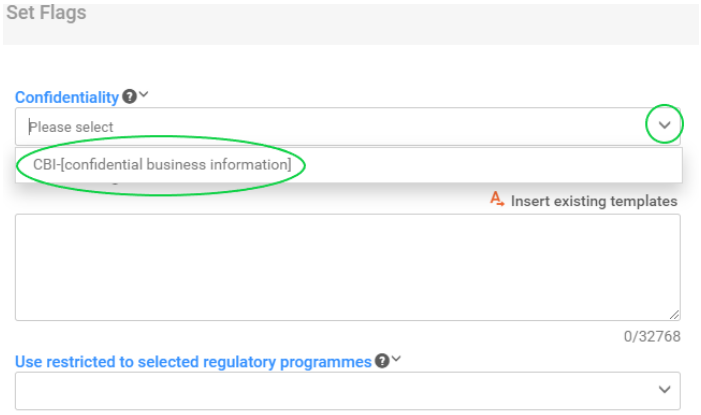
SUBMISSION OF CONFIDENTIALITY REQUESTS IN IUCLID

To request confidential treatment for information contained in an IUCLID entity, document, section, row or field, including any attachment provided thereunder:

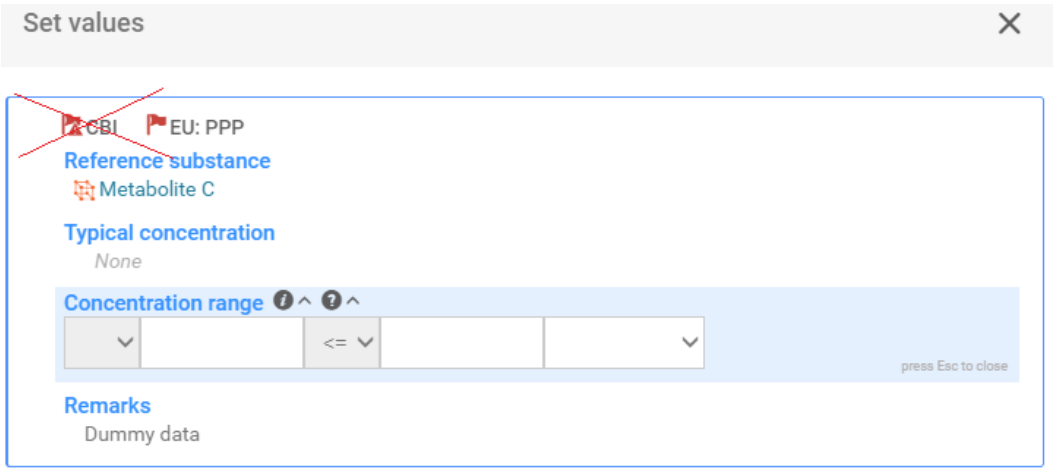
i. set the **CBI flag** by clicking on

- the confidentiality flag pertaining to the relevant entity, document, section, row or field

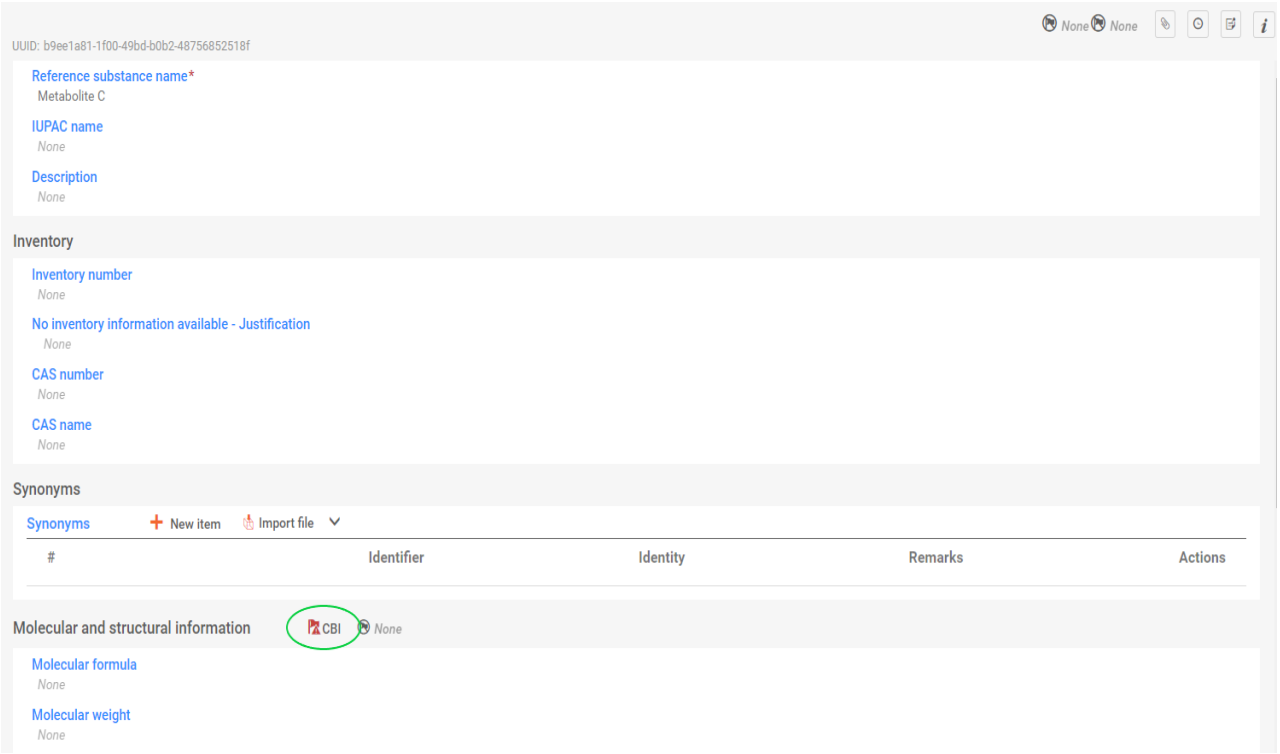
- and the drop-down menu selecting the option "*CBI –[confidential business information]*".



As a general rule, always select the most specific confidentiality flag. For example, if you wish to submit a confidentiality request regarding molecular and structural information in the reference substance, do not use the confidentiality flag related in the IUCLID document where the reference substance is *referenced*, i.e. the **secondary source**.



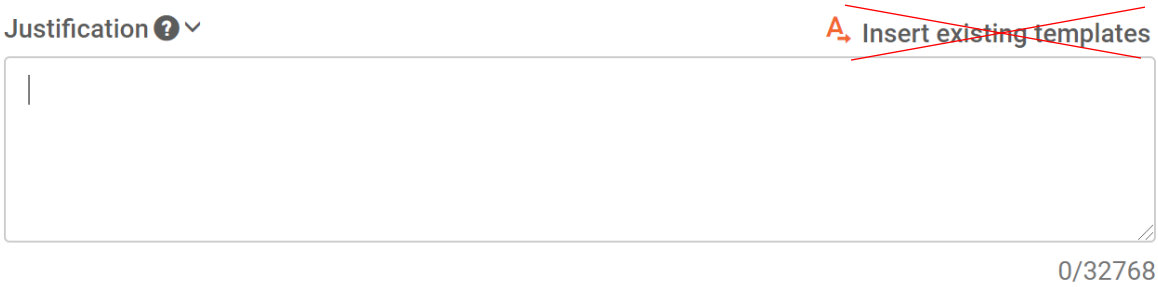
Instead, you should use the confidential flag available for this specific information in the **primary source**, i.e. the reference substance entity.



Do not submit a confidentiality request for fields which do not have the UNLESS_CONF rule as this will have no impact on the filtering applied for dossier publication.

ii. insert a **justification** for each confidentiality request in compliance with the standards set out in the Practical Arrangements. Note that you should **not** use the "*Insert existing templates*"

function, since the available template is not currently tailored to the requirements applicable to dossiers submitted under the EU legal framework governing pesticides.



Instead, please fill in the justification field in line with the requirements set out in EFSA's Practical Arrangements concerning transparency and confidentiality. You can find further details on the interpretation of the provisions in EFSA's Practical Arrangements in the Question and Answers document prepared by EFSA[5].

Where a confidentiality flag covers multiple fields or attachments in an IUCLID entity, document, section or row you are expected to insert a **separate justification** in the text box for each individual field/attachment containing information for which you request confidential treatment. In practice, this may imply that you have to insert several separate justifications in the justification text box of the confidentiality flag. If the information claimed confidential concerns the same subject, e.g. impurity xyz, you may insert a single justification in the justification text box with regard to all fields/attachments covering the same item of information. However, this does not absolve you from the requirement to **clearly identify** each field or attachment, including the exact page, paragraph and line or part thereof, as appropriate, containing information covered by the same justification, see the template justification below. Where the same item of information is provided in different sections or documents in the dossier **each confidentiality flag must be set (to allow automated filtering)** and a complete justification must be provided in the justification text box. In this case the completed justification template text can be reused.

Template justification for confidentiality requests concerning confidential business information (CBI) (note that those parts of the template marked in green indicate the action needed from applicants to complete the justification)

I. Identification of the relevant item: The item claimed confidential can be found in the field(s) [indicate the IUCLID path of the field(s) and, in case of attachment(s), also the file name of each attachment, where the information considered confidential is located. For open text fields, also add a reference to the exact paragraph, line and part thereof, as appropriate, where the piece of information claimed confidential can be found. For attachments, also add a reference to the exact page, paragraph and line and part thereof, as appropriate, where the piece of information claimed confidential is located. Nota bene: as explained above, if you would like to insert only one

[5] https://www.efsa.europa.eu/sites/default/files/2021-03/questions-and-answers-efsa-practical-arrangements.pdf.

justification in the justification field with regard to several fields/attachments because they concern the same item of information, e.g. name and percentage values of impurity xyz, you must **clearly identify** each single field or attachment, as explained above, containing information covered by the same justification].

II. Legal basis: [insert a brief and precise description of the item of information considered confidential, e.g. "*the percentage values of impurities of the active substance*" and insert the legal basis under which you would like to request the item of information concerned to be kept confidential, e.g. "*Article 63(2)(b) of Regulation (EC) No 1107/2009*"].

