

Updated: November 2023

# EFSA User Guide on Confidentiality

*A step-by-step practical guide on confidentiality*



# What is this guide about?

**This guide has been created to help you to easily understand the steps you need to follow in order to comply with the requirements provided for the submission of confidentiality requests.**

In particular, this guide covers the content from the following resources:





- [Practical Arrangements concerning Transparency & Confidentiality](#)
- [Practical Arrangements concerning Confidentiality in accordance with Articles 7\(3\) and 16 of Regulation \(EC\) No 1107/2009](#)
- Video and webinars regarding the submission of confidentiality requests
- [Q&As on the practical arrangements](#)

HOW TO USE THIS GUIDE. By clicking on the icons, you will find on top of the page while reading the guide, you will get access to useful functions and more contents.



# What you will find in this guide?

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

-  **SECTION A** **Requirements for submitting confidentiality requests**  
Here you will find a recap of main information and requirements for the submission of confidentiality requests.
-  **SECTION B** **How to submit confidentiality requests via ESFC Platform**  
Here you will find the link to a video guide and step-by-step passages to the submission.
-  **SECTION C** **How to submit confidentiality requests via IUCLID**  
Here you will find the link to a video guide and step-by-step passages to the submission.
-  **SECTION D** **How to submit confidentiality requests via Portalino**  
Here you will find the link to a video guide and step-by-step passages to the submission.

# Requirements for submitting confidentiality requests



## Content Overview

### Glossary of Technical Terms

**Chapter 1** → Procedural and substantive requirements

**Chapter 2** → Key concepts to keep in mind for Applicants

**Chapter 3** → IT tools for submission

**Chapter 4** → Decision-making process and implementation of confidentiality decisions

# Glossary of Technical Terms



## APPLICANT <sup>1</sup>

“Applicant” means:

- any natural or legal person submitting an application or notification under Union law;
- any natural or legal person submitting scientific data and information for evaluation to the Authority pursuant to established sectoral Union law procedures;
- where permitted under sectoral Union law procedures and/or in the absence thereof, any natural or legal person submitting information voluntarily to the Authority upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the General Food Law Regulation;
- any natural or legal person who has produced information supporting a request from the European Parliament, the Commission and the Member States for a scientific output and therefore having a direct interest with respect to the closed list of information items for which confidentiality treatment can be requested as laid down in the Annex. This definition does not include the European Commission, the European Parliament, other Union Institutions, bodies, offices or agencies, Union Member States, or third countries’ public authorities as such.

## COMPETENT AUTHORITY <sup>3</sup>

“Competent Authority” means any authority or authorities of a Member State responsible for carrying out the tasks established under this Regulation.

## CONFIRMATORY APPLICATION <sup>1</sup>

“Confirmatory application” is a request submitted by the applicant asking EFSA’s Executive Director to review a negative decision that EFSA has taken on confidentiality request(s). Its submission is a prerequisite for an appeal before the Court of Justice of the European Union.

## FOOD (OR FOODSTUFF) <sup>2</sup>

“Food” (or “foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

“Food” includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

“Food” shall not include:

- feed;
- live animals unless they are prepared for placing on the market for human consumption;
- plants prior to harvesting;
- medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- cosmetics within the meaning of Council Directive 76/768/EEC;
- tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- residues and contaminants;
- medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council.

# Chapter 01.1

## Procedural requirements for the submission of confidentiality requests

### REQUIREMENTS

- a Confidentiality requests may only be **submitted via the applicable IT tools** indicated by the Authority whenever an applicant requests information, documents or data forming part of a file submitted for the attention of the Authority to be treated as confidential.
- b **No fees** are attached to the submission or processing of confidentiality requests.
- c Confidentiality requests may only be submitted in the context of one of the **background scenarios** described on the right side of this page.
- d Confidentiality requests may be submitted only with respect to certain parts of the submitted information, provided that they **fall within the scope of the information items** listed in the [Annex of the “Practical Arrangements concerning Transparency and Confidentiality” \(from page 19\)](#), and **verifiable justification<sup>1</sup> is provided** in accordance with substantive requirements for confidentiality requests (see chapter 01.2).
- e Once submitted, the confidentiality requests may be amended by the applicant only when requested to do so by EFSA, and provided that the amendment does not broaden the elements claimed as confidential.

