EFSA User Guide on Confidentiality

A step-by-step practical guide
on the submission and processing of confidentiality requests

Updated April 2025

What is this guide about?

This guide describes the steps underlying the submission and processing of confidentiality requests.

This guide covers the content from the following resources:

- Regulation (EU) 2019/1381, i.e. the "Transparency Regulation"
- Practical Arrangements concerning Transparency & Confidentiality
- Practical Arrangements concerning Confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009
- Q&As on the EFSA Practical Arrangements

SUMMARY

What will you find in this guide?

Click on the letter of the section you want to read to quickly jump to the related page

SECTION A

General requirements regarding the submission and processing of confidentiality requests

CONTENT OVERVIEW

Glossary of Key Concepts in this Guide

Part 1 → IT tools and requirements for the submission of confidentiality requests
Part 2 → Best practices for Applicants to submit confidentiality requests
Part 3 → Decision-making process and implementation of confidentiality decisions

Glossary of key concepts in this guide

CONFIDENTIALITY ASSESSMENT is the process of assessing confidentiality requests on **confidential business information** (**CBI**) or **personal data** (**PD**).

CONFIDENTIALITY REQUESTS are requests to treat certain information, i.e., CBI or PD, as confidential. Confidentiality requests may be made on **scientific data, studies and other information, including supplementary information**, supporting an **application**, **generic mandate** or **call for data** falling under the **Transparency Regulation**.

EXTRACT FROM THE NOTIFICATION OF STUDIES (NOS) DATABASE includes **a list of all studies notified by Applicants to support an application** for which EU law requires EFSA to issue a scientific opinion. The NoS extract shall include: the title and scope of the study commissioned or carried out by the Applicant, the name of the laboratory and testing facility carrying out the study, the starting and planned completion dates.

DRAFT CONFIDENTIALITY DECISION contains the **draft assessment** of the Applicant's confidentiality request. It is drawn up and notified to the Applicant **in case it is intended to reject one or more confidentiality requests**. If the **Applicant disagrees** with the draft decision of EFSA, it may **state its views in writing** or withdraw the application **within two weeks** from the notification of the draft confidentiality decision.

FINAL CONFIDENTIALITY DECISION reflects the **final assessment** of the Applicant's confidentiality requests taking account of the Applicant's comments on the draft decision, if any. It **is notified to Applicants** and marks the end of the confidentiality assessment.

CONFIRMATORY APPLICATION is **a request** an Applicant may submit to EFSA **to reconsider its assessment** reflected in **the final confidentiality decision**.

DECISION ON CONFIRMATORY APPLICATION is the **decision issued by EFSA on the Applicant's request** to EFSA **to reconsider** its final confidentiality decision.

PROACTIVE DISCLOSURE UNDER THE TRANSPARENCY REGULATION implies that, amongst others, **all scientific data and information** supporting requests for authorisations or for approvals under Union law as well as other requests for scientific output should **be made publicly available** in a **proactive** manner and be easily accessible as early as possible in the risk assessment process. This does **not apply** to information duly justified and **accepted as confidential**. An application may be **re-published several times** (i) **after validation** and, if one or more confidentiality request is rejected, ii) **upon implementation** of **the final confidentiality decision/decision on confirmatory application** on the valid/admissible dossier), iii) **after adoption of the EFSA scientific output, if applicable, upon implementation** of **the final confidentiality decision/decision on confirmatory application** on the final version of the dossier (incl. all additional data submitted).

SANITISATION is the process of **irreversibly and permanently masking information** subject to confidentiality requests in the **non-confidential versions** of documents and datasets submitted for publication.

PUBLIC CONSULTATION on the **non-confidential version** of the application or notification made public by EFSA **in accordance with its confidentiality decision**, if any, is launched to **consult the public** to identify whether **other relevant scientific data or studies** are available on the subject matter concerned by the application or notification.

ADDITIONAL OR SUPPLEMENTARY INFORMATION are information submitted by the Applicants during the scientific evaluation after validation of an **application** or acceptance of the **generic mandate** (including a **call for data** launched in the context of an EFSA mandate). EFSA starts to process confidentiality requests on additional or supplementary information **only following the adoption of the EFSA scientific output**, including scientific opinions.

REVIEW OF CONFIDENTIALITY in accordance with Article 39c of the GFL may occur before the adoption of the EFSA scientific output with regard to **information that has been previously accepted as confidential** but may nevertheless need to be **made public**, as it is related to **foreseeable effects on human health, animal health or the environment**.

IT tools for the submission of confidentiality requests

ESFC PLATFORM

IUCLID

PORTALINO

E-SUBMISSION FOOD CHAIN PLATFORM (also called **ESFC**) is used for the majority of applications regarding regulated products.

See section B

IUCLID is used for plant-protection products applications on active substances, microorganisms and maximum residue levels.

See section C

PORTALINO is used for generic mandates (including calls for data) as well as applications and background documents (e.g., pesticides assessment reports) not covered by the first two portals.

See section D

Confidentiality requirements

KEY REQUIREMENTS *following Articles 4(1), 9 and 10 of the EFSA Practical Arrangements (PAs) concerning Transparency and Confidentiality* **and**, *for RMS confidentiality assessment (pesticides), Articles 4, 5 and 6 of the EFSA Practical Arrangements (PAs) concerning Confidentiality in accordance with Articles 7(3) and 16 of Reg. (EC) No 1107/2009*

a. Confidentiality requests may only be **submitted via the applicable IT tools** indicated by EFSA whenever an Applicant requests **scientific data, studies and other information** submitted to EFSA to be treated as confidential

b. **No fees** are attached to the submission or processing of confidentiality requests

c. Confidentiality requests must be supported by a **verifiable justification**. They may be submitted **only with respect to certain parts** of the submitted information that must be **clearly identified** (e.g., by reference to the document, page, paragraph etc., as appropriate) excluding any information that is not subject to the confidentiality request

d. Only information falling under **the items of information mentioned in Article 39(2) GFL and the corresponding provisions** in the sectoral legislation (e.g., Article 63(2) in Regulation (EC) No 1107/2009) may be claimed confidential

e. Confidentiality requests on **CBI** must be in compliance with the **cumulative requirements** in Article 10(b) of the EFSA PAs concerning Transparency & Confidentiality and, for RMS confidentiality assessment (pesticides), Article 6 of the EFSA PAs concerning Confidentiality in accordance with Articles 7(3) and 16 of Reg. (EC) No 1107/2009

f. **Once submitted**, the confidentiality requests may be **amended** by the Applicant **only when requested to do so by EFSA**, in the context of a request for clarification, and provided that the amendment does not broaden the items claimed as confidential

WHEN CAN INFORMATION BE CLAIMED CONFIDENTIAL?

1. ***When*** submitting scientific data, studies and other information supporting applications, including supplementary information ***(Applications)***
2. ***When*** submitting scientific data and information, including supplementary information, supporting requests from the European Parliament, the Commission and Member States for a scientific output ***(Mandates)***
3. ***When*** submitting scientific data and information in response to an EFSA call for data ***(Calls for data)***
4. ***When*** requested by EFSA to submit confidentiality requests (if any) with regards to information on which EFSA's scientific outputs are based (e.g., pesticides assessment reports) or on the output as such (e.g., Renewal Conclusion) ***(Background information & Outputs)***

Confidentiality requirements: focus on point e of previous page

KEY REQUIREMENTS *following Article 10(b) of the EFSA PAs concerning Transparency and Confidentiality* ***and*** *Article 6 of the EFSA PAs concerning Confidentiality in accordance with Articles 7(3) and 16 of Reg. (EC) No 1107/2009*

CUMULATIVE REQUIREMENTS

The document or information for which confidential status is requested:

i. ***is not publicly available***

ii. ***is eligible for legal protection*** and has not been acquired in an unlawful manner

iii. ***does not fall under the definition of "environmental information"*** pursuant to Article 2 of the Aarhus Regulation

iv. ***is demonstrated by the Applicant to potentially harm its interests to a significant degree:*** the Applicant must declare that it reaches the 5% threshold (**potential financial harm criterion**), and that the information is less than 5 years old (**novelty criterion**), or failing to address either of these two criteria, provide an **actual and specific reason** confirming that disclosure would harm the Applicant's interest to a significant degree

N.B. *Failure to comply with the requirements concerning confidentiality requests may trigger a request for clarification to Applicants which will likely delay the processing of the confidentiality requests and consequently the overall progression of the risk assessment*

Best practices: Justifications

In line with **Articles 39(2) and 39(a)(1) of the GFL**, for **each item of information claimed confidential and identified, the Applicants must provide the specific legal basis** supporting their request, with an explanation as to why the information claimed confidential falls under this legal basis, when not self-explanatory. For **confidential business information** the legal grounds are those listed in **the closed-positive list** in **Article 39(2)(a) to (d) of the GFL – or in the corresponding provisions in the sectoral legislation** (e.g., Article 63(2) of Regulation (EC) No 1107/2009).