III. Rationale for award of confidential status: I hereby declare that the item claimed confidential should be granted confidential status because it meets the following cumulative requirements:

a) it is not publicly available;

b) it is eligible or worthy of legal protection and has not been acquired in an unlawful manner;

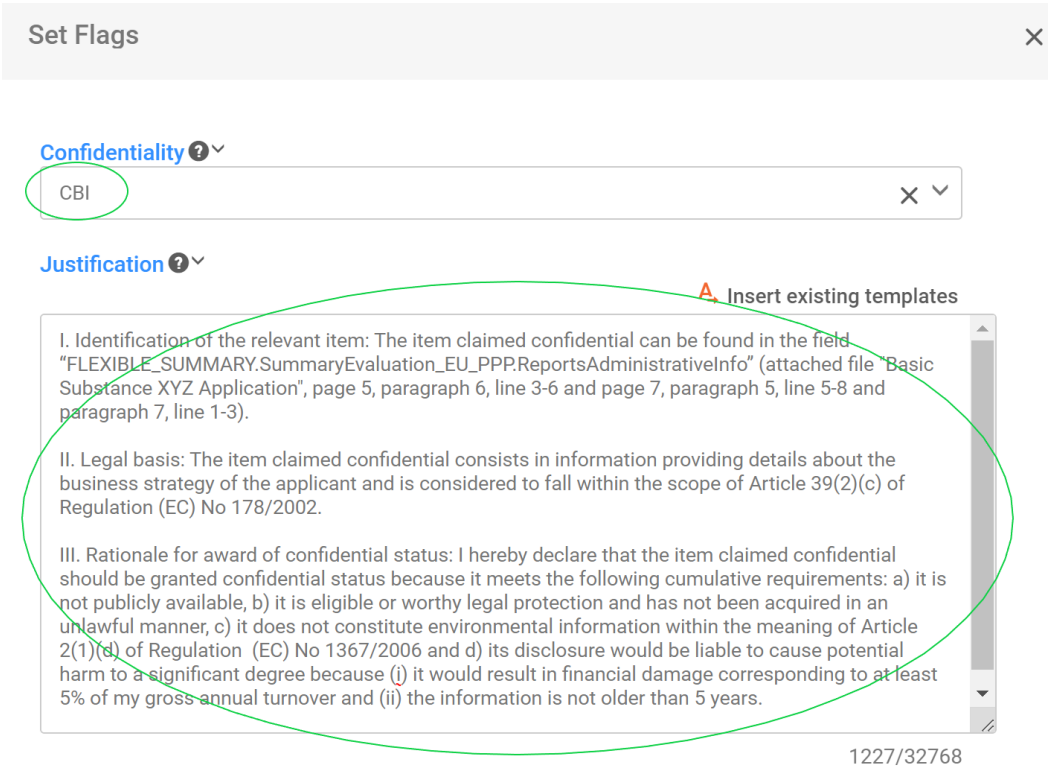
c) it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006; and

d) its disclosure would be liable to cause potential harm to a significant degree because:

- **i.** it would result in financial damage corresponding to at least 5% of my gross annual turnover/earnings, and
- **ii.** the information is not older than 5 years

[provide the rationale for the award of confidential status to the item of information covered by your confidentiality request. **Nota bene**: if you are unable to declare significant harm by reference to the reasons under d) (i) and (ii), other specific and actual reasons may be provided to substantiate why public disclosure may still potentially harm your interests to a significant degree. The rationale for the award of confidential status to the item of information covered by your confidentiality request must be **accurate** and **truthful** reflecting the applicant's good faith in light of applicable legal requirements and guidance documents. Note that the EFSA will perform a **detailed individual examination** of the justification provided and will reject any confidential request supported by a justification that does not meet all of the cumulative requirements set out in Article 10 of EFSA's Practical Arrangements concerning transparency and confidentiality. Moreover, EFSA reserves its right for any action, as appropriate, to address instances where incorrect or inaccurate information was provided willfully or negligently].

Example of compliant[6] justification for CBI confidentiality request



To insert (a) confidentiality request(s) regarding personal data (PD), we encourage you to use the below template PD request(s)[7] depending on the applicable scenario(s). Copy-paste the applicable template(s) into the justification box and supplement it/them with specific information, as appropriate.

Scenario 1, applicable to information classified as personal data "by its very nature": the information concerned by the confidentiality request qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 by its very nature (this applies, for instance, to the name of the author of an unpublished study report, personal contact details, handwritten signatures etc.).

> I would like to request confidential treatment for information contained in or related to study report with report number NNNN (YYYY) titled "XYZ1"/document (YYYY) titled "XYZ1" [please provide the details of the study report/document concerned allowing EFSA to identify it] that qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 by its very nature.

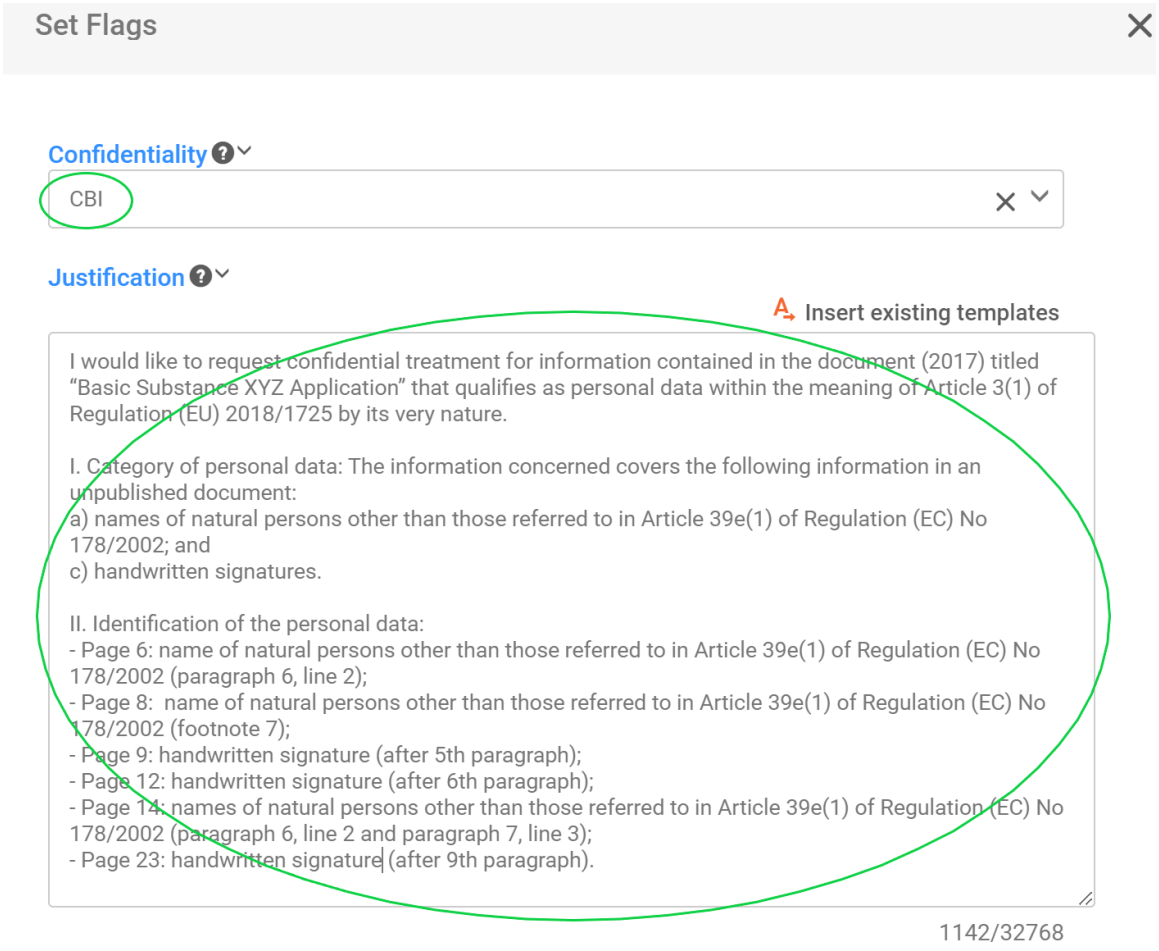
[6] The term "compliant" is used in a procedural sense here having regard to the requirement to provide a "verifiable justification" as reflected in Article 9(4)(b) of EFSA's practical arrangements concerning transparency and confidentiality and Article 5(2)(b) of EFSA's practical arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009, whichever is applicable.

[7] Note that a revised version of the template PD requests may be published as part of an Addendum in keeping with the technical solution deployed for PD requests.

I. Category of personal data: The information concerned covers the following information in an unpublished document:
a) name(s) of (a) natural person(s) other than those referred to in Article 39e(1) of Regulation (EC) No 178/2002; and/or
b) (an) address(es) of (a) natural person(s); and/or
c) handwritten signature(s); and/or
d) personal contact details.
[select whichever of the options among option a), b), c) and/or d) that is applicable and copy-paste it into the justification field. If you select option d) further specify whether it concerns (an) email address(es), (a) direct phone number(s) and/or (a) fax line(s) of (a) natural person(s)].

II. Identification of the personal data: [indicate for each page the exact paragraph(s) and line(s) or part(s), as appropriate, where the personal data in question is/are located. In that context always specify the category of the personal data, as per those categories selected under I].

Example of correct PD request under scenario 1



Scenario 2, applicable to more specific information belonging to the concept of personal data: the information concerned by the confidentiality request constitutes personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 in light of the specific circumstances pertaining to that information (names and addresses of test facilities, GPS coordinates of trial sites etc.).

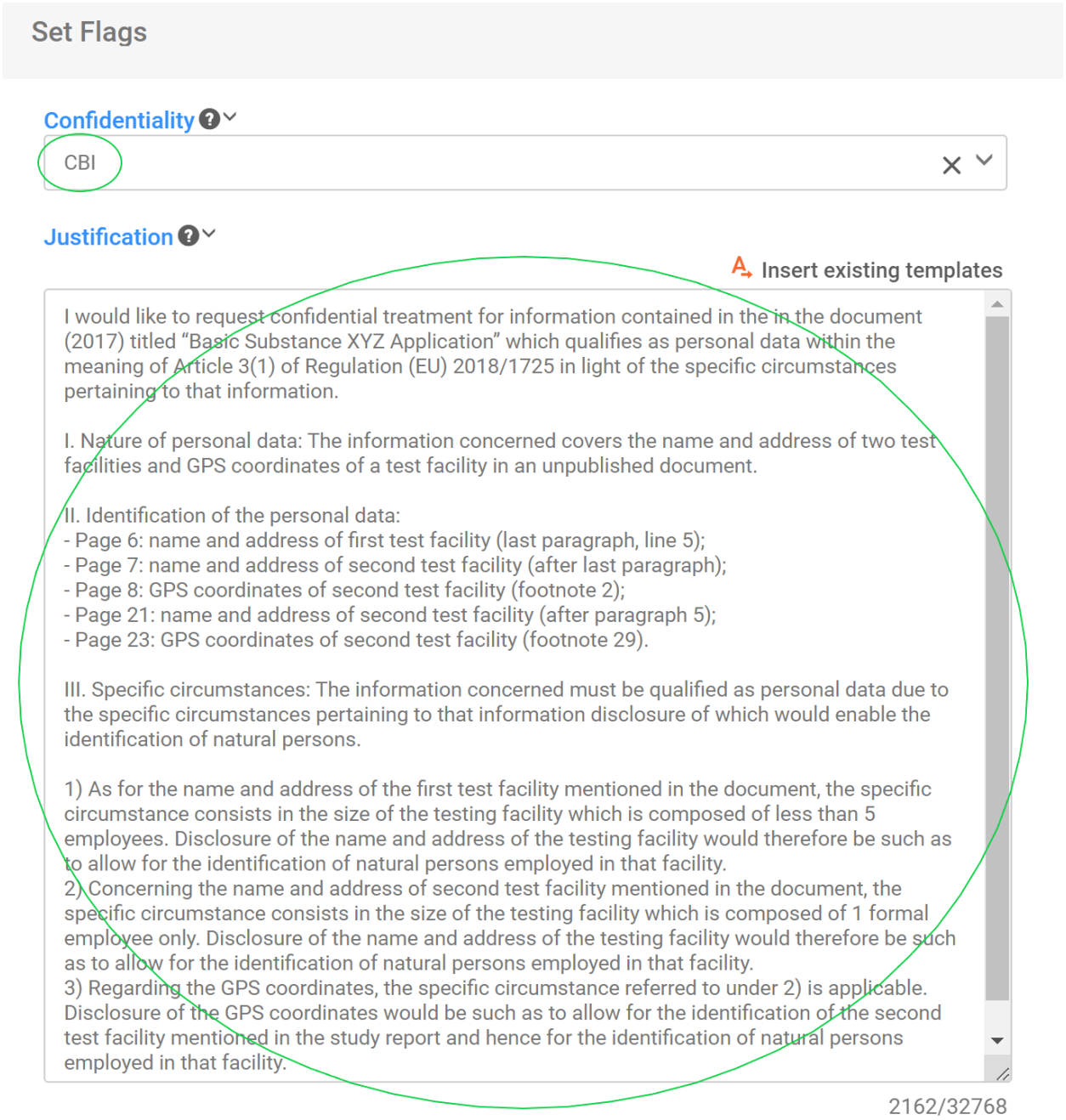
I would like to request confidential treatment for information contained in or related to study report with report number NNNN (YYYY) titled "XYZ2"/ document (YYYY) titled "XYZ2" [please provide the particulars of the study report/document concerned allowing EFSA to identify it] which qualifies as personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725 in light of the specific circumstances pertaining to that information.