### BACKGROUNDS FOR SUBMISSION

- a Submission of scientific data, studies and other information supporting applications under relevant Union law provisions, including supplementary information upon request by the Authority;
- b Submission of scientific data and information to Authority for evaluation pursuant to established procedures under Union law<sup>2</sup>;
- c Where permitted under established sectoral Union law procedures or in the absence thereof, voluntary submission of scientific data and information upon which the Authority is expected to base its scientific outputs within the meaning of Article 38(1)(d) of the General Food Law Regulation. This includes submissions made in response to public calls for data, other than those covered by point (b) above;
- d Submission of scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, pursuant to Article 38(1)(c) of the General Food Law Regulation.
- e EC, EP, other Union institutions, bodies, offices or agencies, Union Member States or third countries' public authorities only insofar as they submit a confidentiality request on behalf of a business operator.

### NOTES

(1) verifiable justification means that the Applicant must be able, at any time, to support on EFSA's request any of the statement they make with evidence (e.g. about the novelty or annual turnover criteria);

(2) Article 8(4) of Regulation (EC) No 1925/2006 read in conjunction with Commission Implementing Regulation (EU) No 307/2012.



# Glossary of Technical Terms

## HAZARD <sup>2</sup>

“Hazard” means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect.

## PLANTS <sup>3</sup>

“Plants” means live plants and live parts of plants, including fresh fruit, vegetables and seeds.

## PLANT PRODUCTS <sup>3</sup>

“Plant products” means products of plant origin in an unprocessed state or having undergone only simple preparation, such as milling, drying or pressing, but excluding plants.

## RISK <sup>2</sup>

“Risk” means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

## SANITISATION <sup>1</sup>

“Sanitisation” means the process of masking or unmasking scientific data, studies and other information in accordance with a confidentiality request or with a confidentiality decision, including the masking of personal data in accordance with Article 39e(2) of Regulation (EC) No 178/2002.

## SUBSTANCES <sup>3</sup>

“Substances” means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

### SOURCES

- (1) “Practical Arrangements concerning Transparency and Confidentiality” – Article 3
- (2) “Regulation (EC) No 178/2002 of the European Parliament and of the Council” – Article 2 and Article 3”
- (3) “Regulation (EC) No 1107/2009 of the European Parliament and of the Council” – Article 3



For more information, see also [Questions and Answers on the EFSA Practical Arrangements, Section C, Question 2.](#)


# Chapter 01.2

## Substantive requirements (minimum content) for confidentiality requests

### REQUIREMENTS TO BE SATISFIED TO OBTAIN THE CONFIDENTIAL STATUS

**05** The public disclosure of the document or information may potentially harm the interests of the Applicant to a significant degree<sup>3</sup>.

In some cases, the **harm that may be caused amounts to at least 5%** of the gross annual turnover/income for a year (regard should be had to the definition set out in Article 2(5) of Directive 2013/34/EU). In principle, the **statement on the turnover/earnings** should be made about the legal or natural person for the benefit of which the application is submitted. In case of **multiple confidentiality requests on the same document**, harm caused by the disclosure may be calculated in a cumulative manner, by adding up the financial damage that may be sustained in respect of each element claimed confidential with regard to that document. The **potential harm** caused by the disclosure, may be **calculated in a cumulative manner** by considering confidentiality requests concerning different documents, provided these are linked logically or functionally. By way of example, different confidentiality requests on different documents belonging to the manufacturing process may be considered in a cumulative manner, for the purpose of meeting the 5% threshold.