EFSA recommends:

a **a clear identification of the information items claimed confidential** (*see* article 10(a) of EFSA's PAs concerning Transparency and Confidentiality):

V PROVIDE THE EXACT LOCATION OF EACH DISTINCT ITEM claimed as confidential. Depending on the tool, this can include a detailed reference to the exact field and, for attachments, to **file name**, **page number, paragraph**, **section** or **line number** and, if short, **a direct quote of information**

X Avoid claims like '*throughout the document*', '*entire document*' or '*on all pages*'

b **a clear identification of the legal ground for each information item claimed confidential** (*see* article 9(4)(a) of EFSA's PAs concerning Transparency and Confidentiality):

V PROVIDE THE SPECIFIC (1) LEGAL GROUND (e.g., **letter (a)** of Article 39(2) of Regulation (EC) No 178/2002 – manufacturing process) on the basis of which confidentiality is requested **FOR EACH DISTINCT ITEM** identified and claimed as confidential

X Avoid claims of the same information under various legal grounds listed in the closed-positive list of Article 39(2)(a) to (d) of the GFL – or in the corresponding provisions in the sectoral legislation; or **based on generic legal references** (e.g., Article 39(2) of Regulation (EC) No 178/2002)

N.B. *Specific instructions for confidentiality justifications submitted via IUCLID and Portalino are available in Section C (IUCLID) and Section D (Portalino) of this User Guide, respectively.*

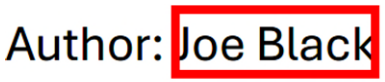
Best practices:
Submission of confidential and non-confidential versions

In line with **Article 39(a)2 of the GFL**, Applicants shall provide a **non-confidential version and a confidential version** of the information submitted. In that context, Applicants shall ensure that all the confidential and non-confidential **versions** of documents/datasets **perfectly match**, with the only difference that **in the confidential version the items claimed confidential are marked, while in the non-confidential version for publication the same items are irreversibly masked**.

EFSA recommends:

a To earmark or box the items claimed confidential in the confidential version

The "earmarking" or "boxing" **must enable the explicit and distinct identification of information** concerned by the Applicant's confidentiality request. In addition, the "earmarking" or "boxing" **must not impair the readability of the information concerned and must be reversible** (considering that EFSA may need to remove the "earmarking" or "boxing", if the corresponding confidentiality request has been rejected).



b To irreversibly mask the items claimed confidential in the non-confidential version for publication purposes

The items must be irreversibly masked and blocked out through a dedicated functionality. Several technical solutions commonly in use dispose of a feature which allows the masking of information, once the file is closed and saved as a masked version.

N.B. *X Avoid the mere highlighting in black or any other way to hide information out of the specific sanitisation functionalities, as it may not lead to the permanent and irreversible masking of the items claimed confidential. X Avoid the complete removal of entire sentences, paragraphs, items, pages performed by deleting the information without irreversibly masking it, as this would imply the non-correspondence between the confidential and the non-confidential versions.*

How does EFSA decide on confidentiality requests

EFSA:

a. **handles** the confidentiality decision-making process in accordance with Article 39 to 39e of the GFL and, if applicable, sectoral legislation, following EFSA Code of Good Administrative Behaviour

b. **assesses** confidentiality requests in view of the procedural requirements and of the compliance with the minimum substantive requirements set in the EFSA PAs (*see* previous pages in SECTION A, Part 1 of this Guide)

c. **draws up and notifies a draft decision** on the confidentiality requests to the Applicant (applicable only in case EFSA intends to reject one or more of the Applicant's confidentiality requests)

d. **adopts and notifies a final decision** on the confidentiality requests to the Applicant

e. **communicates the decision** on the confidentiality requests to the Commission and the Member State's competent authorities or EU Reference Laboratory involved in the risk assessment process

f. **assesses a confirmatory application**, if the Applicant wishes that EFSA reconsiders its position. The decision on the confirmatory application may be subject to an action before the General Court or to a complaint regarding maladministration before the European Ombudsman

N.B. ADDIONAL OR SUPPLEMENTARY INFORMATION

*The same process steps are applied by EFSA **to additional or supplementary information** that may be provided by the Applicants during the risk assessment.*
*EFSA starts to process confidentiality requests on additional or supplementary information **only following the adoption of the EFSA scientific output**.*

N.B. REVIEW OF CONFIDENTIALITY

***Before EFSA issues its scientific outputs, including scientific opinions**: if **EFSA** granted confidential status to certain items meant to be included in the conclusions of scientific outputs, including scientific opinions, it **can review** their **confidential status** in case the items relate to **foreseeable effects on human health, animal health or the environment** (see Article 39(4)(b) and 39c of the GFL). In this case, EFSA will reopen the decision-making process and will start a new confidentiality assessment on those items.*

Implementation of the confidentiality decision

a. In accordance with the confidentiality decision, **the masking** of information to which EFSA has granted confidential status or **the unmasking** of information to which EFSA has not granted confidential status is ensured and implemented by EFSA. For dossiers submitted via **IUCLID**, the **implementation** is performed **by the Applicants** (*see* Section C of this User Guide)

b. **EFSA <u>may</u>** exceptionally, in limited and specific cases, **share the masked version of documents and datasets with the Applicant** prior to their publication for verification of the consistency between the confidentiality decision and the way in which it has been implemented

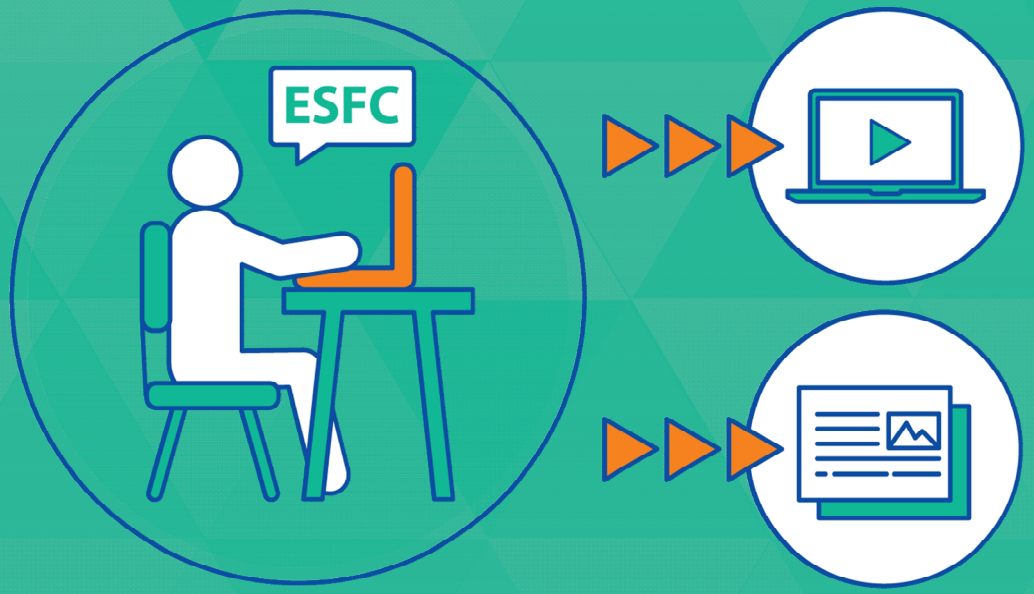
c. **The masked documents and datasets –** including the masked version of the NoS extract, if applicable **- are published** by EFSA on the OpenEFSA Portal upon adoption of the confidentiality decision

d. As a general rule, there are three moments at which scientific data and info submitted by Applicants are **proactively published** by EFSA: **i.** after the application dossier is deemed valid or admissible (for generic mandates: after the general mandate is accepted), **ii.** before the public consultation (taking into account the outcome of the confidentiality assessment), and **iii.** after publication of the scientific output, including scientific opinions

N.B. *Documents and datasets submitted to EFSA by Applicants are proactively published by EFSA,* ***save for information duly justified and accepted as confidential*** *(this pre-supposes that* ***the Applicant submits confidentiality requests****).*

SUMMARY

Requirements regarding the submission and processing of confidentiality requests in ESFC



Follow the link to → ESFC User Guide

Watch the video tutorial

CONFIDENTIALITY IN ESFC
Connect to the ESFC User Guide

WHAT IS ESFC?

The **E-SUBMISSION FOOD CHAIN PLATFORM** (also called ESFC) is used for most of application dossiers regarding **regulated products**

HOW TO BUILD THE APPLICATION DOSSIER IN ESFC

The **list of domains** and of the related procedures and requirements is defined in **Chapter 4 of the ESFC User Guide**

HOW TO REQUEST CONFIDENTIALITY

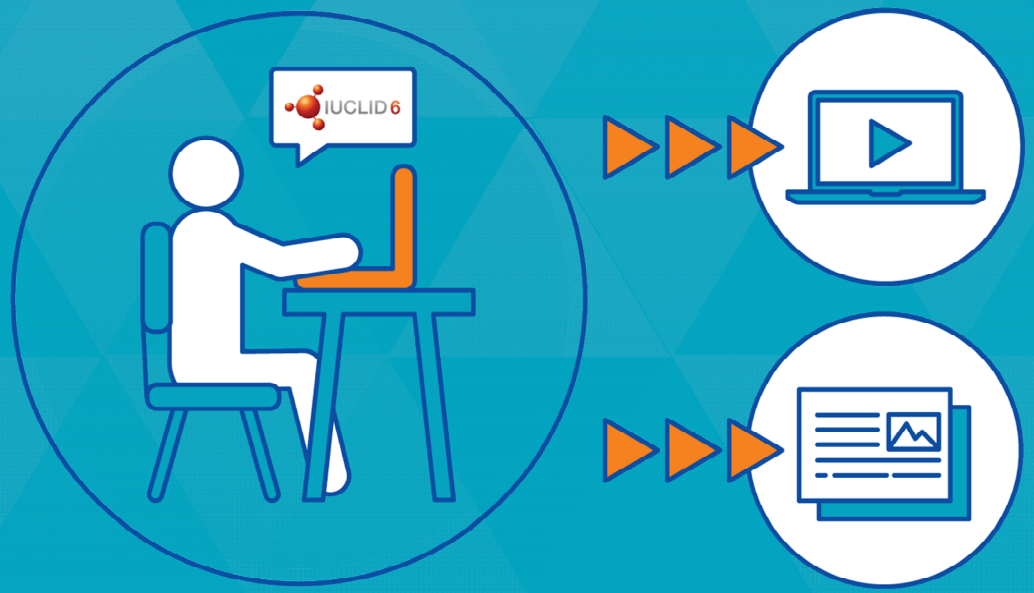
Step-by-step instructions on **how to request confidentiality** are detailed in **Chapter 11 of the ESFC User Guide**

PROACTIVE DISCLOSURE

See page 12 of this Guide for general information about proactive disclosure. The way how the application dossier is made **publicly available** by EFSA for dossiers submitted via **ESFC** is described in **Chapter 12 of the ESFC User Guide**

SUMMARY

Requirements regarding the submission and processing of confidentiality requests in IUCLID



Follow the link to → IUCLID webpage

CONFIDENTIALITY IN IUCLID

Connect to → IUCLID 6

WHAT IS IUCLID?