I. Nature of information: The information concerned covers [indicate the type of information concerned, e.g. name and address of a test facility] in an unpublished document.

II. Identification of the information: [indicate for each page the exact paragraph(s) and line(s) or part(s), as appropriate, where the information in question is/are located. In that context always specify the type of information concerned, e.g. name and address of a test facility.].

III. Specific circumstances: The information concerned must be qualified as personal data due to the specific circumstance(s) pertaining to that information disclosure of which would enable the identification of (a) natural person(s). The specific circumstance(s) consist(s) in [provide a description of specific circumstances pertaining to the information which would allow EFSA to confirm that the information concerned constitutes personal data within the meaning of Article 3(1) of Regulation (EU) 2018/1725. If you refer to different types of information under I., add a specific description for each type of information as listed under I. If there are different instances pertaining to the same type of information, e.g. name and address of test facility A and name and address of test facility B, start with the instance mentioned first in the study report/document concerned without mentioning actual personal data].

Example of correct PD request under scenario 2



Note: An addendum to this manual maybe published with further details on the treatment of Personal Data. In the interim period, the CBI feature can be used to indicate the presence of personal data, as indicated above.

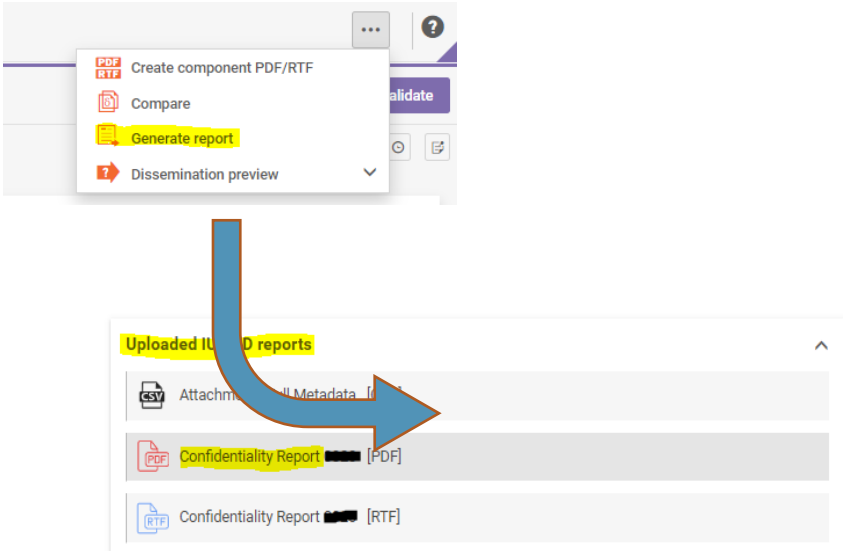
Before submitting your dossier, EFSA urges you to verify that your justification is fully readable and understandable. The justification field is a simple free text field which does not recognise most formatting options (e.g. underlining, putting text in bold or italics), in particular table structures. Therefore, applicants are strongly advised against copy-pasting information from tables, including, e.g., word or excel tables, into the IUCLID justification field.

In principle, only the justification box can be used to support your confidentiality request. This means that confidentiality requests must be adapted to the justification box and, to the extent possible, to the character limit.

It is only in ***exceptional* circumstance**s where the number of requests and their justification is so long that it cannot fit in the character limit that an attachment can be used to ensure the part of the justification exceeding the character limit may be provided. Note that the use of an attachment is not acceptable, if the length of the justification is compatible with the character limit or is due to the unnecessary repetition of the same text or of quotation of text from relevant legal acts EFSA has already access to.

If in these exceptional cases, an attachment is provided to complement the justification provided in the justification box, it must be provided as a confidential document in the field "*AttachedConfidentialDocument*" under the IUCLID summary, record or section containing the field or attachment to which the confidentiality justification relates. The text in the justification box must also expressly refer to the attachment, with the name of the attachment and the field where it can be found.

To verify all your confidentiality requests, you can generate the IUCLID report "*Confidentiality report*" under "*Uploaded IUCLID reports*":



The Confidentiality report allows the applicant to identify:

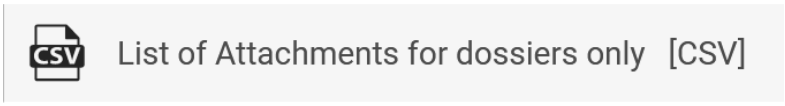
i. the IUCLID sub-sections and/or fields where a confidentiality flag has been set (with an hyperlink), and
ii. the corresponding justification provided.

CORRECT SUBMISSION OF ATTACHMENTS IN IUCLUD

For each attachment submitted there must *always* be a public version uploaded under the field "*Attached(Sanitised)DocumentsForPublication*". If no confidentiality request is submitted on the attachment, no other version of the attachment than the public version needs to be submitted. However, if a confidentiality request is made on the attachment, the applicant must *also* upload a confidential version of the attachment under the field reserved for confidential attachments "*AttachedConfidentialDocument*" with all information claimed confidential boxed or earmarked (but *not blackened*) in the confidential attachment. Moreover, in that case, content- and layout-wise, the public version of your attachment must be fully identical with the confidential version, save for information that is duly blackened in line with your confidentiality request(s).

For published literature where *copyright is not owned for reproduction the original publication should be provided in the* "*AttachedConfidentialDocument*" field and a bibliographic citation provided in the "*Attached(Sanitised)DocumentsForPublication*"

To verify whether you have submitted your attachments correctly, you are recommended to generate the IUCLID Attachment report for the dossier



RIGHT TO BE HEARD AND MEANS OF REVIEW

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

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

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

c. after the adoption of a decision on a confirmatory application, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.[8]