 For more information, see also [Questions and Answers on the EFSA Practical Arrangements, Section C, Questions 10-11-12.](#)

In case of **absence of such confirmation, a justification must be provided** on the reason why the applicant was unable to confirm that the harm caused would have reached 5% of the gross annual turnover/earnings for legal persons or annual earnings for natural persons and whether the possible harm would nevertheless not go below 1% of the gross annual turnover/income for a year. Second, in other situations, **if the applicant cannot establish that the harm that may be caused by disclosure reaches at least 5%**, or, in the alternative, is not able to provide appropriate reasons as to why they were unable to establish that the harm reaches 5% while confirming that it does not go below 1%, or, in the further alternative, simply submits that **the harm cannot be calculated**, they must provide a specific reason as to why they consider that disclosure would nonetheless potentially harm their interests to a significant degree thereby establishing that information would merit protection under Article 4(1)(b)1 or (2) of Regulation 1049/2001, having regard to relevant case-law.

### NOTES

(3) The harm should be of a significance corresponding at least to 5% of the gross annual turnover for legal persons, or the gross annual earnings for natural persons, for the financial year preceding the calendar year of the submission of the confidentiality request. If the quantified harm does not reach this percentage or the Applicant is unable to calculate its impact on their earnings, the Applicant must provide a specific reason as to why they consider that any public disclosure would potentially harm their interests to a significant degree.



# Chapter 01.2

## Substantive requirements (minimum content) for confidentiality requests

### ELEMENTS THAT APPLICANTS SHOULD PROVIDE WHEN SUBMITTING A CONFIDENTIALITY REQUEST

- a a clear identification of the relevant parts that, in their opinion, **qualify for confidential treatment**, accompanied by a detailed reference to the exact place where this information is located;
- b a text explaining comprehensively and clearly **why the information should be granted confidential status**. This must include an explanation of why the following requirements are satisfied, as explained on the right.

### REQUIREMENTS TO BE SATISFIED TO OBTAIN THE CONFIDENTIAL STATUS

- 01 **The document or information for which confidential status is requested is not publicly available** or it cannot be nevertheless considered to be known beyond a limited number of persons: the information concerned is not largely apparent, or it may not be deduced, from information of which the public is aware, or, failing that, the information concerned may not be accurately deduced by businesses in light of their expertise, in particular where the relevant market is characterized by a high degree of transparency.  
If the document or part of the document on which the confidentiality request is a scientific publication available to the public upon the payment of a fee and the applicant do not hold the necessary right to ensure a legitimate proactive disclosure to the public by EFSA, a relevant statement must be provided;
- 02 The document or information for which confidential treatment is requested is **eligible for legal protection** and has not been acquired in an unlawful manner;
- 03 The document or information for which confidential status is requested does, or does not, **fall under the definition of “environmental information”** pursuant to Article 2 of the Aarhus Regulation;
- 04 The document or information for which confidential status is requested **has been finalized in the form in which it was submitted to the Authority up to five years** prior to the submission of the confidentiality request. If the document or information is older than five years, the applicant shall provide a specific reason as to why public disclosure of that information would still potentially harm its interests to a significant degree;

# Chapter 02

## Key concepts to keep in mind for Applicants

- 01 Confidentiality requests may concern **only certain parts** of the submitted dossiers (as written in the Transparency Regulation)
- 02 There are **no fees**
- 03 If you submit a confidentiality request, you must do so using the **appropriate tool**, providing the appropriate justification, and following the right procedure
- 04 You must **indicate the legal basis** (confidential ground)
- 05 You **must demonstrate** why the item should be kept confidential
- 06 You must **identify** clearly the **information claimed confidential** and indicate references
- 07 You need to make sure that the **earmarking of the confidential version** corresponds to exactly the same information items that have been masked in the non-confidential version. Ensure that **masking is done in an irreversible manner**
- 08 You are supposed to **provide clarifications** only if requested to do so by EFSA, and you must submit clarifications within the deadline set by EFSA
- 09 Remember to **monitor your account** in the relevant tool, in order to react quickly to requests for clarifications or consultations on the draft decisions
- 10 Consider the **possibility of submitting a confirmatory application** in case you are not satisfied with the outcome of the first confidentiality decision
- 11 If you submit information or documents to EFSA and you do not submit a confidentiality request, consider it will be **made proactively available** by EFSA at the moment (depending on the applicable process):
  - the application dossier is deemed valid or admissible, or
  - the public consultation is closed, or
  - the general mandate is accepted, or
  - the scientific output is adopted




More information on Confidentiality Requests can be found in [EFSA's Toolkit material](#) and in the [Commission website \(Topic: Food Safety\)](#).