The **INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE (IUCLID)** is the tool used by EFSA for managing pesticide application dossiers, more specifically: active substances (new active substances and renewals, including micro-organisms, as well as basic substances), basic substances and MRLs

HOW TO BUILD THE APPLICATION DOSSIER IN IUCLID

Please refer to the **IUCLID part** of the applications toolkit section on the EFSA webpage

HOW TO REQUEST CONFIDENTIALITY

- If the confidentiality request relates to **CBI**, Applicants need to set a confidentiality flag (**CBI flag**) in IUCLID, applicable both to **i. IUCLID fields** and **ii. attachments**. As far as IUCLID fields are concerned, only fields subject to the filter rule **UNLESS_CONF** can be claimed confidential (consult the latest version of the filter configuration file available **here** to verify the applicable filter rules)
- Applicants need to provide a **justification** in the corresponding **justification box** for all confidentiality requests submitted, **both on CBI and on personal data**

PROACTIVE DISCLOSURE

See page 12 of this Guide for general information about proactive disclosure. In IUCLID the **non-confidential (masked) version** of an application dossier is made **publicly available** by EFSA via a semi-automated process based on the principle that every field used in pesticide application dossiers has been assigned a **filter rule**, which determines whether the underlying information will be published, not published, or whether it can be claimed confidential via the **confidentiality flagging functionality** (for fields subject to the filter rule UNLESS_CONF). However, prior to publication, manual intervention may still be required from the Applicant to implement EFSA's confidentiality decision (*see* page 30 of this Guide)

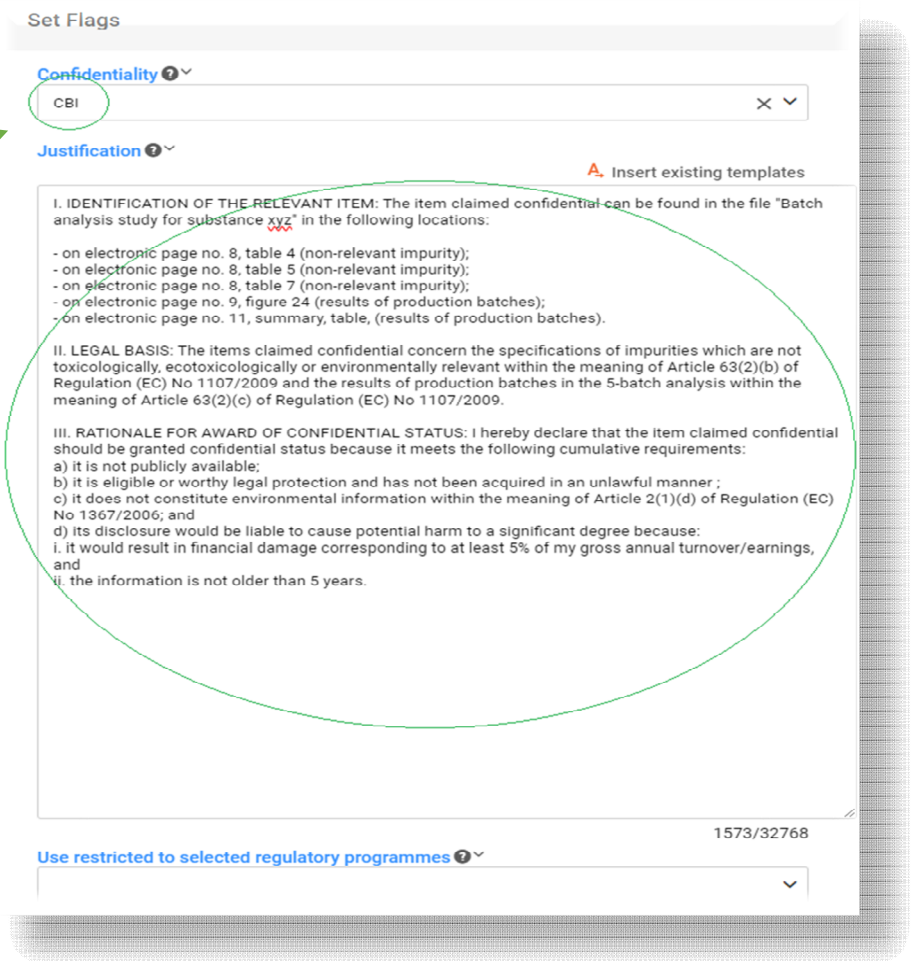
Submitting confidentiality requests: CBI - Technical requirements (1)

For claims concerning confidential business information (CBI) the Applicant must:

i. **set a CBI flag** by picking the value 'CBI' from the confidentiality picklist; and

ii. **provide a justification** supporting the CBI flag in the justification box.

The Applicant can claim confidential both a) **IUCLID fields** subject to the filter rule 'UNLESS_CONF' and b) certain information in **attachments** uploaded in the IUCLID record/summary or linked in the IUCLID record/summary as literature reference.

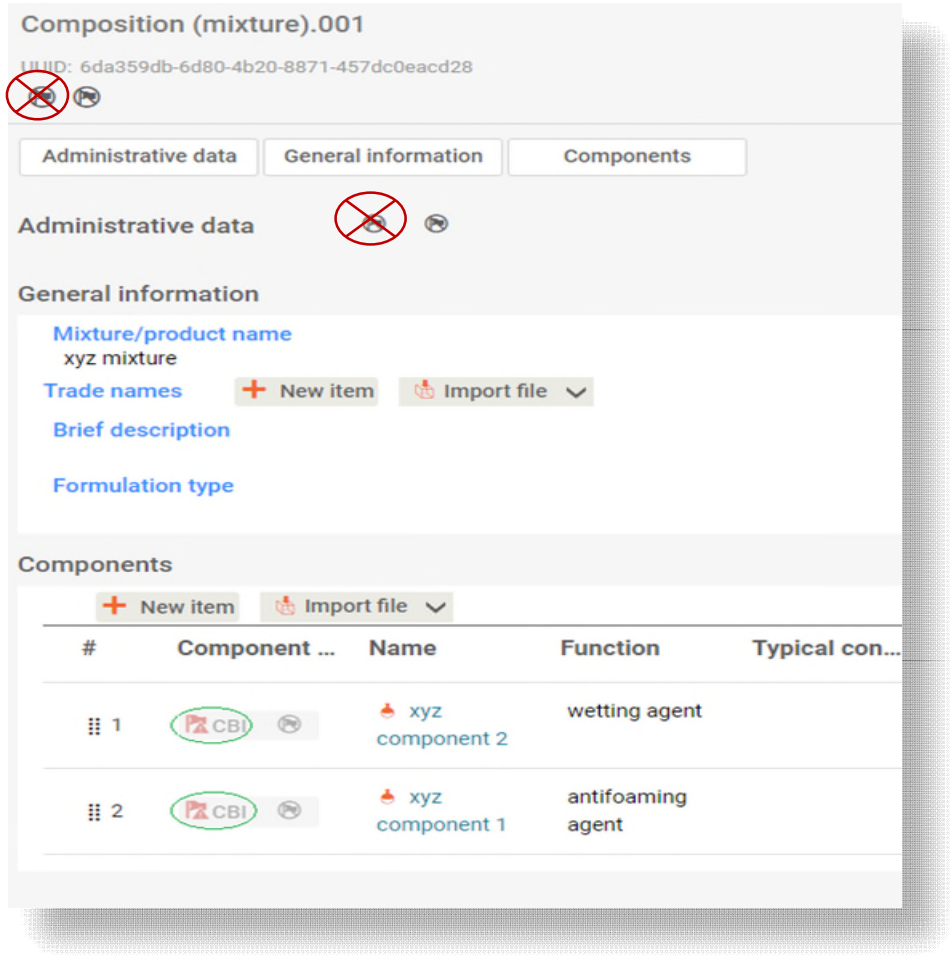


Submitting confidentiality requests: CBI - Technical requirements (2)

As a general rule, the **specific confidentiality flag** covering the information that the Applicant would like to keep confidential must be selected.