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

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

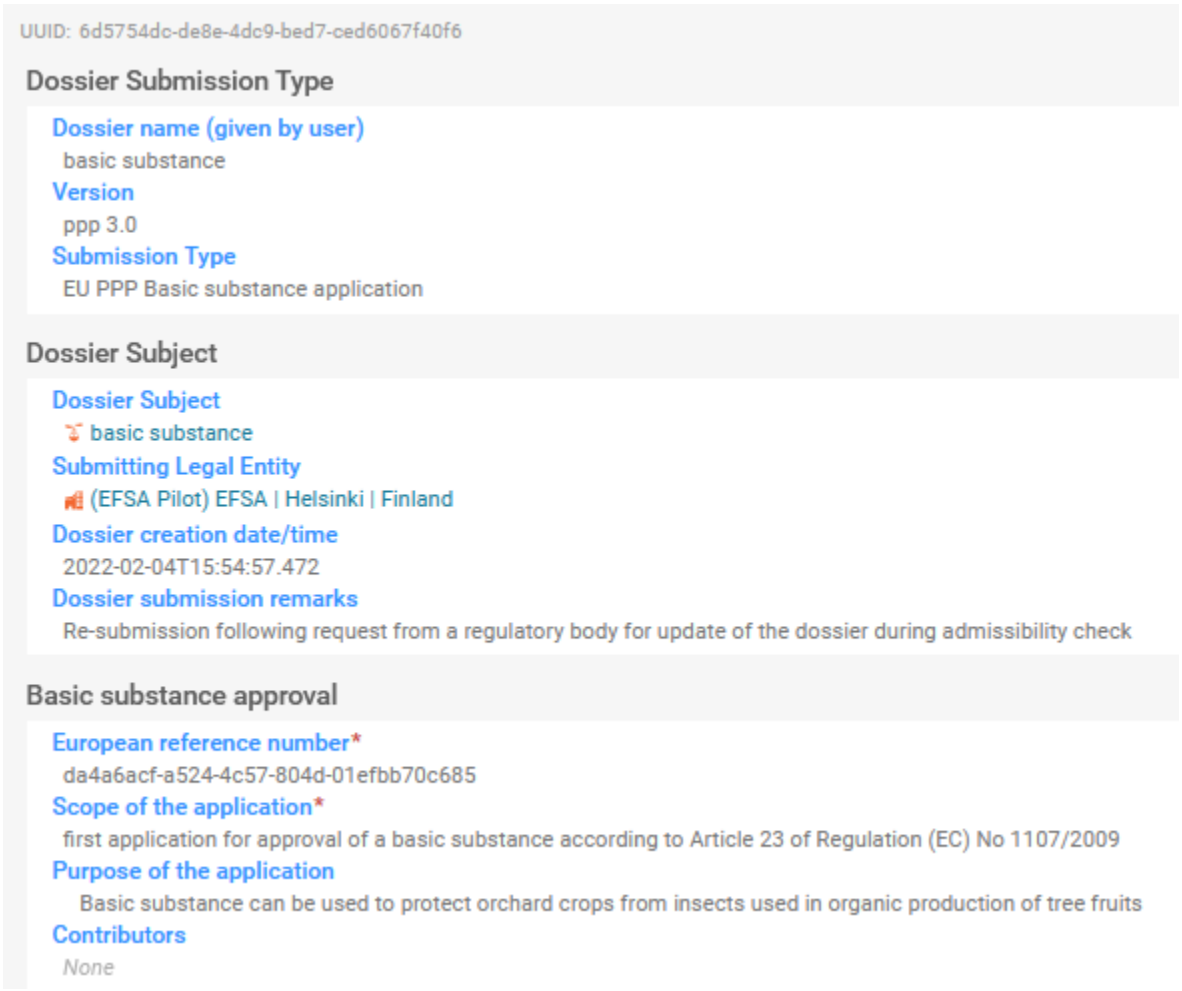
EU PPP Basic substance application

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

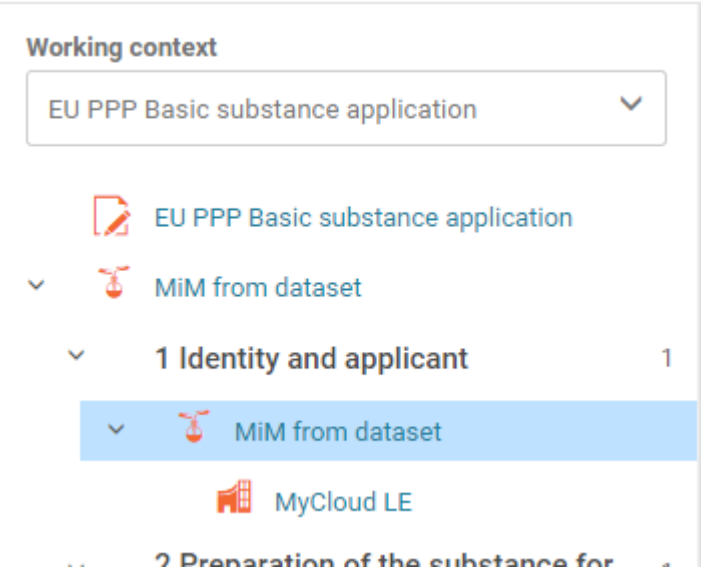
DOSSIER.EU_PPP_BASIC_SUBSTANCE_APPLICATION		
Name	**Instructions**	**Data type**
Dossier template	Working context: select EU PPP basic substance application	Header 1
Dossier name (given by user)	Short name for the dossier (this should be maintained in all versions). Refer to the basic substance name in the text.	Text
Dossier submission remark	Use this field to report useful additional information on the submission. The EFSA question number, if allocated, can be reported in this field. e.g. EFSA-Q-2021-00475. If the dossier is being resubmitted indicate the reason for the re-submission e.g. ' 'Re-submission following request from a regulatory body for update of the dossier during validity check' or 'Re-submission following request from a regulatory body for update of the dossier during evaluation' or 'Re-submission following a request from a regulatory body for update of confidentiality claims'	Text area
Basic substance approval		Header 1
European reference number	Contains the unique number to identify all versions of a dossier submitted under a regulatory action. This is a UUID generated from IUCLID, click on the 'cycle' button. This UUID is used in communications about the status of the substance approval. In case a new version of the dossier is re-submitted, applicants should NOT generate a new European reference number.	Text

Scope of the application	Select either 'first application for the approval of a basic substance according to Article 23 of Regulation (EC) No 1107/2009 Or 'extension of the application to support additional use(s)'	Closed list
Purpose of the application	Describe briefly the reasons to support the substance as basic substance and the envisaged uses in plant protection. Add when possible, information on its traditional use in agriculture (e.g. interest for organic agriculture).	Text
Contributors	Optional: Indicate the contributors to this application where organisations other than the submitting legal entity have contributed to the preparation of the dossier	Text
Pre-application information		Header 1
Pre-application identification	**Click on the "red cross" to add the pre-application identifiers, if applicable.** https://www.efsa.europa.eu/sites/default/files/2021-07/user-guide-notification-of-studies.pdf	
Pre-application identifier	Enter any pre submission identifiers issued whilst notifying studies in the EFSA notification of studies (NoS) system.	Text
Studies requiring NoS justification	**Click on the "red cross" to add information on studies requiring Notification of Studies (NoS) justification, if applicable.**	
EFSA study Identification	List all Notification of Studies identifiers which are present in the database linked to the Pre-application identifiers (see above) but are not included in the dossier.	Text
Justification	Justification for the absence of the NoS ID in the dossier	Multi-line text
Attached information		Header 2
Attachment	Attach administrative documents to support the application. Documents with confidential or personal information should not be attached here (e.g. letters). Remarks are used to indicate the topic/reason for including the attachment Section 4 Application template, studies, bibliography and confidentiality requests should be used for including	Single file attachment

	confidential attachments in the dossier. This is recommended as these documents foresee the possibility to upload confidential and non- confidential/sanitised versions of the same attachment.	
Remarks	Specify the motivation and the nature of the attachment.	Text area
Attachment		



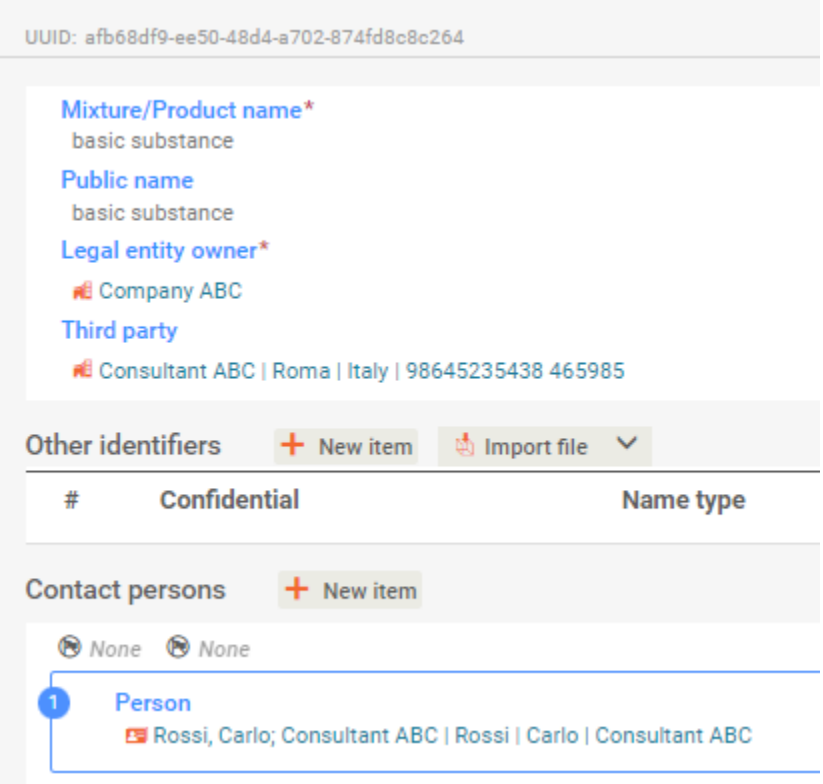
1 Identity and applicant



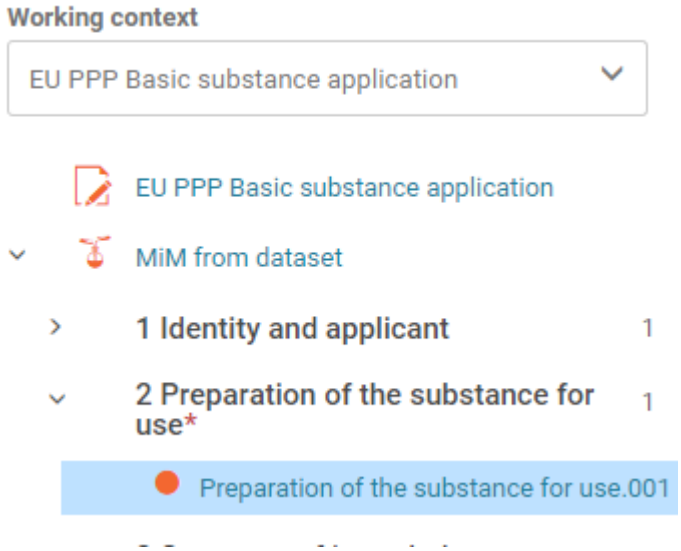
Purpose:
This document covers the data requirements:
Applicant and contact person
Trade name of a substance as available on the market

Mixture v.6.4 (Final)		
Name	**Instructions**	**Data Type**
Mixture/Product name	This must be completed; this information is also included in the dossier header as 'Dossier subject' Provide a name of a basic substance for which an approval is requested.	Multi-line text
Public name	Common name of the basic substance	Multi-line text
Legal entity owner	This must be completed; this information is also included in the dossier header as 'Submitting Legal Entity'. When submitting a dossier through the Submission Portal the same legal entity should be used, third party consultants may do this as foreign entities. Links the dossier to the Legal entity of the dossier owner.	Entity reference field
Third party	In case a third party prepares the dossier the legal entity of the third party can be added here	Entity reference field

Other identifiers	Provide all former and current trade names under which the substance is normally marketed.	
Contact persons	Select the entity with the contact details for the application. This information will be used for communication with the applicant. This information is not published.	Entity reference field



2 Preparation of the substance for use – Flexible record



Purpose
Detailed quantitative and qualitative information on the composition of the plant protection product/preparation
Product formulation type and function of component
According to Art. 23 (1) (c) of the PPP Regulation basic substances should be useful in plant protection either directly or in a product consisting of the substance and a simple diluent. In some cases, the substance can be used as such. When the substance is not to be used directly, sufficient information should be provided for the mixture(s) which is (are) expected to be prepared by the users.

The preparation for use may be simply the same as a substance for which the approval is sought.

The preparation for use may be an undiluted or pre-diluted mono-constituent substance or plant extract. The linked reference substances[9] should include main components, impurities etc.

FLEXIBLE_RECORD.MixtureComposition – v.7.1 (Final)		
Name	**Instructions**	**Data Type**
Administrative data		Header 1
	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality
General information		Header 1

[9] A reference substance is an entity which provides details on the identity of a component in the preparation e.g CAS number or Chemical formula

Mixture/product name	Name of formulation/preparation reported. In case of multiple formulations more than one document can be completed. For example "preparation for use 1", "pre-dilution 1" etc	Text
Trade names		
Country		Multi select open list
Trade name	In case a preparation for use is available on the market in a ready-to-use form, indicate the relevant trade name(s), the name(s) of manufacturer(s) and (a) link(s) to the relevant website(s) (if available).	Multi-line text
Trade names		
Brief description		Text
Formulation type	Select the formulation type according to the international coding system for pesticides from the scroll down list	Multi select open list
Components		Header 1
Component flag	See Confidentiality Requests Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality
Name	Link to reference substance for all components If a component of the mixture is confidential it is important that the confidentiality flag of the reference substance entity is also set to CBI to ensure substance identifiers are not shown in the mixture composition document.	Entity reference field
Function	Indicate the function of the component in the formulation. For all mixture formulations in the dossier a single component with the function 'active substance' must be reported. The reference substance with the function 'active substance' must be the same for all mixture composition documents included in the dossier.	Open list
Typical concentration	Complete the Typical concentration reporting %w/w. For relevant impurities the range including the maximum content is required.	Half-bounded with open list (Decimal)
Concentration range		Range with open list (Decimal)
Remarks	Describe in detail the recipe (or dilution process) for the preparation of the substance as it will have to be applied for use in plant protection. All the required transformation steps have to be thoroughly explained, as a sort of recipe for the preparation and/or the use. The recipe for the preparation of the substance for use will become an integral part of the specifications for the use of the basic substance and will be included in the Review Report.	Text area

Substance of concern	Not relevant for Basic substance. The approval as a basic substance is possible only if a substance is not a substance of concern (see Art 23 of the Regulation (EU) No 1107/2009)	Check box
Generic component identifier (GCI)	Not relevant for Basic substance	Check box
Interchangeable component group (ICG)	Not relevant for Basic substance	Check box
Standard formula (SF) component	Not relevant for Basic substance	Check box
Substance generated in situ (from one or more precursors, at the place of use)		Check box