For applications for specific products, you may refer to the corresponding EFSA's administrative guidance documents and webinars ([Publications | EFSA \(europa.eu\)](#))

# Chapter 03

## IT tools for submission



▶▶▶ **ESFC PLATFORM**

▶▶▶ **IUCLID**

▶▶▶ **PORTALINO**

**E-SUBMISSION FOOD CHAIN PLATFORM** (also called **ESFC Platform**) is used for the majority of application dossiers regarding regulated products. [For a detailed step-by-step guide for the submission using the tool see section B](#)

**IUCLID** is used for plant-protection products application dossiers on active substances, microorganism and maximum residue level. [For a detailed step-by-step guide for the submission using the tool see section C](#)

**PORTALINO** is used for application dossiers not covered by the first two portals. [For a detailed step-by-step guide for the submission using the tool see section D](#)

# Chapter 04.1

## Decision Making Process

- a** Possible **request for clarification** from EFSA
- b** **Mandatory consultation** with Applicant on the draft decision
- c** **Communication** of the final decision
- d** Possibility to file confirmatory application during a two-week timeline

In case EFSA confirms confidentiality status to certain items, it can review the confidentiality decision in case it adopts a scientific output identifying foreseeable effects (related to the items that have been granted confidential status) on human health, animal health or the environment. In this case, EFSA will reopen the decision-making process and will start a new assessment.

Once the decision-making process is over, the Applicant will have the possibility to **challenge the legality of the confirmatory application** before the General Court or raise maladministration to the Ombudsman.

# Chapter 04.2

## Decision on confidentiality requests

- a Confidentiality requests in accordance with Article 39 to 39e of General Food Law Regulation **are processed by EFSA** following the Union and the Authority's code of Good Administrative Behaviour.
- b The confidentiality requests will be assessed in view of the procedural requirements for the submission of confidentiality requests and of the compliance with the minimum substantive requirements (see previous page).
- c The Authority must:
  - **decide upon confidentiality requests** concerning additional or supplementary information provided once the scientific output is adopted/approved/endorsed;
  - **issue a decision** on confidentiality requests no later than ten calendar weeks from the receipt of a confidentiality request (i.e., when the application has been considered valid or admissible and the Authority has been requested to provide a scientific output);
  - **notify the Applicant** of its reasoned decision on the confidentiality request;
  - **communicate the decision** on the confidentiality request to the Commission and the Member State's competent authorities or EU Reference Laboratory involved in the risk assessment process.



For more information, see also [Questions and Answers on the EFSA Practical Arrangements, Section C, Question 18.](#)

# Chapter 04.3

## Steps of the implementation of confidentiality decisions (if the decision is not challenged)

- a **EFSA sanitises the information**, data sets, documents, etc. in accordance with the confidentiality decision, by ensuring the blackening of all information to which it grants confidential status.
- b **EFSA may share the sanitised version** of documents prior to their dissemination with the applicant for verification of the consistency between the confidentiality decisions and the way in which they have been implemented.
- c **The sanitised documents are published** on OpenEFSA Portal at the earliest two weeks after notification of the confidentiality decision.
- d **For dossier submitted via IUCLID:** sanitisation of dossier is temporarily delegated to applicants (until further update of IUCLID).

A **withdrawal of application dossier** can be made prior to the adoption of the confidentiality decision or after the adoption of the confidentiality decision.