For example, if the Applicant wishes to submit a confidentiality request regarding **some specific components** of the mixture, **they should not use** the confidentiality flag at the top of the IUCLID document or linked to the administrative data section of the IUCLID document.

Instead, **they should use** the confidentiality flag available at the **individual component level** – *see* screenshot on the right →



N.B. *For the specific case of confidentiality flags at component level, note that the confidentiality flag will be devoid of purpose for components with the function "active substance", "active substance (other, not to be assessed)", "safener" or "synergist" as components with this function are published by default.*

Submitting confidentiality requests: CBI - Justification template

I. **IDENTIFICATION OF THE RELEVANT ITEM: The item claimed confidential can be found in** [indicate the IUCLID path of the field(s) and, in case of attachment(s), also the file name and the exact paragraph, page, line and part thereof, as appropriate]

II. **LEGAL GROUND FOR EACH DISTINCT ITEM CLAIMED CONFIDENTIAL:** [insert a brief and precise description of the item claimed confidential, e.g. "*information about the identity of a manufacturing site whose disclosure may reveal commercial links between a producer and the applicant*", and insert the legal ground under which the item can be claimed confidential, e.g. "*Article 39(2)(b) of Regulation (EC) No 178/2002*"]

III. **RATIONALE FOR THE AWARD OF CONFIDENTIAL STATUS → I hereby declare that the item claimed confidential should be granted confidential status, since 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 ('the Aarhus Regulation'); 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**

[if you are unable to declare significant harm by reference to the reasons under d) (i) and (ii), **another specific and actual reason** may be provided to substantiate why public disclosure may still potentially harm your interests to a significant degree]

N.B. *The parts of the template marked in* ***brown*** *can be copy-pasted into the justification box, while the parts in* ***blue*** *are to be filled in by the Applicant. This template implements the general requirements on pages 7-9 of this Guide with regard to IUCLID.*

Submitting confidentiality requests: CBI – Legal grounds

General CBI legal grounds

Article 39(2)(a) – (d) of Regulation (EC) No 178/2002 ('GFL') applicable to pesticide dossiers via Article 63(2)(a) of Regulation (EC) No 1107/2009 ('PPP Regulation')

- **Manufacturing Process**
  letter (a) of Article 39(2) of GFL
- **Commercial Links**
  letter (b) of Article 39(2) of GFL
- **Commercial Information**
  letter (c) of Article 39(2) of GFL
- **Quantitative Composition of the Subject Matter of the Request**
  letter (d) of Article 39(2) of GFL

PPP-specific CBI legal grounds

Article 63(2)(b) – (d) of 'PPP Regulation'

- **Non-Relevant Impurities**
  letter (b) of Article 63(2) of PPP Regulation
- **Results of Production Batches**
  letter (c) of Article 63(2) of PPP Regulation
- **Complete Composition of a PPP**
  letter (d) of Article 63(2) of PPP Regulation

N.B. *In the following pages (21-25), indicative and abstract examples of items are reported in the third and fourth columns:*

- ***items typically considered to fall under the legal ground concerned*** *marked as* ***CAN**** *and*
- ***items typically considered NOT to fall under the legal ground concerned*** *marked as* ***CANNOT****.

However, the assessment may vary depending on the concrete case and the circumstances at play.

SECTION C → Requirements regarding the submission and processing of confidentiality requests in IUCLID

GENERAL CBI LEGAL GROUNDS	TYPICAL LOCATIONS IN IUCLID	EXAMPLES OF ITEMS THAT CAN* FALL UNDER THIS LEGAL GROUND	EXAMPLES OF ITEMS THAT CANNOT* FALL UNDER THIS LEGAL GROUND
Manufacturing Process letter (a) of Article 39(2) of GFL *'the **manufacturing or production process**, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, **except for information which is relevant to the assessment of safety**'*	Such information may be typically found in: • IUCLID section 1.8 of the substance dataset • Document J	✓ **Method of Manufacture (synthesis pathway) of the active substance;** ✓ **Synthesis of the active substance** ✓ **Technical Synthesis Process of the active substance** ✓ **Safety Data Sheet of the starting materials** ✓ **Details about the starting materials/ Description of the starting materials** ✓ **Raw materials information** ✓ **Discussion of Formation of Impurities** ✓ **Absence of non-relevant/significant impurities** ✓ **Information on the presence, absence and/or identification of additives** ✓ **Production steps** ✓ **Manufacture data sheet** ✓ **Manufacturing Process** ✓ **Method of manufacturing** ✓ **Batch/Lot size** Specifically for Microorganisms: ✓ **Any information related to fermentation and cultivation** ✓ **Genome sequence, including the Whole Genome Sequencing or the names of the genomes** ✓ **Genome assembly, including assembly ID/name** ✓ **Standard operating procedure**	
Commercial Links letter (b) of Article 39(2) of GFL *'**commercial links** between a producer or importer and the applicant or the authorization holder, where applicable'*	Such information may be typically found in: • IUCLID section 1.2 of the mixture and substance dataset • IUCLID section 1.8 of the substance dataset • Document J and various study reports	✓ **Name of a legal person (other than the Applicant), its acronym, its contact details (postal address phone and fax number, website, email address, etc.)** ✓ **Manufacturer** ✓ **Supplier (test item supplier, test substance supplier)** ✓ **Manufacturing development code numbers (e.g. batch number/Lot number/ Test Substance number ('TSN')/ sample number etc.)**	

SECTION C → Requirements regarding the submission and processing of confidentiality requests in IUCLID

GENERAL CBI LEGAL GROUNDS	TYPICAL LOCATIONS IN IUCLID	EXAMPLES OF ITEMS THAT CAN* FALL UNDER THIS LEGAL GROUND	EXAMPLES OF ITEMS THAT CANNOT* FALL UNDER THIS LEGAL GROUND
Commercial Information letter (c) of Article 39(2) of GFL '***commercial information*** *revealing* ***sourcing***, ***market shares*** *or* ***business strategy*** *of the Applicant*'	Such information may be typically found in: • IUCLID section 1.2 of the mixture and substance dataset • IUCLID section 1.8 of the substance dataset • Document J and various study reports	✓ **Name of a legal person (other than the Applicant), its acronym, its contact details (postal address phone and fax number, website, email address, etc.)** ✓ **Manufacturer** ✓ **Supplier (test item supplier, test substance supplier)** ✓ **Manufacturing development code numbers (e.g. batch number/Lot number/ Test Substance number ('TSN')/ sample number etc.)** ✓ **Price of a study (e.g. several cost items related to an experiment)** ✓ **Quantities of substance used for a study (e.g. in each batch/lot)** ✓ **Letters of access (LoA) or Letter of Supply or Sample submission letters** ✓ **Annual tonnage of an approved active substance produced in Kg**	
Quantitative Composition of the Subject Matter of the Request letter (d) of Article 39(2) of GFL '***Quantitative composition*** *of the* ***subject matter*** *of the request,* ***except for information which is relevant to the assessment of safety***'	Such information may be typically found in: • IUCLID section 1.4 of the mixture dataset (especially in the mixture composition document) • IUCLID section 1.8 of the substance dataset • IUCLID section 1.9 of the substance dataset • Document J	Specifically for Microorganisms: ✓ **Description of the characteristics of the genome, including through comparisons of genomes**	× **Information on the active substance as such** is usually not considered to fall under this legal ground, because either such information is relevant to the assessment of safety, or it falls under the more specific legal grounds Article 63(2) letter (b) or (c) of the PPP Regulation (*see* next page)

SECTION C → Requirements regarding the submission and processing of confidentiality requests in IUCLID

PPP-SPECIFIC CBI LEGAL GROUNDS	TYPICAL LOCATIONS IN IUCLID	EXAMPLES OF ITEMS THAT CAN* FALL UNDER THIS LEGAL GROUND	EXAMPLES OF ITEMS THAT CANNOT* FALL UNDER THIS LEGAL GROUND
Non-Relevant Impurities letter (b) of Article 63(2) of PPP Regulation *'the **specification of impurity of the active substance** and the **related methods of analysis** for impurities in the active substance as manufactured, **except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant** and the **related methods of analysis** for such impurities'*	Such information may be typically found in: • IUCLID sections 1.8, 1.9, 2.4 or 4 of the substance dataset • Attachments under IUCLID section 11.2 of the substance dataset • Document J	Regarding non-relevant impurities: ✓ **Information regarding non-relevant impurities e.g.:** • Identification of the non-relevant impurity • Amount of the non-relevant impurity in the technical material: maximum content, concentration range and % w/w level • Reference standards of the non-relevant impurity • Method of analysis, analytical methods, impurity screening, quantitation of the non-relevant impurity • Results of studies validating analytical methods insofar as it may allow for the identification of non-relevant impurities and/or disclose information linked to Results of Production Batches (Art. 63(2)(c)) • Chromatogram, spectrum, graph or any other form of diagram/plot on the non-relevant impurity • Information about non-relevant impurities under the header '*Discussion on the formation of impurities*' or '*Identity of impurities included in the reference specification*' ✓ **Statement on the absence of non-relevant/significant impurities** ✓ **Information on the number of non-relevant impurities** ✓ **Chemical category / group / family of non-relevant impurities** insofar as it may allow for the identification of non-relevant impurities ✓ **Information on non-relevant impurities in Certificates of Analysis** ✓ **Information linked to QSAR analysis, *in silico* studies, read-across analysis** insofar as it may allow for the identification of a non-relevant impurity ✓ **Information on those phys-chem properties of non-relevant impurities** which may enable identification of non-relevant impurities ✓ **Chromatogram, spectra, graphs and any other diagram/plot on the relevant impurity if they have several peaks** and hence may also show non-relevant impurities ✓ **Chromatogram, spectrum, graph or any other form of diagram/plot concerning the technical material** (insofar as susceptible to revealing information on non-relevant impurities and not only on the pure active substance)	Regarding non-relevant impurities: × **Information on the (eco)toxicological and fate properties of a non-relevant impurity** Regarding relevant impurities: × **Information regarding relevant impurities,** e.g.: • Identification of the relevant impurity • Amount of the relevant impurity in the technical material: maximum content, concentration range and % w/w level • Reference standards of the relevant impurity • Method of analysis, analytical methods, impurity screening, quantitation of the relevant impurity • Phys-chem, (eco)toxicological and fate properties of a relevant impurity × **Statement on the absence of relevant impurities** × **Chromatogram, spectra, graphs and any other diagram/plot on the relevant impurity if they only have one peak** and hence only relate to the relevant impurity Regarding the active substance: × **Chromatogram, spectrum, graph or any other form of diagram/plot concerning the pure active substance** (hence not susceptible of revealing information on non-relevant impurities) Specifically for Microorganisms: × **Information on the CFU/g or percentage of TGAI in the product**