General information

Mixture/product name
basic substance

Trade names + New item Import file

1 Country
None

Trade name
No bugs

Brief description
This preparation requires only dilution in water

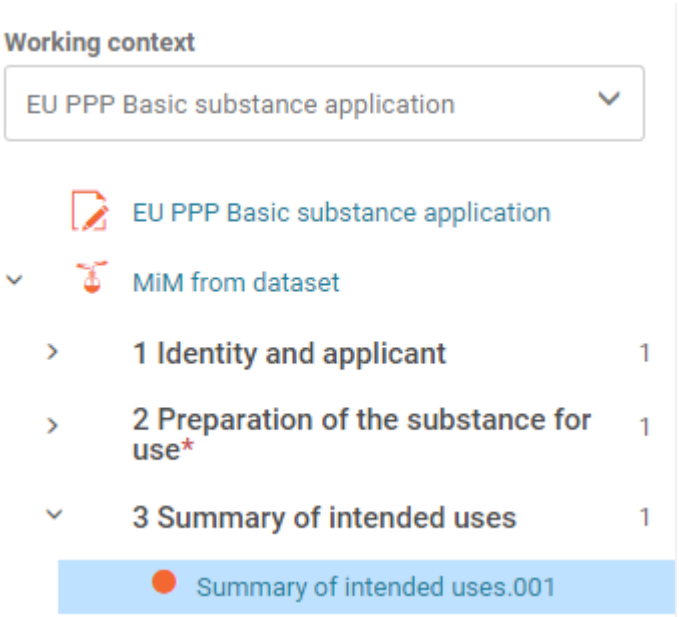
Formulation type
✓PO Pour-on

Components

+ New item Import file

#	Componen...	Name	Function	Typical co...		Con...	Remarks
1	None None	Water | Water | 7732-18-5	diluting agent	90	% (v/v)	None	None
2	None None	basic	active substance	10	% (v/v)	None	Extract basic is mixed with water. The preparation should be used within 48 hours of mixing

3 Summary of intended uses – Flexible record



Purpose
The IUCLID GAP form implements the following data requirements:
- Details of intended use
- Application rate
- Method of application
- Number and timing of applications and duration of protection
- Necessary waiting periods or other precautions to avoid phytotoxic effects on succeeding crops

If you click on the red plus sign next to the header 'Summary of the intended uses' you can create a new GAP.
Please note that separate GAP documents need to be created, if the GAPs differ in one or more of the parameters. For some fields multiple options from a picklist can be selected. Please read carefully below the instructions to see whether in a given case a separate GAP document needs to be created or whether it is appropriate to describe the different use options in one form.

FLEXIBLE_RECORD.GAP – v. 2.1		
Name	**Instructions**	**Field Path**
Administrative data	The general rules on confidentiality requests apply in setting the flags Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Header 1

Product	This field is mandatory. Click on the red plus sign to link the GAP to an existing Preparation (composition as reported in Section 2). If no preparation is available in the inventory, create first a new one	Endpoint reference field
Description of key information	The free text field can be used to give a short explanation/description of the GAP. This information is not mandatory. For GAPs that involve different application methods at different growth stages (e.g. drench application at sowing followed by foliar application at a later growth stage), the GAP should be split in separate GAPs (in the example the first GAP being the drench application, the second the foliar use). In this field, the GAPs belonging to a sequential application should be labelled (e.g. GAP 1 of 2, GAP 2 of 2).	Header 1
Purpose of the GAP		Header 2
Active substance / microorganism / basic substance applications		Multi select closed list
MRL applications	Not relevant for basic substances	Multi select closed list
Crop information		Header 2
Crop/treated object	Information on the crop/treated object is mandatory. A picklist is implemented to describe the crop or object to be treated with the product. The picklist is based on EPPO codes which have been enhanced with additional information to make them more user friendly/self-explanatory. The extended EPPO codes cover the following types of information: • the first 5 digits are the EPPO code (see EPPO Plant Protection Thesaurus at http://eppt.eppo.org) (e.g. PIBSX), • followed by the scientific name of the crop (PIBSX Pisum sativum); • in brackets, the crop name in English is reported (PIBSX Pisum sativum (English pea); • for the most important crops, the corresponding food code of the MRL food classification is reported after a dash (code of Annex I of Regulation (EC) No 396/2005). For some crops, more than one food code is applicable (e.g. PIBSX Pisum sativum (English pea) - 0260030, 0260040, 0300030).	Multi select open list with remarks

	In the current version of IUCLID, the link with the food codes of the MRL legislation has been established only for codes listed in Part A of Annex I of Regulation (EC) No 396/2005; food codes listed in Part B of Annex I, the connection to the crop code has not yet been implemented (the link will be included in the next release of IUCLID). Please note that not for all codes all four name elements are available. To find the codes for the crop/object, the user can either use the hierarchy search tool which requests to choose between crops or treated products. Alternatively, a text string (e.g. the EPPO code, the scientific name) can be directly entered in the search window, resulting in a subset of matching options. In the hierarchy tool, the user should first select between the two highest hierarchy levels 'crops' or 'treated product'. Treated products is relevant only for post-harvest uses and for uses on non-crop objects (e.g. treatment of railways). As a next step, a text string (EPPO code, scientific name, name of the crop in English or the food code of the MRL legislation) can be inserted. EPPO codes matching with the search term are displayed in yellow, and the user should select the relevant one. For post-harvest treatment of food products, two EPPO codes are available (HARFO and HARPO) which were combined with all food codes (Part A) of Annex I of Regulation (EC) No 396/2005: • If the treatment with the product is intended on the fresh harvested product (e.g. oranges), the code combining HARFO and the respective food code should be selected (e.g. 3HARFO – Oranges – 011020). • For GAPs describing a use on a processed harvested product (e.g. raisins), the code HARPO in combination with the food code should be used (e.g. 3HARPO – Table grapes – 0151010). In general, codes for crop groups should not be selected. Instead the EPPO codes for the individual crops should be chosen. A multiple selection of crop codes is allowed, only if all parameters of the GAP are identical for all crops selected. If the GAPs differ for the individual crops in one or several fields, a separate GAP form needs to be completed. To facilitate the work to complete separate GAP forms, an existing GAP can be copied and modified for the respective parameters. Further remarks on the crop/treated product can be reported in a free text field, which is created when the user clicks on the symbol . Remarks are necessary to specify whether food or feed has been in contact with the plant protection product indirectly	

	if one of the following codes for treated product has been selected: 3IRRWO – irrigation water (treatment of) BULBO – bulbs, tubers, corms (treatment of) PLABO – plant base (treatment of) SEEDO – seeds (treatment of) WOUNO – wounds (treatment of)	
Genetical modification of crop	If relevant, describe variety of genetically modified crops on which the use of the product is intended to be used or authorised.	Closed list with remarks
Crop destination(s)	The field is not mandatory. Please select the relevant EPPO code for crop destination. Multiple selection is allowed (e.g. grown for animal consumption (3ANICD) and grown for human consumption (3HCOND)). In remarks field more details on the crop destination can be described. See also EPPO code list https://gd.eppo.int/PPPUse/3CRODK	Multi select open list with remarks
Authorisation zone	Not relevant for Basic Substances	Closed list
MRL zone	Not relevant for Basic Substances	Closed list
Country or territory	Select the country or the territory related to the GAP. The selection of more than one country is possible if the same GAP applies.	Multi select open list
Crop location (F/G/I)	This data element is mandatory for GAPs that refer to crops (children codes listed under crops and children codes of '3HARVO harvested crops (treatment of)'. For other GAPs the field should remain empty. The available picklist contains EPPO codes with detailed descriptions of the cases. I: Code to be used for crops grown or stored in closed walk-in buildings. This code includes for example mushroom houses and structures for witloof chicory or rhubarb forcing. G: A walk-in, static, closed place of crops production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of products into the environment. F: Fields and other structures which do not prevent release of products into the environment. For crops grown outdoor (F), more details can be reported using the more specific subcodes. The detailed description of the subcodes is provided in the picklist.	Multi select closed list with remarks

Pest / disease to be treated		Header 1
Target organisms	Select 'New item' and compile the block consisting of 'Scientific name', 'Common name', 'Development stage of target pest' and 'Development stage of target plant'. See detailed descriptions below.	
Scientific name	Select the appropriate code and scientific name from picklist. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). At least one target organism needs to be defined in a GAP. It is possible to select more than one target organism, if the GAP parameters are identical for the different target organisms. If the target organism is not listed, select 'other' and specify. If a scientific name is not relevant or not known, select 'no data'. Any remarks can be entered in the supplementary remarks field, for instance any code for target organism if required according to a programme-specific guidance. If so, indicate the type of coding system in parentheses, e.g. 'I.1.1.1 (EU BPD)'. Please make sure that the scientific name entered in this field matches with the organism described in the field 'Common name'.	Open list with remarks
Common name	Please add the common name of the target organism in this field that matches with the Scientific name.	Text
Development stage of target pest	For insecticide and fungicide uses, indicate the developmental stage of the target organism/pest (e.g. development stage of the insect or of the disease for diseases caused by fungi). If no appropriate description is available in the list, select 'other:' and specify the development stage in the remarks. If the development stage is not known or not further specified, select 'not specified'. If the development stage is not relevant/applicable, leave field empty. Multiple selection of terms is allowed.	Multi select open list with remarks
Development stage of target plant	For herbicide uses, indicate the developmental stage of the target plant. In the picklist BBCH codes have been implemented. Although these codes have been developed for describing the development stages of crops, they can be used in analogy for the target plants. Any remarks can be entered in the supplementary remarks field, for instance an alternative description of the developmental stage which is not available in the picklist.	Multi select open list with remarks
Major/minor use	Not relevant for basic substances	Closed list with remarks

Application target

The target to be treated can be selected from a picklist.
The following terms are implemented:

Picklist value	Description
Foliage/Plant	Application to a plant or the leaves of a plant.
Seed / Seed Pieces	Application to a small object produced by a plant from which a new plant can grow.
Propagation Stock	Application to a specimens of a plant, used for breeding by natural processes from the parent stock.
Root/Bulb	Applications (such as dip applications) to a rootball (the compact mass of roots), or bulb (a part of plants that functions as a food storage during dormancy).
Bark	Application to or into the tough, protective outer sheath of the trunk, branches, and twigs of a tree or woody shrub.
Stump / cut stem	Application to the recently cut of a tree or woody shrub (excludes cut flowers).
Containerized plant	Application to a plant and soil grown in a movable container.
Agricultural Commodity	Post-harvest application to an agricultural product that can be bought and sold (*e.g.*, treatment to grain, fibre, cut flowers, packaged animal feed, *etc*).
Soil (surface)	Application to the ground in which plants can grow.
Soil (subsurface)	Application below the ground, or immediately incorporated.
Water	Application to water in systems, pools, pipes, tanks or other containers, or bodies of water, such as lakes, ponds, bays, estuaries, oceans, reservoirs.
Air	Application directed to a space, rather than a specific target. Examples of these types of applications include foggers, mosquitocides, ozone generators, knock-down insecticides, etc. This does not include aerial broadcast applications over a crop because the target is the crop, not the air over the crop.
Surface	Application to the interior and/or exterior boundaries of an inanimate object. Examples of these types of applications include boat hulls, countertops, hives, nests, etc.