For more information, see also [Questions and Answers on the EFSA Practical Arrangements, Section C, Question 20.](#)

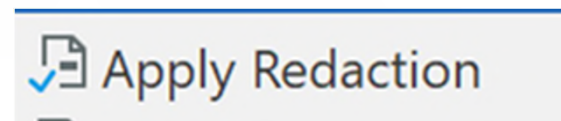
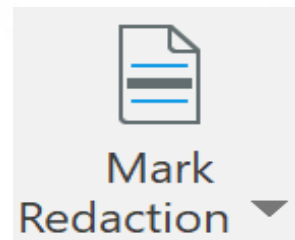
# Chapter 04.3

## Steps of the implementation of confidentiality decisions – tips on sanitisation

**IN THE NON-CONFIDENTIAL VERSION**, the items deemed confidential by the applicant must be **permanently** masked. Technically, it can be achieved by using a redaction tool which ensures that the redacted item is irreversibly blocked out through a dedicated functionality.

Several technical solutions commonly in use dispose of a feature which allows to apply the marked redaction in an irreversible manner over the items deemed confidential, once the file is closed and saved as a redacted/sanitized version.

Example of redaction functionalities:



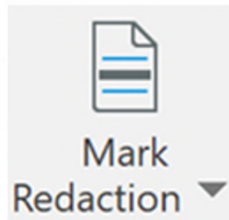
# Chapter 04.3

## Steps of the implementation of confidentiality decisions – tips on sanitisation

**IN THE CONFIDENTIAL VERSION**, the items deemed confidential by the applicant should be boxed or earmarked. Technically, it can be achieved by using a technique that allows to box the confidential information and data, for example using a “mark redaction” function to select an area in order to display the items deemed confidential as labelled.

Example:

Dear Sir or Madam



**NB:** The “earmarking” or “boxing” must not result in an irreversible redaction and therefore it is not meant to protect the dissemination of the information claimed confidential but rather to ensure its explicit and distinct identification during the confidentiality assessment phase.



# Chapter 04.3

## Steps of the implementation of confidentiality decisions – tips on sanitisation

### FAILURES IN REDACTING

The mere use of “highlights” in different colours or earmarking the relevant text with black/white/coloured shapes or objects and drawing or any other way to blacken/hide the information other than the specific redaction functionalities may not lead to the permanent and irreversible masking of the items deemed confidential.

EFSA recommends that, before submitting a non-confidential version of a document where redaction has been applied, you test the irreversibility of the applied redactions to verify whether the items deemed confidential are effectively blocked out, for example:

*Author:* 

- 1) If the cursor is pointed over the black shape and, by copy-pasting, text/items deemed confidential can be pasted in a blank document, the item has been blackened but not blocked out: no redaction has been applied.
- 2) If the black shape/box/rectangle is moved or deleted as an object and there is no text underneath, the item deemed confidential is not only blackened but also irreversibly blocked out: the redaction has been correctly applied. On the contrary, if the black shape is moved or deleted and the text underneath still shows up, the item has been blackened but not blocked out: no redaction has been applied.

Furthermore, please note that the complete removal in the non-confidential version of entire sentences, paragraphs, items, pages performed by deleting the information without applying the redaction must be avoided as this would imply the absence of the said elements from the documents that moreover would not correspond to their confidential version.

Redaction of embedded non-display data or metadata must be applied permanently and irreversibly through the dedicated functionality, before the file is closed and saved as a redacted/sanitized version.