SECTION C → Requirements regarding the submission and processing of confidentiality requests in IUCLID

PPP-SPECIFIC CBI LEGAL GROUNDS	TYPICAL LOCATIONS IN IUCLID	EXAMPLES OF ITEMS THAT CAN* FALL UNDER THIS LEGAL GROUND	EXAMPLES OF ITEMS THAT CANNOT* FALL UNDER THIS LEGAL GROUND
Results of Production Batches letter (c) of Article 63(2) of PPP Regulation '***results of production batches*** *of the active substance including impurities*'	Such information may be typically found in: • IUCLID sections 1.8, and 1.11 in the substance dataset • Document J and various study reports such as tables detailing results of production batches within an attachment (e.g. Document J, five-batch analysis, analytical profile of batches)	✓ The **content of tables named, e.g., profile of assays, batch analysis data, presenting the results of the 5-batch analysis/Results of production batches/Composition of batches** (including rows/columns regarding information and percentage on relevant impurities, non-relevant impurities and the active substance) ✓ **Analytical profile of production batches** (batch analysis, quality control data, etc.) ✓ The results of the **determination of the various substances** in the context of the 5-batch analysis ✓ The **percentage / content of the active substance or impurities in a specific production batch** (including degree of impurity and information allowing for indirect identification of the percentage/content of the active substance) insofar as revealing **non-relevant impurities/results of production batches** ✓ The **specification derived from the specific different sources** of the substance in Document J or other attachments ✓ **Criteria/parameters for the validation of analytical methods for the identification of the a.s. in the technical material** insofar as they may reveal **results of production batches and/or identification of non-relevant impurities (Art. 63(2)(b))**	× **Content of active substance and relevant impurities in batches/lots on (eco)toxicological and fate studies** × Information on the **method of analysis of the active substance and relevant impurity(ies)** × Information on the **manufacturing date/production date of batches/lots** × Sentences such as '***The sources comply with the Implementing Regulation***' or '***No change to the approved minimum purity of the active substance is being proposed***' or '***it can be concluded that the technical product is technically equivalent to the EU reference specification***' or '***We propose to maintain the same specification limit for renewal***' Specifically for Microorganisms: x **Information on batches/lots used for the test on the Microbial Pest Control Product (MPCP) and related results/technical properties**

SECTION C → Requirements regarding the submission and processing of confidentiality requests in IUCLID

PPP-SPECIFIC CBI LEGAL GROUNDS	TYPICAL LOCATIONS IN IUCLID	EXAMPLES OF ITEMS THAT CAN* FALL UNDER THIS LEGAL GROUND	EXAMPLES OF ITEMS THAT CANNOT* FALL UNDER THIS LEGAL GROUND
Complete Composition of a PPP letter (d) of Article 63(2) of PPP Regulation *'information on the complete **composition of a plant protection product**'*	Such information may be typically found in: • the IUCLID mixture • IUCLID section 1.4 of the mixture dataset (especially in the mixture composition document) • Document J	✓ Information items that, in conjunction with other components of the Plant Protection Product, may be liable to reveal **the complete composition of a Plant Protection Product**, i.e.: • information on **co-formulants** (e.g., CAS number, any other identification number, the precise content/ratio in various measures of the co-formulant - note that a general threshold e.g. "above 10%" cannot be claimed confidential -, the trade name, statement that there are/are no co-formulants (including whether or not methods are required for co-formulants, as this may indirectly reveal the presence of co-formulants)) • **Safety Data Sheets of a co-formulant** • information on **mixture and/or Plant Protection Product as a whole** (e.g., regarding identity, content, ratio, trade name or other identifiers) ✓ **Description of the formulation process**	× The **identity, purity, minimum/maximum content, and current/proposed specification of the active substance** (except if it is part of the results of production batches, *see* row above) or of **synergists, safeners or other active substances contained in the product formulation** × **Safety Data Sheets of active substances, synergists or safeners** × Information on the **(eco)toxicological properties/hazard classification of all the components present in the product** × Information on **isomers** in the following cases: if the isomers a) compose the active substance (i.e. the active substance is a "racemic mixture" or "fixed mixture") or b) the isomer is the active substance itself, they need to be treated as the active substance × Information about the **identity or content of components constituting the active substance**: if an active substance is made up of various components which form an integral part of the active substance itself, the information related to such components needs to be treated as the active substance

N.B. As for any reference to **Document J** in pages 21-25 of this Guide, please note that for **chemical active substance applications** submitted **as of IUCLID 6 Version 9**, the IUCLID document 'FLEXIBLE_RECORD.Manufacturer_EU_PPP' along with its field to provide the **Document J attachment will be no longer available** (**for Microorganisms, as of April 2026**).

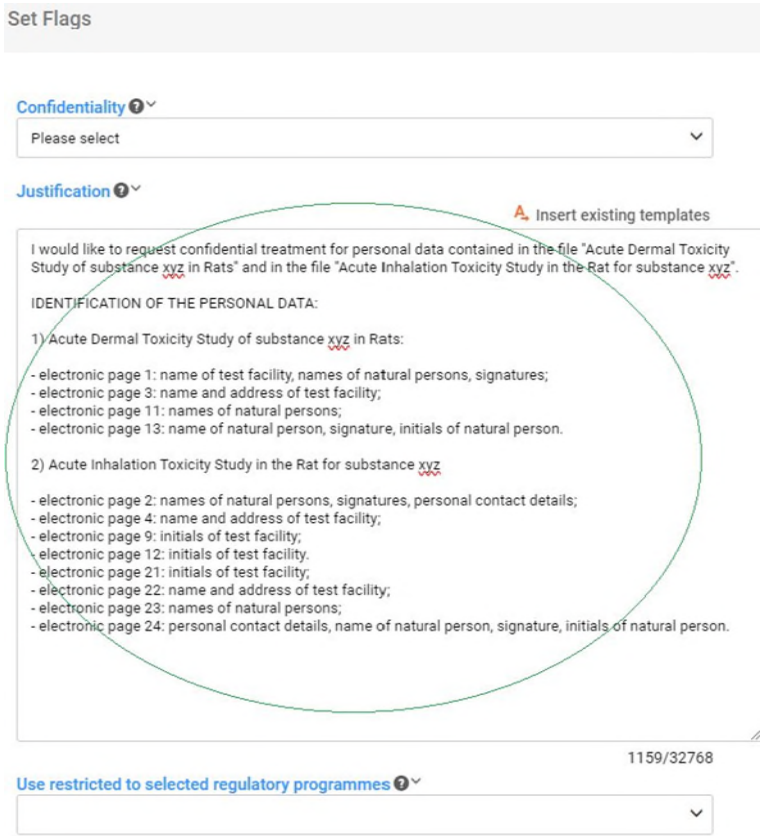
Submitting confidentiality requests: PD – Technical Requirements

For claims concerning personal data (PD) the Applicant must:

ONLY provide a justification supporting the request in the justification box.

No CBI flag must be set (this mean that the Applicant should NOT select any value from the confidentiality picklist) – *see* screenshot on the right

The Applicant can only claim confidential PD in an attachment uploaded or linked in an IUCLID record/summary.



N.B.