Header 2

	<table><tr><td>Non-porous Surface</td><td>Surfaces where liquids will not absorb such as ceramic, porcelain, glass, metal, plastic/vinyl, rubber, stainless steel.</td></tr><tr><td>Porous Surface</td><td>Surfaces where a liquid is likely to absorb such as fabric, drywall, composition board surfaces, paint films and surfaces, plaster surfaces, and wood.</td></tr><tr><td>other</td><td></td></tr></table>Please select the most appropriate treatment target.	
Method of application	Information on the application method is mandatory. Select the treatment/application method relevant for the GAP. The picklist is based on the EPPO list (https://gd.eppo.int/taxon/). If no EPPO code is available to describe the method of application, select 'other:' from the picklist and describe the method of application in the remarks. Examples for methods of application with no EPPO codes are listed below: - bait treatment - basal bark treatment - dabbing/rubbing - [local treatment] - incorporation into compost - material incorporation or impregnation - [no class] - paint - [local treatment] - paste guns for volatile substances - pressure treatment - prune/wound treatment - [local treatment] - soil bed solarization The remarks field can be also used to provide further details on the EPPO code selected to describe the method of application. Examples for further specification of some EPPO codes are listed below: Circulating water application (3CWATM) - hydroponic/aquaponic water treatment Fogging (3FOGGM) - mechanical fogging - thermal fogging Fumigating (3FUMIM) - fumigation: enclosed spaces - fumigation: vacuum chamber - gassing Injecting (3INJEM) - stem injection Placing (3PLACM) - doseable matrix dispensors for volatile substances	Open list with remarks

	- retrievable active dispensors for volatile substances - retrievable passive dispensors for volatile substances - non retrievable active dispensors for volatile substances - non retrievable passive dispensors for volatile substances Spraying (3SPRYM): - air assisted broadcast spraying - high volume spraying - low volume spraying - ultra low volume spraying - application in overhead irrigation water - banded spraying - spot treatment (spraying) Spreading (3SPRDM) - granules application in row - granules application overall If different application methods are foreseen on a crop (e.g. seed treatment followed by foliar broadcast), two uses should be described as separate GAPs, including in the remarks that the two GAPs are combined.	
Application equipment	Select the types of application equipment used. This information is used in the operator and worker exposure scenarios	Multi select open list with remarks
Growth stage and season	Click on 'New item' and compile the block of fields that comprises the following fields: Growth stage of crop (first application), Growth stage of crop (last application), Treatment season. If the GAP foresees treatments at different treatment windows (e.g. first treatment window before flowering, second treatment window after flowering), the block can be repeated. Information on the growth stage is mandatory if the GAP refers to a crop; if the GAP refers to treatment of non-crop objects (children of 3NOCFO), it is not required; if the GAP refers to treatment of harvested crops (children codes of 3HARVO), BBCH 99 should be entered; if the GAP refers to children codes of 3CRPAO (treatment of crop parts), it is not required. If number of applications is greater than 1, the information on the growth stage needs to be reported for the first and the last application. Treatment season is not mandatory.	
Growth stage of crop (first application)	This field is intended to describe the growth stage of the crop at the first treatment with the product. The picklist offers the BBCH codes which describe the phenomenologically similar growth stages of all mono- and dicotyledonous plant species (source: BBCH Monograph edited by Uwe Meier, Julius Kühn-Institut, 2018, doi: 10.5073/20180906-074619). Select the growth stage of the crop at first application. If a treatment is foreseen at one specified growth stage, select	Open list with remarks

	the BBCH code only in this field (Growth stage of crop (first application)). For a range, also select the relevant BBCH code in the field 'Growth stage of crop (last application)'. If necessary, more details on the treatment timing shall be reported in remarks (e.g. a description of the timing/growth stage at the application to specify more detailed the timing of the application (e.g. pre-plant, before transplant, etc.). The letters in bracket after the description of the crop development show to which plant group the respective definition refers. (D = Dicotyledons, M = Monocotyledons, G = Gramineae, P = Perennial plants, V = Development from vegetative parts or propagated organs). Please note that BBCH codes 71 to 79 is not used, if the main fruit growth happens in principal growth stage 8.	
Growth stage of crop (last application)	Please select from the picklist the growth stage of crop at last application. See above (Growth stage of crop (first application)) for further details.	Open list with remarks
Treatment season	For autumn/winter sown crops, report whether the treatment is foreseen in autumn/winter or in spring/summer. Multiple selection is allowed. If necessary, any other restrictions for the treatment season can be reported in the remarks field, selecting the option 'other:'	Multi select open list with remarks
Number of applications (range)	Information on the number of applications is mandatory. Report the number of applications (e.g. 1 – 3). If only one treatment is foreseen, report '1' in the lower numeric field.	Precise range (Decimal)
Re-treatment interval (in days)	Enter the interval between treatments (re-treatment interval); if relevant, a range for minimum interval and maximum interval between treatments, expressed in days, can be reported.	Precise range (Decimal)
Application rate per treatment (product) – range	Mandatory information. For reporting the application rate, follow the recommendations on dose expression for preparation for use (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate (for the formulation) per treatment. Use the second numeric field to report the upper application rate per treatment. Select the most appropriate unit to express the application rate. For applications on crops, the application rate should preferably be expressed as application rate per hectare. See also below application rate per treatment for target a.s. (range).	Range with open list (Decimal)
Remarks on application rate	Any further explanations related to the application rate can be provided in this field.	Text

	For 3-dimensional crops, the application rate expressed on leaf wall area can be reported in addition to the application rate reported per hectare.	
Water amount per treatment / spray volume	Preparation for use applied after dilution with water, the minimum and maximum amount of water used in spray application (spray volume) should be reported.	Range with open list (Decimal)
Concentration of formulation in dilution	Preparation for use applied after dilution with water, report the concentration of the formulation in the solution.	Range with open list (Decimal)
Safener/ synergist/ adjuvant added	Not relevant for Basic substances.	Closed list with remarks
Application rate per treatment for target a.s. (range)	It is mandatory to report the application rate for the target a.s. In most cases, the target a.s. is the basic substance for which the approval is requested. For plant extracts or UVCB substances, the target a.s. might be understood as the main active component. The field is intended to specify the application rate for the target active substance (i.e. the a.s. defined in the active substance dataset (EU PPP Active substance information) of the IUCLID dossier). For reporting the application rate, follow the recommendations on dose expression for products (EPPO General Standard PPI/239(3)). Enter the numeric value in the first numeric field corresponding the lower application rate per treatment. Use the second numeric field to report the upper application rate per treatment.	Range with open list (Decimal)
Maximum annual application rate (a.s.)	If restrictions need to be defined for the annual application rate (in case of crops which have more than one harvest per season), please report the maximum annual application rate for the active substance. The application rate should be reported for the a.s. (not the variant).	Half-bounded with open list (Decimal)
Non-target a.s.	No	FLEXIBLE_RECORD.GAP.PestDiseaseTre

		ated.ApplicationDetails.NonTargetAS
Non-target a.s.	Not relevant for Basic Substances	Entity reference field
Application rate per treatment for other a.s. (range)	Not relevant for Basic Substances	Range with open list (Decimal)
Maximum annual application rate for other a.s.	Not relevant for Basic Substances	Half-bounded with open list (Decimal)
Treatment window (for dispensers)	For dispensers or similar application forms, the duration of treatment window needs to be reported.	Text
Seeding rate	Field relevant for seed treatments only. Enter the seeding rate: For crops where the seeds are usually sold by number of units (e.g. sugar beet, maize, sunflower), the seeding rate should be expressed as unit/ha (unit is usually 100.000 individual kernel). For seeds sold by weight (e.g. cereals the seeding rate is normally expressed in kg or g seeds /ha or m^2. If 'other:' is selected as unit, describe the seeding rate unit in the additional field.	Half-bounded with open list (Decimal)
Planting density	The field is not mandatory. Describe the planting density (number of plants per ha or m^2).	Text
Pre-harvest interval	Mandatory field. Specify the minimum pre-harvest interval (PHI) in days (i.e. the minimum time between the last treatment of a crop and the harvest). This field should also be used to describe the time between post-harvest treatment of a food/feed item and the placement on the market. Enter a single numeric value. The qualifier '>' can be used together with a PHI to describe treatments at early development stages of the crop where the PHI cannot be specified more accurately. 'Not applicable' can be selected where the pesticide is applied to empty storage rooms, or for treatment of fields after harvest. In case 'not applicable' is selected, further clarifications need to be provided in the field 'additional information'.	Open list with remarks
Re-entry period livestock	The field is not mandatory. This field should be used to describe the minimum re-entry period (hours/days) for livestock, i.e. the time that needs to elapse before animals may enter treated pastures.	Unit measure with Closed List (Decimal)
Withholding period animal feed	The field is not mandatory. This field is intended to define the minimum time (in days) between harvest of a feed crop and the use of the feed.	Unit measure with Closed List (Decimal)

Re-entry period	The field is not mandatory. Describe the minimum re-entry period (in days or hours) for workers in the field/room treated with pesticide, in order to safeguard human health. If no re-entry period is defined/required, select 'not applicable'.	Unit measure with Closed List (Decimal)
Waiting period handling treated product	The field is not mandatory. This field is intended to describe the minimum waiting periods (hours/days) that need to be respected between treatment and handling of treated products (e.g. handling of products after fumigation).	Unit measure with Closed List (Decimal)
Ventilation practices	The field is not mandatory. If relevant, please describe the ventilation practices to be carried out after indoor treatments, to safeguard human health.	Multi-line text
Plant-back interval	The field is not mandatory. If relevant, please describe the plant-back interval (expressed as days) that has to be respected (e.g. in case of crop failure) before the planting of succeeding crops is allowed.	Unit measure with Closed List (Decimal)
Restrictions	The field is not mandatory. If relevant, please report any relevant restrictions that would have an impact on the risk assessment e.g.: - geographical restrictions, - restriction related to use of other a.s., - maximum number of applications per season for a.s. belonging to the same group (e.g. dithiocarbamates, triazoles), - restrictions for rotational crops, - PPE, - buffer zones, - temperature range at application, - soil incorporation depth and time, - restricted soil type, - restriction to crops grown in artificial substrate, - restriction to be used only in crops grown in hydroponic systems, - restriction to crops grown in pots/no connection to natural soil, - restrictions to be used in crops up to a certain crop height, - minimum percent soil organic matter, - restrictions to protect pollinators, - restriction regarding application equipment.	Multi-line text
Type of user	The field is not mandatory. Please select one or several terms from the picklist (professional/non-professional/other:). If other is selected, please provide more details in the remark field.	Multi select open list with remarks
Additional information	Any relevant information on the GAP that cannot be reported in any of the data fields above should be entered in this field.	Header 1

Product _basic substance

Characteristics of the mixture composition:

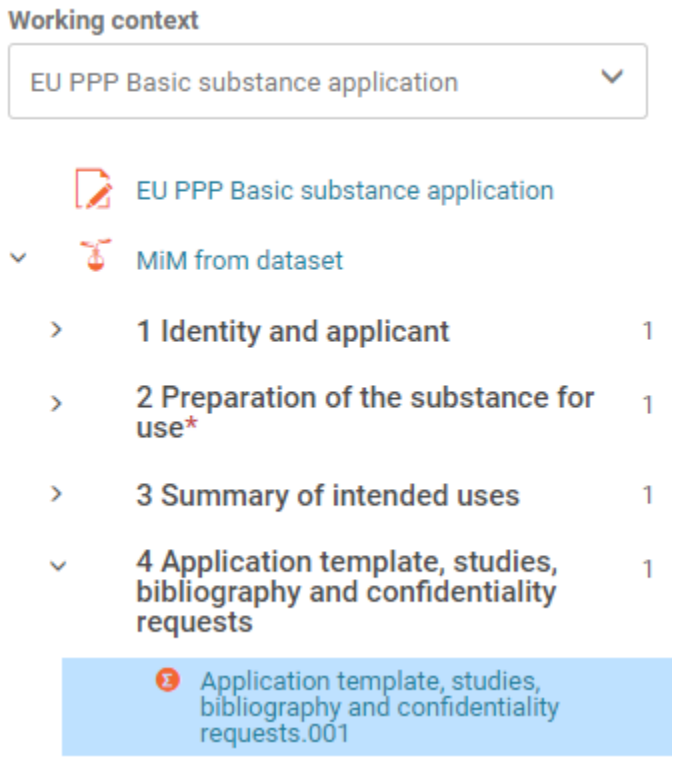
- formulation type: PO Pour-on
- active substance: basic : 10 % (v/v) (Extract basic in mixed with water. The preparation should be used within 48 hours of mixing)
- other components:
- - diluting agent: Water : 90 % (v/v)

GAP table:

Table 1.1.

Crop / situation	MS / country	F, G or I	Pests controlled	Application				Application rate per treatment			PHI	Remarks
				Method / kind	Growth stage and season	No	Interval	A.s.	Water	Conc. dilution		
Malus domestica (Apple) (MABSD) Pyrus communis (Common pear) (PYUCO) American persimmons/Virginia kaki (3HARFO)		F	wasps	dripping (3DRIPM)	(summer)	>=1 - <=5	>=10 d	ca.25 g/L				Crop destination: grown for harvesting fresh (3HFRED) NOTE: more information in corresponding GAP document (key/additional information).

4 Application template, studies, bibliography and confidentiality requests



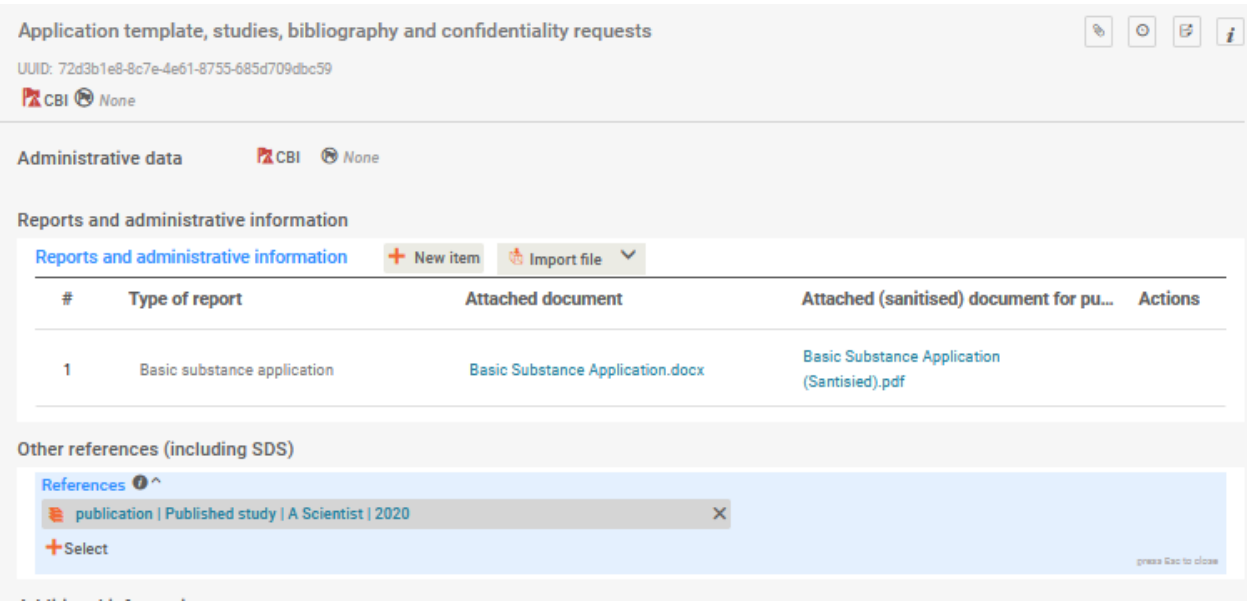
Purpose

Summarise the overall conclusions for the basic substance

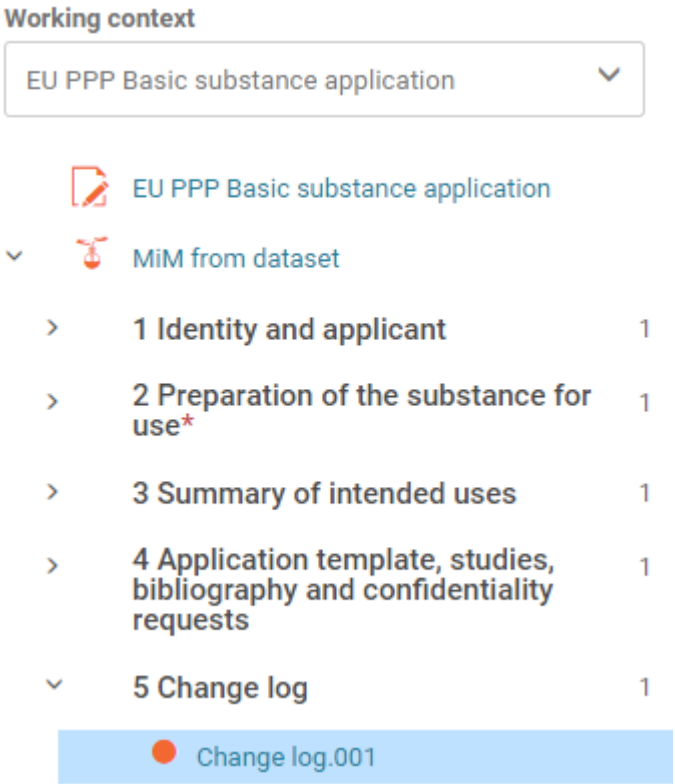
The completed Application template and literature references should be included in this document

FLEXIBLE_SUMMARY.SummaryEvaluation_EU_PPP – v.1.1 (Final)		
Name	**Instructions**	**Data type**
Administrative data	See administrative data	Header 1
	Use this field to set flags for confidentiality and regulatory purpose(s). Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality
Reports and administrative information	**Filled in application template has to be uploaded.**	Header 1
Reports and administrative information		
Type of report	Indicate the type of document that has been uploaded e.g. '**Application template'**	Multi-line text
Attached confidential document	Upload the completed **Application template**. In this document if any information is claimed confidential then it must be boxed or earmarked. Only DOC or PDF formats are allowed for file upload. 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 request(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) document for publication	Upload a sanitised version of **the Application template** with confidential information blackened. Note: if there is no confidential material it is sufficient to just upload the Application template in Attached (sanitised) document for publication	Single file attachment

	Only PDF format is allowed for file upload. 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.	
Reports and administrative information		
Other references (including SDS)	The literature reference entity should be completed for each literature reference and test study report relied upon in the application All literature references can then be included in the dossier in the 'Other references (including SDS)' section. Simply click on select to add each of the literature reference entities. **Each literature reference has to be uploaded individually, in a non-compressed format (please note that uploading content in a .zip or .rar file is not allowed).**	Header 1
References		Literature reference list
Additional information		Header 1
Additional information	Overall summary of the main conclusions for the substance or mixture can be entered here	Rich text area


Application template, studies, bibliography and confidentiality requests
UUID: 72d3b1e8-8c7e-4e61-8755-685d709dbc59
CBI None
Administrative data CBI None
Reports and administrative information
Reports and administrative information
New item
Import file
Type of report Attached document Attached (sanitised) document for pu... Actions
1 Basic substance application Basic Substance Application.docx Basic Substance Application (Santisied).pdf
Other references (including SDS)
References
publication | Published study | A Scientist | 2020
Select

5 Change log


Working context
EU PPP Basic substance application
EU PPP Basic substance application
MiM from dataset
1 Identity and applicant 1
2 Preparation of the substance for use* 1
3 Summary of intended uses 1
4 Application template, studies, bibliography and confidentiality requests 1
5 Change log 1
Change log.001

Purpose
This document can be completed if the scope of the application is 'extension of the application to support additional use(s)'
The document allows the differentiation between 'New' and 'Previously used' documents

FLEXIBLE_RECORD.ChangeLog – v.1.0 (Final)		
Name	**Instructions**	**Data type**
General information		Header 1
	See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants	Confidentiality
Summary	Provide any additional explanation needed in order to facilitate the compilation of the final list of the tests and studies relied upon and whether the study was already submitted in the first approval.	Rich text area
Change log		Header 1
Change log entries	Create an entry in the table for each test or study	
Link to document	Select each of the IUCLID documents included in the dataset	Endpoint reference field
Status	For each of the documents indicate if the document is 'new', 'previously used' 'obsolete' or 'updated'	Closed list
Remark	In the remark indicate for which data point the study has been previously used	Multi-line text
Change log entries		

Referenced entities

Reference substance

Purpose
Chemicals: Identity of the 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

The Reference substance inventory gives the possibility to use the same information for the same chemical/microorganism identity avoiding duplicate data entry and to ensure that the data is centrally managed and updated. Each reference substance can be linked to an unlimited number of substance or mixture datasets.