# How to submit confidentiality requests via ESFC Platform



## Content Overview

**Chapter 1** → Sources

**Chapter 2** → About ESFC Platform

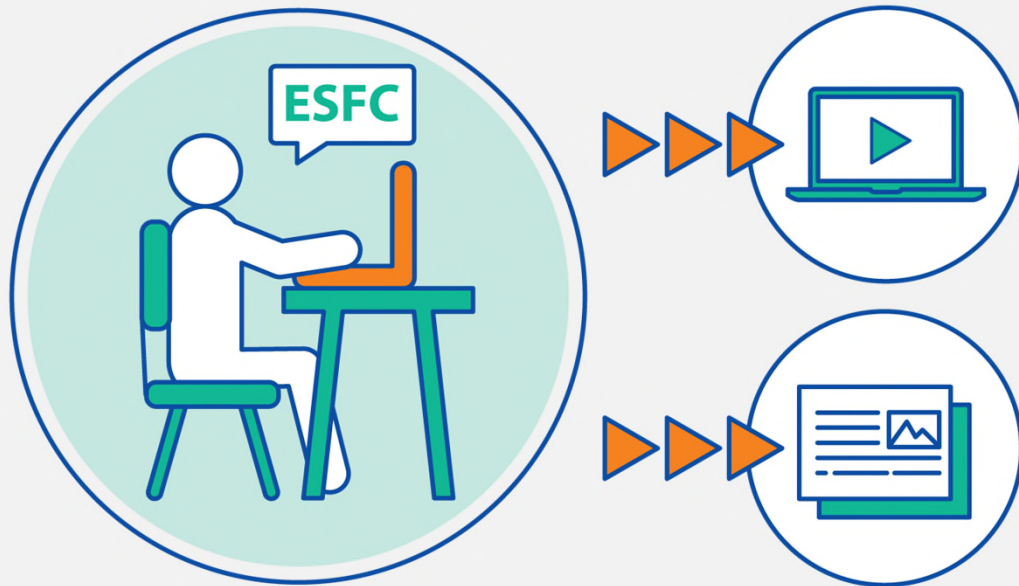
**Chapter 3** → How to submit confidentiality requests for documents uploaded into the E-Submission Food Chain platform

**Chapter 4** → How EFSA receives confidentiality requests, and when the confidentiality assessment process starts

**Chapter 5** → How EFSA informs the Applicant of the sanitised version of the confidential document

# Chapter 01

## Sources



### WATCH THESE USEFUL VIDEOS

[Confidentiality for applicants/business operators \(28:53 to 38:12\)](#)  
[E-Submission Food Chain platform - YouTube](#)

or

### READ THE INSTRUCTIONS IN THE FOLLOWING PAGES

And note that from now on, we will refer to the applicant as "you"

# Chapter 02

## About ESFC Platform

### WHAT IS ESFC PLATFORM?

**E-SUBMISSION FOOD CHAIN PLATFORM** (also called ESFC Platform) is used for the majority of application dossiers regarding regulated products:

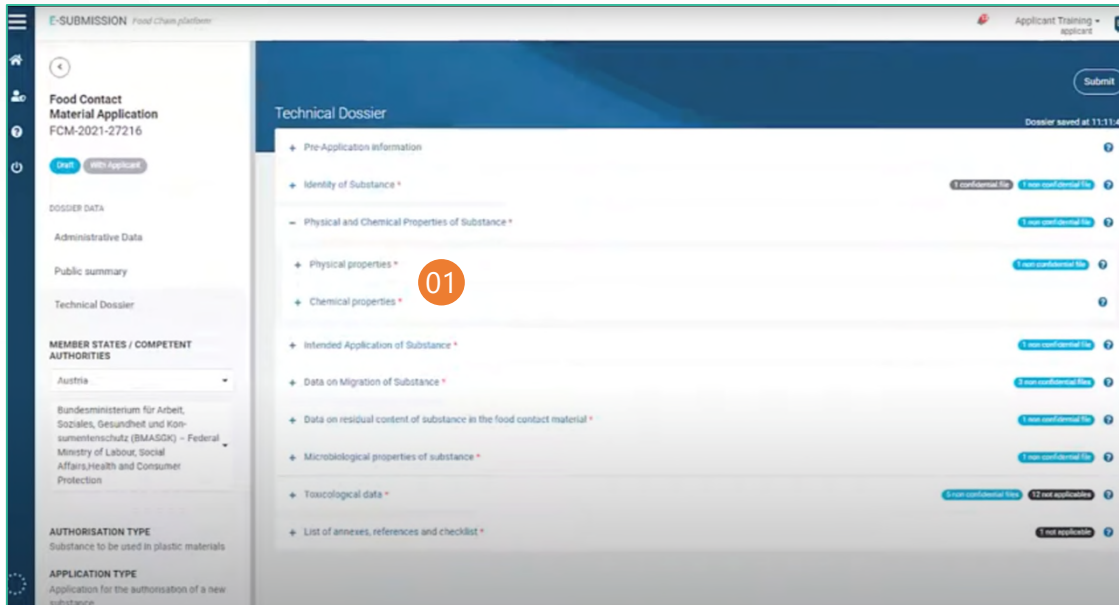
**01)** substances used in feed and food (such as additives, enzymes, flavourings, nutrient sources, infant formulae); **02)** food contact materials (plastic food contact materials substances, recycling processes, active and intelligent materials and substances); **03)** novel foods; **04)** genetically modified organisms; **05)** processing aids (e.g. decontamination substances); **06)** health claims; **07)** alternative methods for animal-by products.