- ***'Legal entity' document**: a **functional mailbox** address and the number of a **switchboard** must be provided in the 'Legal entity' since this is always published. **Personal contact details** should be included in the 'Contact' document – **NOT in the 'Legal entity'**.*

- *'**Contact' document**: **personal contact details** are subject to the filter rule 'NOT_PUBLISHED' which implies that they will be **automatically removed** from the 'Contact' document when the dossier is disseminated – **no need to submit a confidentiality request**.*

- ***Literature reference' document**:*
  - *i. IUCLID field concerning **author names** is subject to the filter rule 'STUDY_REF_AUTH_PPP', which implies that author names are **automatically removed** from the literature reference for all unpublished studies when the dossier is disseminated - **no need to submit a confidentiality request**.*
  - *ii. IUCLID fields concerning **test lab** and **report number** are subject to the filter rule 'STUDY_REF_PPP', which implies that the test lab/report no. are **automatically removed** from the literature reference for all unpublished studies when the dossier is disseminated - **no need to submit a confidentiality request**.*

Submitting Confidentiality Requests: PD – Justification Template

I would like to request confidential treatment for personal data contained in the file [please provide the file name of each attachment, where the information considered personal data is located]

IDENTIFICATION OF THE PERSONAL DATA: [for each attachment indicate the page, the section/header, and if appropriate, the exact paragraph(s) and line(s) or part(s) thereof, where the personal data in question is/are located. In that context always specify the category of the personal data from the categories set out in the following non-exhaustive list of personal data categories:

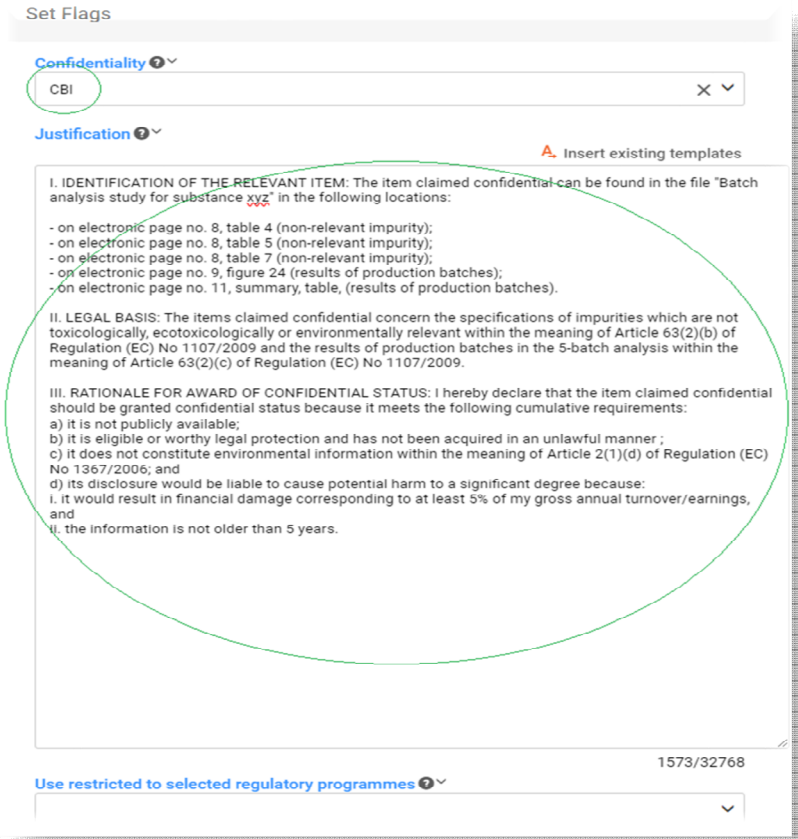
1) name of natural person
2) initials of natural person
3) address of natural person
4) signatures
5) personal contact or financial details
6) images of individuals
7) name of legal person other than the Applicant (e.g., test facility/laboratory/trial site/animal supplier, manufacturer)
8) Initials/acronyms of legal person other than the Applicant
9) address of legal person other than the Applicant
10) contact or financial details of legal person other than the Applicant
11) GLP compliance number
12) quality management system/ISO certificate number
13) validity code
14) trial/study number
15) GPS coordinates of test facility/laboratory/trial site
16) images of test facilities/laboratory/trial sites
17) detailed local maps/excerpts from regional or national maps showing location of test facility/laboratory/trial site (this does not cover high-level maps of Europe or world maps only showing the country in which the test facility/laboratory/trial site is located)
18) other: please specify]

N.B. The parts of the template marked in **brown** can be copy-pasted into the justification field, while the parts in **blue** are to be filled in by the Applicant. Note that for categories 7) – 18) the qualification of the information as personal data may depend on the specific circumstances at hand, therefore, EFSA reserves the right to reclassify the information following review of the Applicant's confidentiality request.

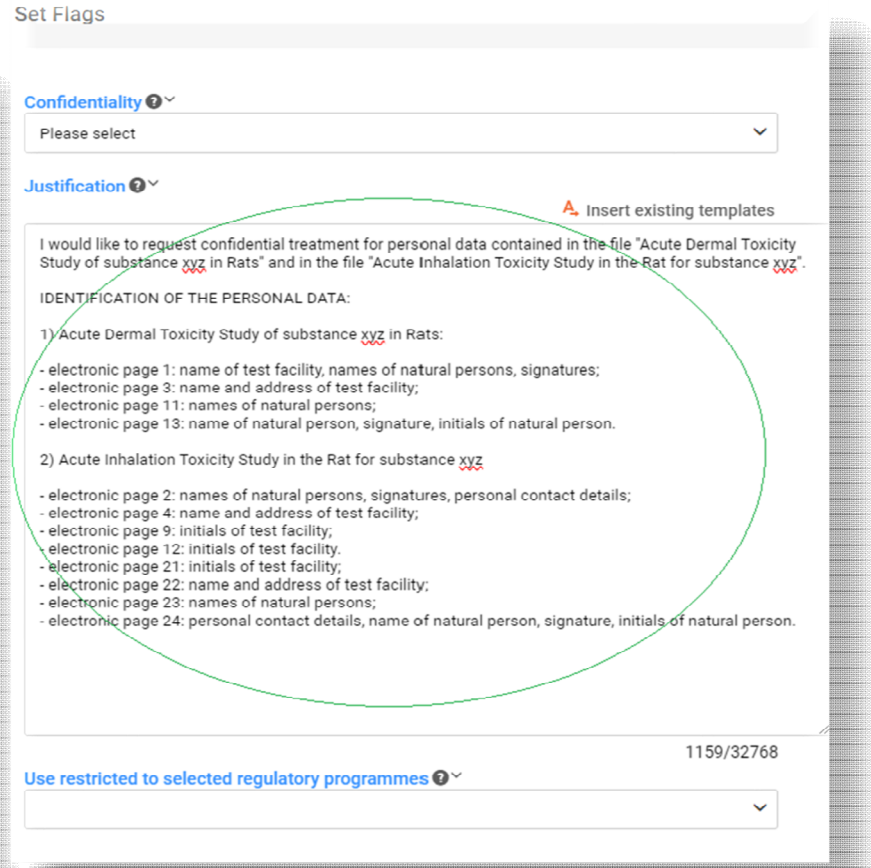
Examples of Compliant Justifications in relation to CBI and PD

Example of a compliant justification in relation to CBI in a IUCLID field

Example of a compliant justification in relation to CBI in an attachment



Example of a compliant justification in relation to personal data in an attachment



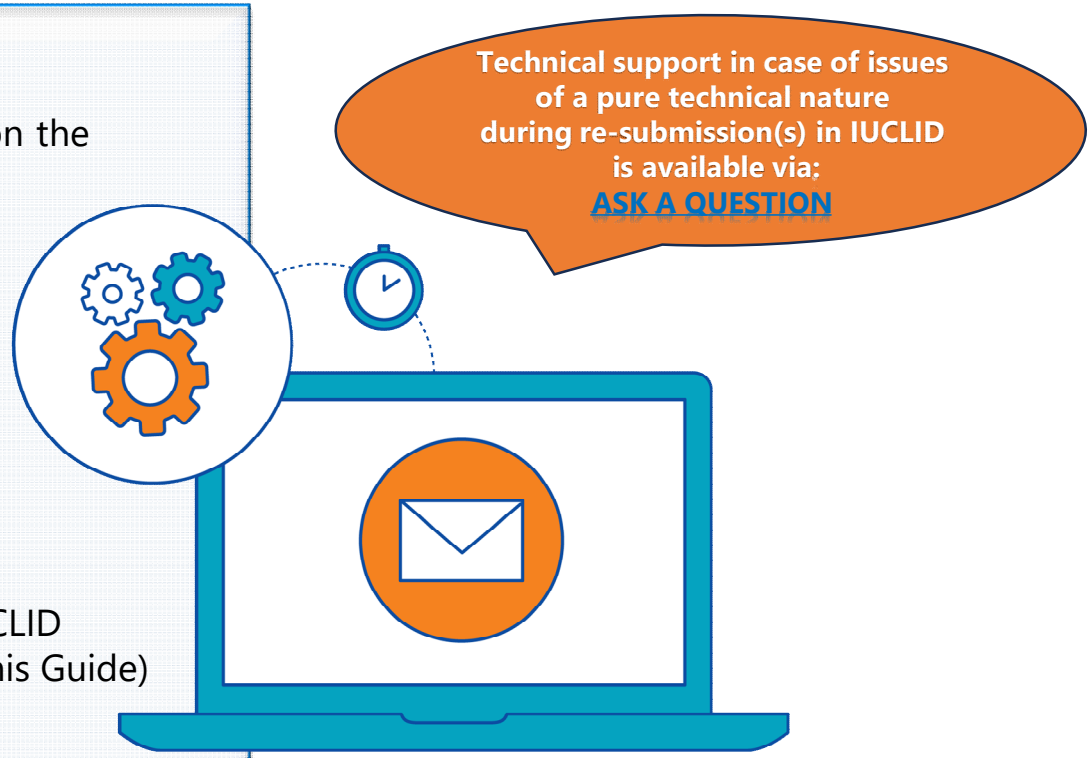
How confidentiality requests in IUCLID are processed

EFSA:

- contacts the Applicant **by email** in case of optional request for clarification on the "*list of confidentiality claims*" IUCLID report/dossier
- notifies the **decision(s)** as encrypted attachment **by e-mail**

THE APPLICANTS:

- **resubmit their dossier** in IUCLID in reply to EFSA's request for clarification
- provide their comments on the draft decision **by email**
- implement EFSA's confidentiality decision by **resubmitting their dossier** in IUCLID if one or more confidentiality requests are (partially) rejected (*see* page 30 of this Guide)
- may submit confirmatory application, if any, **by e-mail**



N.B. *It is important to provide adequate contact details within a dossier (generic contact details in the Legal Entity and personal contact details in the Contact Entity) and to make sure they are up-to-date. EFSA uses these contact details for all communications with the Applicant in relation to the application dossier, including for the confidentiality assessment and implementation.*

How to implement a confidentiality decision in IUCLID

The Applicant is responsible for implementing a confidentiality decision - whether from EFSA or from the Rapporteur Member State (RMS) - in IUCLID as follows:

a **For attachments**

- if the items claimed confidential and **masked** in the non-confidential (sanitised) version for publication are **accepted**, **no action** is required (in exceptional cases the item claimed confidential may be accepted, but action may still be required from the Applicant, e.g., if the Applicant omitted sanitising personal data which has been claimed and accepted as confidential)

- if the items claimed confidential and **masked** in the non-confidential (sanitised) version for publication are **rejected**, the Applicant will be required:
  i. to remove the confidentiality flag in the related IUCLID record/summary (only applicable in case of a fully rejected confidentiality request on an attachment); and
  ii. to unmask/disclose the items for which the confidential status has not been granted in the non-confidential version for publication*

b **For IUCLID fields**

- in case of **acceptance**, **no action** is required
- in case of **rejection**, the Applicant will be required **to remove the confidentiality flag**

c Having made the necessary changes in their IUCLID datasets according to (a) and (b), the Applicants will need to:

- **re-submit** their application dossier by
  i. exporting as a light dossier (recommended option)
  ii. submitting the updated dossier by means of the **ECHA submission portal**

- **inform EFSA – or the RMS - of the re-submission by** replying to the **e-mail** notifying them of EFSA's Decision on the Confidentiality Requests.

N.B. *the confidentiality request can be* ***partially rejected*** *(e.g., accepted for personal data as compliant with Article 39e of Regulation (EC) No 178/2002, but rejected for (some of) the items that the Applicant identified as confidential business information (because they are publicly available, or the legal ground is not correct, or the attachments are fully masked following a generic legal basis* etc.). *In this case only the rejected items will need to be unmasked by the Applicant and no flag removal will be required.*

TIPS AND RECAP FOR APPLICANTS

1. **Provide adequate contact details within an application dossier** (generic contact details in the Legal Entity and personal contact details in the Contact Entity) and make sure they are **up-to-date**

2. **Make reasonable recourse to confidentiality requests on CBI,** by carefully evaluating **whether your claim is really necessary to protect your commercial interests** and, if so, make sure it is in line with the requirements, including applicable filter rules

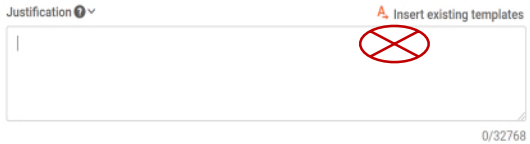
3. **Make sure your confidentiality requests on CBI are compliant**: specify the legal basis of each distinct CBI element claimed confidential, substantiate your claim (using the justification template) and, importantly, clearly identify the elements claimed confidential in attachments, if relevant; make sure you claim confidential and earmark only what is absolutely necessary and avoid too broad and unjustified claims/earmarking (e.g. do not earmark/mask whole pages if only a specific element – e.g. name of an impurity – is considered confidential, etc.)

4. **Engage with EFSA during the confidentiality assessment:** make effective use of the engagement opportunities, i.e., **i.** provide thorough and timely feedback to the request for clarification sent by EFSA (optional) regarding your confidentiality requests, **ii.** submit clear and complete comments upon consultation on the EFSA draft decision (mandatory) and **iii.** use the 'ASK a question' form, in case of issues during re-submissions

5. For **Joint Submissions, submit the same confidentiality requests in relation to the same literature reference as other Applicants**, so as to avoid inconsistencies

6. **Make sure PD and CBI in the non-confidential version of attachments is duly masked:** in line with the legislative requirements the non-confidential version of the dossier is published upon admissibility/validity "as submitted by the Applicant", i.e. as redacted/sanitised by the Applicant. *See* page 10 of this Guide

7. **Do 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 application dossiers



8. **Reminder that when the CBI flag is set at the section level:**
   - **the flag and the associated justification(s) will apply to all the fields/attachments within that section**
   - **separate justifications must be inserted in the text box for each individual field/attachment containing information for which confidential treatment is requested** (in practice, this may imply to insert several separate justifications in the justification text box of the confidentiality flag)

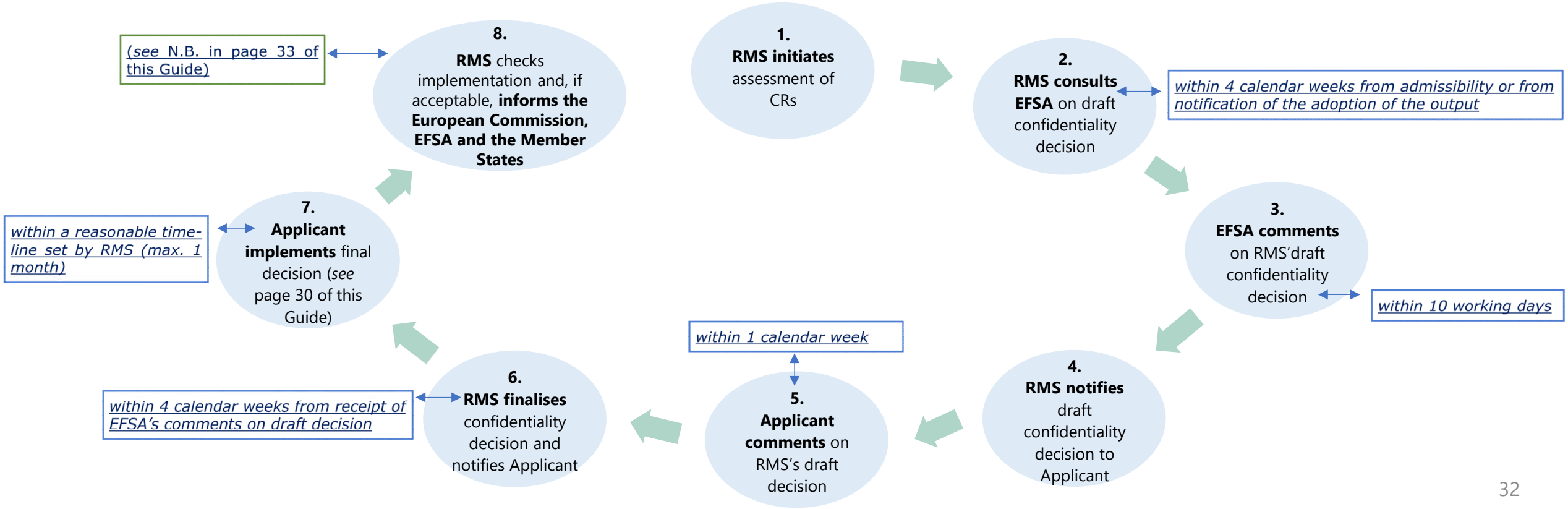
9. **Upload a justification attachment ONLY IF the justification is so long that it cannot fit in the character limit of the justification text box.** It must be provided as a confidential document in the field 'AttachedDocument' (subject to the filter rule 'NOT_PUBLISHED') under the IUCLID summary/record containing the field or attachment to which the confidentiality justification relates. The text in the justification text box must also expressly refer to the attachment, with the name of the attachment and the field where it can be found

10. **Limit the use of the attachment section of endpoint study records and avoid any duplication of attachments in the endpoint study record and in literature reference**: most attachments are to be provided in the literature reference (study report but also Metapath files, addendums or kinetic fitting reports). In principle, the attachment field of the endpoint study record should not be used (except in the case of image files linked to endpoint study reports, e.g., degradation pathways)

Confidentiality assessment of the Rapporteur Member States

General overview of the decision-making cycle

In line with **Article 7(3) of Regulation (EC) No 1107/2009**, the confidentiality requests submitted with an **application for the approval of an active substance** (**NAS**) or for **an amendment to the conditions of an approval** (**AMEND**) shall be assessed by the RMS. In line with **Article 7 of the EFSA Practical Arrangements concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 1107/2009**, the following steps and timelines apply to the **confidentiality assessment of the RMS** on **i. the admissible application dossier** upon declaration of admissibility (first confidentiality assessment) AND on **ii. the final application dossier** (on the additional data submitted during the risk assessment) upon notification of adoption of EFSA OUTPUT (second confidentiality assessment).