Reference substance/s can be exported and shared from the Reference substance entity manager

Name	Instructions	Type
	Set confidentiality and regulatory program flags. See Confidentiality of dossiers submitted via IUCLID - practical instructions for applicants **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	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 **microorganisms** 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 **microorganisms** the taxonomic information family, genus, species, strain, serotype, pathovar or any other denomination relevant to the micro-organism should be reported. In addition it should be indicated whether the microorganism - is indigenous or non-indigenous at the species level to the intended area of application - is a wild type - is a spontaneous or induced mutant - has been modified using techniques described in Part 2 of Annex IA and in Annex IB to Directive 2001/18/EC (*) of the European Parliament and of the Council	Text template

Inventory	Can be used to select existing substances with pre-assigned EC numbers.	Header 1
Inventory number	Can be used to select existing substances with pre-assigned EC numbers.	Entity reference list
No inventory information available - Justification	Not relevant for Basic Substance	Open list with remarks
CAS number	CAS Registry Number	Text
CAS name	CAS name	Multi-line text
CIPAC number	CIPAC number	
Synonyms		Header 1
Synonyms	List any synonyms for the substance For **microorganisms** alternative names should be added in the table and the accession number/s from internationally recognised culture collections EFSA paramCode should be added in the table	
	Set confidentiality and regulatory program flags	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		Text
Synonyms		
Molecular and structural information		Header 1
		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	Multi-line text

	https://cactus.nci.nih.gov or generated by ChemSketch or ChemDraw	
Structural formula	The structural formula for the active substance https://chem.nlm.nih.gov/chemidplus/structure3D/viewer/ ChemSketch, ChemDraw	Image
Remarks	See molecular formula	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		Single file attachment
Remarks on structure file		Text
Chemical structure files		
Related substances	Not relevant for Basic Substance	Header 1
Identifier		Open list
Identity		Text area
Remarks		Text
Relation		Open list
Group / category information		Multi-line text

Literature reference

Purpose
Storage of bibliographic metadata with attached documents including full study reports and published scientific papers
Linking studies to the Notification of Studies Database
Used as the data source in OECD harmonised templates and DOMAIN Endpoint Study Records.
It is important to create a Literature reference for all studies used as evidence in the dossier. This would also include all relevant studies selected for full-text assessment identified from a literature search (when required).

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	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 'published' for relevant studies identified from a literature search to address data requirements **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)' The other reference types can also be used	Open list
Title	Title of the study report, publication or other report type	Text
Author	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, click on 'New item' and compile relevant fields accordingly. -	
Study ID type	Select 'Notification of studies (NoS) ID' when reporting an NoS ID or studies started after March 2021	Open list
Study ID	Report the relevant identification number	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'. This section should also be used to include justifications in cases where a study was notified and the NoS ID is reported but the notification date is after the starting date of the study (delayed notification)..	Text area
Other study identifier(s)		
Attachments		
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'. Use 'other' to indicate the type of content of the other sets of attachments e.g. addendum	Open list
Attached confidential document	The applicant has selected the option "publication (copyright not owned for reproduction)" from the drop-	Single file attachment

	down list pertaining to the field "GeneralInfo.ReferenceType": a copy of the relevant publication in PDF format along with the relevant bibliographic references/ citations needs to be provided for scientific assessment purposes only. The uploaded attachment will not be included in published dossier but the citation will be published. 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.	
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.	Single file attachment

	Other supporting documentation e.g. addendum can be uploaded.	
Attachments		
Remarks	Additional remarks on the uploaded literature reference content can be added here	Text

Links to support material

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

Legal entity (including contact entity)

Purpose:

Submissions require a Legal entity which has to be defined including contact details prior to submission. A Legal Entity (LE) may represent anything between a complex business structure and a simple organised business, for example, a corporation, a company, or a single person. LEs are identified by their name, universally unique identifier (UUID), address, country, and general contact information. You can create a LEO via ECHA accounts

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.

The 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. The information provided in the Legal Entity is published. Hence, no personal information relating to natural persons should be provided under these fields... **!Do not include personal e-mail addresses and telephone numbers!**

Note that the 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.

You can add more legal entities within the IUCLID application via the inventory.

Field name	Instructions	Path
General information		LEGAL_ENTITY.GeneralInfo
Legal Entity name	Name of the legal entity i.e. Company name	LEGAL_ENTITY.GeneralInfo.LegalEntityName
Legal entity type	Select one legal entity type from the dropdown menu. If other, please include an explanation in the free text field below.	LEGAL_ENTITY.GeneralInfo.LegalEntityType
Remarks	Any additional information on the legal entity, if relevant	LEGAL_ENTITY.GeneralInfo.Remarks
Other names	Other names can be specified and if needed these names can be marked as confidential	LEGAL_ENTITY.GeneralInfo.OtherNames
Address	See Confidentiality Requests	LEGAL_ENTITY.GeneralInfo.ContactAddress.DataProtection
Address 1	Street address of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address1
Address 2	Secondary address, if relevant	LEGAL_ENTITY.GeneralInfo.ContactAddress.Address2

Postal Code	Postal code of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Postal
Town	Town of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Town
Region/State	Region/State of the legal entity	LEGAL_ENTITY.GeneralInfo.ContactAddress.Region
Country	Select the country in which the legal entity is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	LEGAL_ENTITY.GeneralInfo.ContactAddress.Country
Phone	Phone number of the legal entity (this field must not contain personal data, therefore e.g. the number of a switchboard should be provided)	LEGAL_ENTITY.GeneralInfo.ContactAddress.Phone
Fax	Fax number of the legal entity (this field must not contain personal data)	LEGAL_ENTITY.GeneralInfo.ContactAddress.Fax
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)	LEGAL_ENTITY.GeneralInfo.ContactAddress.Email
Website	Legal entity website	LEGAL_ENTITY.GeneralInfo.ContactAddress.WebSite
Identifiers	Optional: Other identifiers can be reported. Legal entity identifiers, Regulatory programme identifiers, and Other IT system identifiers. Each type contains a menu from which relevant sub-types of identifier can be selected. For example, Legal entity has an option for DUNS (Data Universal Numbering System for identification of a Legal Entity. Click on New Item and set values. See Confidentiality Requests.	LEGAL_ENTITY.Identifiers

Contact information	An address can be defined for a contact person of the Legal entity and links can be made to one or more Contact entities	LEGAL_ENTITY.ContactInfo
Contact Person	This can be managed in the Contact entity manager	
General information		CONTACT.GeneralInfo
Contact type	Select one contact type from the dropdown menu. If other, enter the appropriate contact type in the free text field below.	CONTACT.GeneralInfo.ContactType
Last name	Last name of the contact person. Note that this field is mandatory	CONTACT.GeneralInfo.LastName
First name	First name of the contact person.	CONTACT.GeneralInfo.FirstName
Organisation	Name of the Organisation. Note that this field is mandatory	CONTACT.GeneralInfo.Organisation
Department	e.g. Scientific Department	CONTACT.GeneralInfo.Department
Title	Title of the contact person (e.g. Mr.).	CONTACT.GeneralInfo.Title
Phone	Phone number of the contact person	CONTACT.GeneralInfo.Phone
Mobile	Mobile phone number of the contact person	CONTACT.GeneralInfo.Mobile
Fax	Fax number of the contact person	CONTACT.GeneralInfo.Fax
Email	Email address of the contact person	CONTACT.GeneralInfo.Email
Address 1	Street address of the contact person	CONTACT.GeneralInfo.Address1
Address 2	Secondary address, if relevant	CONTACT.GeneralInfo.Address2
Postal Code	Postal code of the street address of the contact person	CONTACT.GeneralInfo.Postal
Town	Town of the contact person	CONTACT.GeneralInfo.Town
Region/State	Region/State of the contact person	CONTACT.GeneralInfo.Region
Country	Select the country in which the contact person is located from the dropdown menu. If other, enter the appropriate country information in the free text field below.	CONTACT.GeneralInfo.Country
Remarks	Any additional information, if relevant	CONTACT.GeneralInfo.Remarks

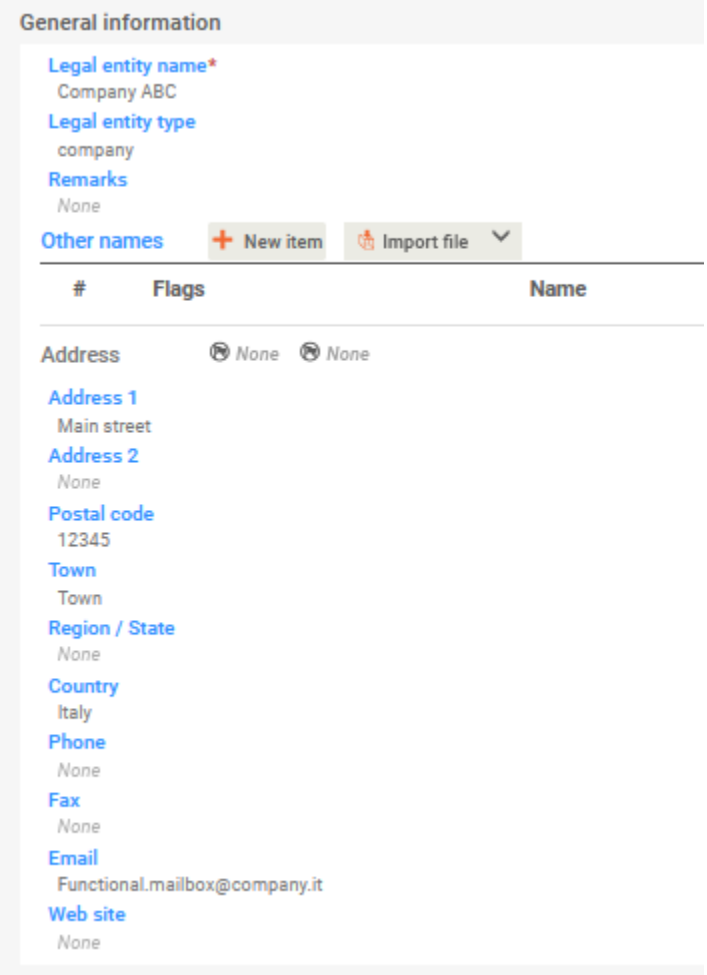
Links to support material:

https://echa.europa.eu/support-echa-accounts-and-eu-login

https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_html_en.pdf/9d01cb53-902d-dbb6-fb00-fa141688c395

https://echa.europa.eu/documents/10162/21721613/echa_accounts_en.pdf

https://www.youtube.com/watch?v=4JGsQUbGYqw



Validation Assistant Rules

Rule Description	Validation Assistant Message
***QLT_PPP_037**: each CFD must be justified, in case justification is provided it must have CFD*	Data protection' is incomplete. If the Confidentiality flag is checked the Justification must be completed
***BR_PPP_036** European reference number in UUID format*	Dossier header is incomplete. European reference number field must be filled in and the format must be UUID.
***BR_PPP_062**: Reference substances in Mixture compositions must be identified*	Components of the mixture composition. Reference substance information is not complete. The reference substance must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name. For microorganisms the species and strain should be reported in the IUPAC name. In the case of extracts or other cases where an IUPAC name cannot be defined this field should be completed e.g. 'Extract of ginger' or 'Unknown mixture'
***BR_PPP_086** Section 2: Preparation of the substance for use - At least one Mixture composition must be present*	Section 2: Preparation of the substance for use. A mixture composition document must be completed. Provide details on the preparation.
***BR_PPP_087**: Each Mixture composition must have at least one Component, each component must have 'Name' filled in*	A mixture composition document must be completed. The components of the mixture, preparation or formulation must be listed and associated with a reference substance entity, substance dataset or mixture dataset. For each component the 'Name' field must be completed
***BR_PPP_088**: "Active substance" component must have only reference substance or substance entities linked*	Mixture composition is incomplete. The component with the Function = 'active substance' must be linked in the 'Name' field to a reference substance or substance dataset
***BR_PPP_089** Mixture composition is incomplete*	Mixture composition is incomplete. There must be one component with the Function = 'active substance'. The function 'active substance (other, not to be assessed)' can be used for active substances which are included in the application but not for approval