### NOTES

- To support a dossier through the risk assessment, you will need to provide complete and unedited information. Some documents will need no request for confidentiality at all, so these will not submit the confidentiality process.
- All documents flagged as non-confidential will be automatically disseminated on the OpenEFSA portal once the dossier is considered valid. That point of validation also starts EFSA's confidentiality assessment process.
- All documents flagged as “containing confidential information” will also be automatically disseminated in their non-confidential version as submitted by the Applicant.

# Chapter 03

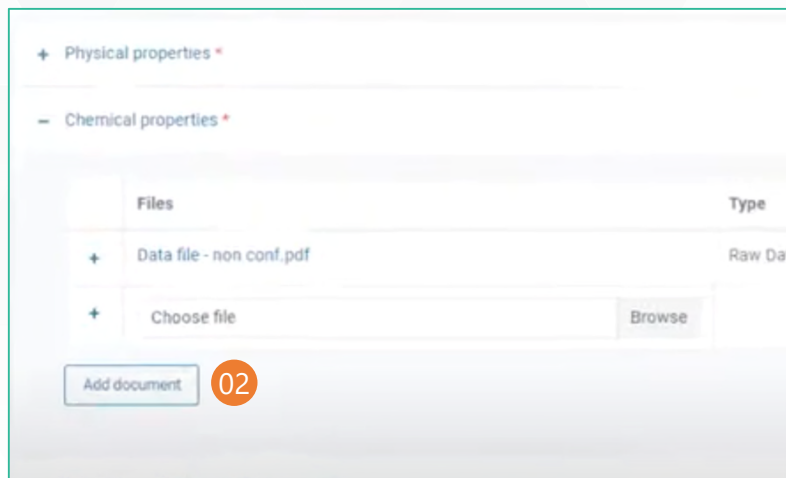
## How to submit confidentiality requests for documents uploaded via ESFC platform



### 01. ENTER THE PLATFORM

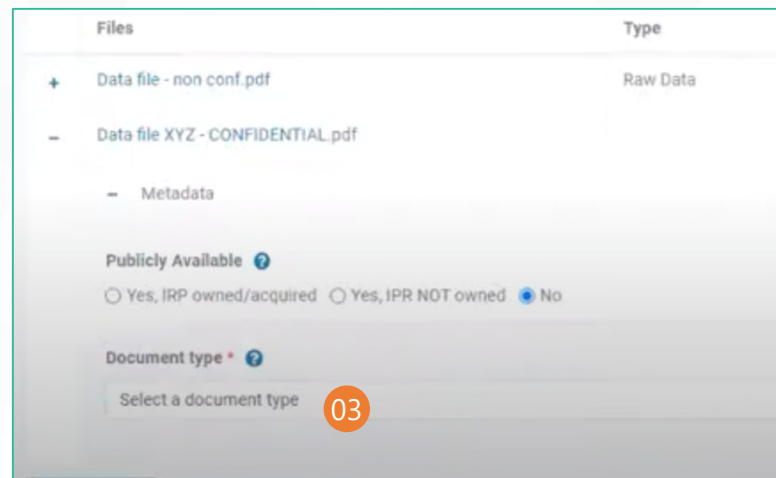
Enter the E-Submission Food Chain platform and log-in.  
Click on the tab "Technical Dossier" on the left of the page.  
Click on the relevant category/topic.