Guidelines for RMS to process and assess confidentiality requests

NAS/AMEND application dossiers

a Essential *preliminary* steps for the RMS

- **Initiate the confidentiality assessment** by generating the "***list of confidentiality claims***" via the "Report Generator" function:
  - i. **MUST: do NOT delay this step** as the public consultation can only be launched on the version of the IUCLID dossier reflecting the outcome of the confidentiality assessment. Hence, **delays in the confidentiality assessment may delay the risk assessment**
  - ii. **RECOMMENDATION**: start the confidentiality assessment upon receipt of the e-mail from EFSA about the publication of the dossier following dossier validation
- **Contact EFSA** through the Ask a question function on the official EFSA website in case of technical issues/questions
- **Request clarification** from the Applicant when information provided by them does not allow the RMS to draft a confidentiality decision (e.g., missing non-confidential versions of attachments (using **validation assistant**), missing justification(s) or justifications with missing legal ground/imprecise identification of the information claimed confidential in the "***list of confidentiality claims***" (*see* requirements on pages 17-27 of this Guide)

b Essential steps regarding the assessment for the RMS

- **Proceed with the confidentiality assessment** based on the **requirements for CBI** (*see* pages 17-25 of this Guide) and **PD requests** (*see* pages 26-27 of this Guide)
- Include a **thorough** and **specific** reasoning detailing the **outcome for each confidentiality request** in the confidentiality decision. **NB**: as interlinked with the confidentiality assessment on the NAS/AMEND application dossier, also confidentiality requests on the related Notification of Studies extract need to be assessed by the RMS

c Tips to facilitate EFSA's consultation for the RMS

(Article 7(6) of the EFSA PAs concerning Confidentiality in accordance with Articles 7(3) and 16 of Reg. (EC) No 1107/2009 requires the **RMS to consult EFSA** by sharing the draft confidentiality decision):

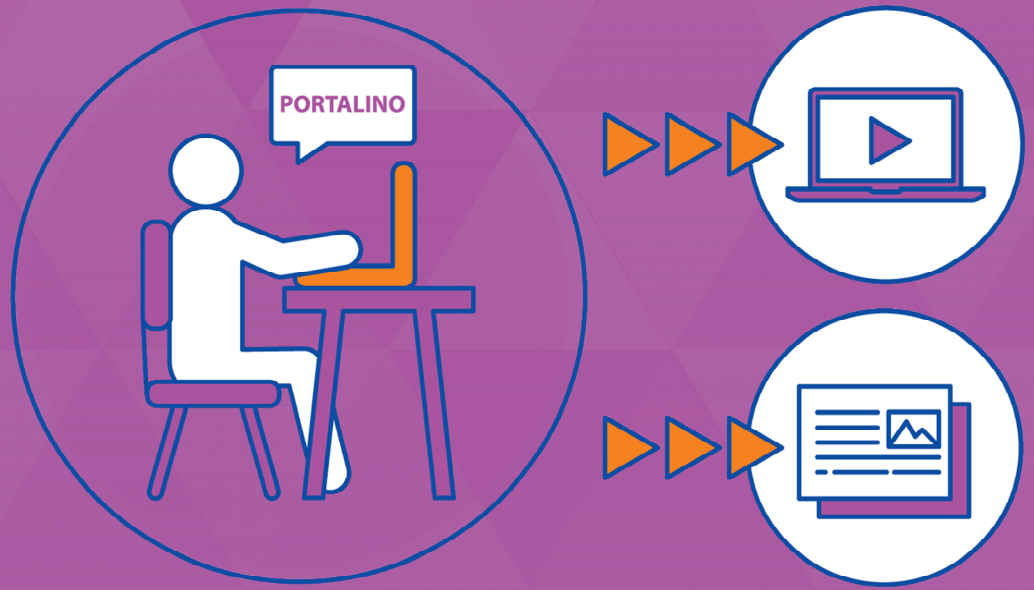
- Before sharing the draft confidentiality decision with EFSA for consultation, **carry out a diligent preliminary check and assessment** (*see* (a) and (b)); if there are any procedural/technical issues preventing the RMS from doing so (e.g., lack of/poor identification of the information claimed confidential; absence of justification/incomplete justification; absence of specific legal ground (e.g., "Article 63(2)(c) of Regulation (EC) No 1107/2009 – results of production batches") this should be flagged to the Applicant and addressed **BEFORE sharing the draft confidentiality decision with EFSA**
- **Share draft decision** with the Confidentiality Pesticides team in **an editable format** (i.e. Word/RTF)
- Include the **proposed i) assessment and ii) outcome** (accepted, rejected or partially rejected) **for EACH confidentiality request IN WRITING** in the draft decision

N.B. Upon conclusion of the confidentiality assessment (*see* point 8. of page 32 of this Guide), **the RMS shares** with **EFSA** (FDP FDP@efsa.europa.eu, LA confidentialityrequestassessment@efsa.europa.eu, PREV pesticides.peerreview@efsa.europa.eu and RAL RAL@efsa.europa.eu):

- i. **the final confidentiality decision** (note this must be a definite document detailing the explicit and written position of the RMS with regard to each confidentiality request)
- ii. **the UUID of the version of the IUCLID dossier** correctly implementing the final confidentiality decision and
- iii. **the Notification of Studies (NoS) Extract**, **sanitised** in accordance with the RMS confidentiality decision on the Applicant's confidentiality requests, if any, on the NoS extract

SUMMARY

Requirements regarding the submission and processing of confidentiality requests in Portalino



Follow the link to → Portalino User Guide

Watch the video tutorial

CONFIDENTIALITY IN PORTALINO

Connect to the Portalino User Guide

WHAT IS PORTALINO?

The **PORTALINO** is EFSA's tool that enables Applicants to request confidentiality for **data supporting dossiers, mandates, calls for data** and for **other information** (e.g., **pesticides background documents such as assessment reports**) that are out of scope of ESFC or IUCLID, as listed in point 2 **on page 5 of the Portalino User Guide**

HOW TO BUILD THE APPLICATION IN PORTALINO

How to register, access and submit data is described in points 3, 4, 5 and 6 on **pages 6 to 16 of the Portalino User Guide**

HOW TO REQUEST CONFIDENTIALITY

Step-by-step instructions about **how to request confidentiality** are detailed in point 6 on **pages 14 and 15 of the Portalino User Guide**

PROACTIVE DISCLOSURE

See page 12 of this Guide for general information about proactive disclosure

Submitting confidentiality requests

The requirements governing the submission of confidentiality requests also apply to Portalino submissions:

See **Section A of this Guide,** pages 7-10

To identify the information claimed confidential the Applicant must provide useful information in the ***Confidentiality Excerpt*** and ***Section*** and:

- ✓ **provide a direct quote** of the information claimed confidential in the *Confidentiality Excerpt* if the information is short
- ✓ **otherwise describe the information** claimed confidential
- ✓ **precisely identify the location(s)** of the information item(s) claimed confidential **by referring to the page number(s), section(s), paragraph or line number(s)** (rather than % of the page) where the confidential information is located
- × **Avoid** claims like '**throughout the document**' or '**on all pages**' if this is not the case
- × **Avoid repetition of the same information** under *Confidentiality Excerpt* and *Section*

✓ **Example 1**

- **Excerpt:** 'Joe Black, ADM Research Analytical Manager'
- **Section:** Pages 1, 3 and 5

✓ **Example 2**

- **Excerpt:** 'names, email addresses and signatures'
- **Section:** Pages 1 to 22

✓ **Example 3**

- **Excerpt** 'According to the Commission Regulation (…) already authorized as feed additives'
- **Section:** 'Section 2.1, page 3, paragraph 2 to page 4 paragraph 5'

How confidentiality requests in Portalino are processed

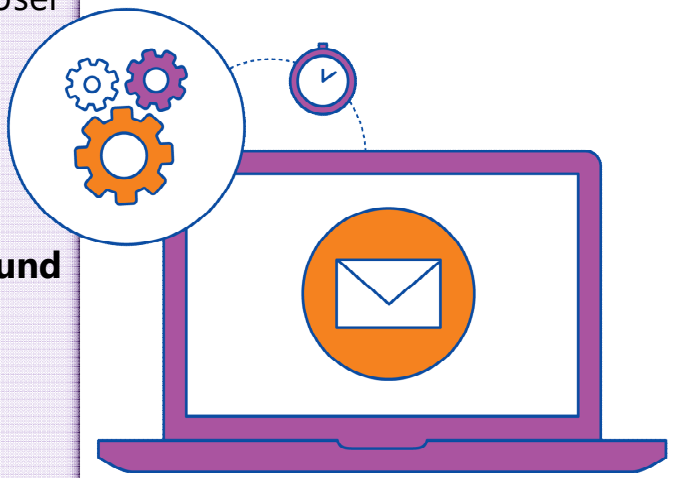
EFSA:

- contacts the Applicant **by email** in case of optional requests for clarification (**for pesticides background documents** the e-mail can be complemented with a **Request** via the tool enabling the Applicant to edit the submission)
- **uploads the decision(s) directly in Portalino** (**for pesticides background documents** confidentiality decision(s) are notified as encrypted attachment(s) by e-mail)
- if needed, modifies the documents for publication (by masking/unmasking according to the confidentiality decision) to **implement its confidentiality decision** (*see* page 12 of this User Guide)

THE APPLICANTS:

- reply to EFSA's request for clarification/information **by e-mail** (**for pesticides background documents**, if requested, by resubmitting documents via the tool)
- provide their comments on the draft decision **by email**
- may submit confirmatory application, if any, **by e-mail**

In case of issues of a technical nature during submissions in Portalino, Applicants can contact EFSA's IT technical support at servicedesk@efsa.europa.eu



CONTACT EFSA

- Ask a question: central entry point for questions both on technical/IT-related matters and on the content of confidentiality and proactive transparency requirements

- If expressly suggested by EFSA, Applicants, Member States or other stakeholders may also directly liaise with the Legal Affairs Unit of EFSA writing to the dedicated functional mailbox for confidentiality matters