## 02. UPLOAD THE DOCUMENT



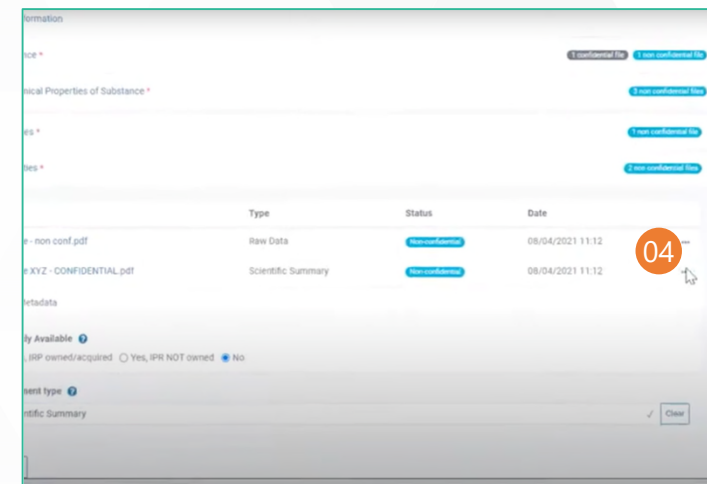
Now you have to upload the confidential and unredacted version of the document by clicking on "Choose file". At this point, do not consider the "Status" of the document, which is set by default to "Non-confidential".

## 03. SELECT THE DOCUMENT TYPE



Once uploaded, define the document type by clicking on "Select a document type" and choosing the type from the drop-down menu.

## 04. REQUEST CONFIDENTIALITY



Click the three dots on the right in correspondence to the document you have just uploaded and select "Request confidentiality treatment". At that moment, the Status of the document switches to "Confidential".

## 05. ADD CONFIDENTIAL GROUND

Indicate under which information items listed in the *Annex of the Practical Arrangements concerning Transparency and Confidentiality* each redacted element corresponds. Click "Add confidential ground" to select one legal ground from the pull-down list (the list of grounds is as provided by the Transparency Regulation). Remember there is help available in every section: if you need help, hover your mouse over the question mark in the corresponding section.

## 06. PROVIDE JUSTIFICATION

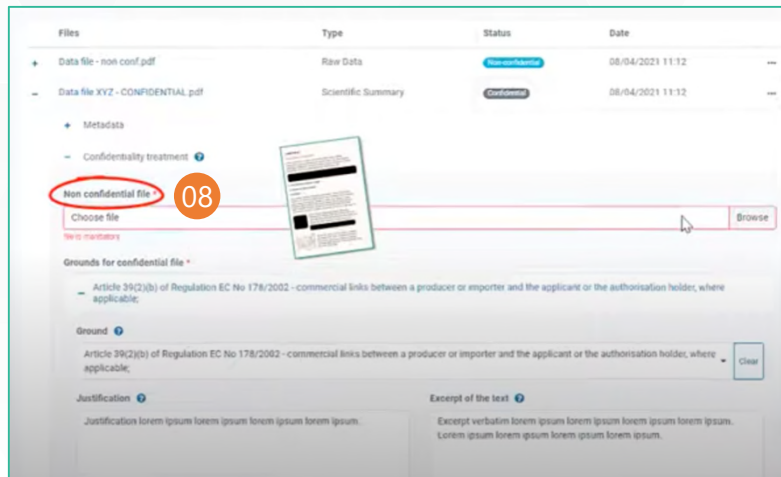
Provide a verifiable justification in the "Justification" field, the text excerpt of that information in the "Excerpt of the text" field, and its document position in the "Related section" field.

**Multiple confidentiality requests can be made on the same information element, introduced separately, by clicking "Add confidential ground".**

## 07. SELECT THE CONDITIONS

Select from the "CONDITIONS CHECK LIST" one or several applicable conditions that explain the disclosure risks for each selected confidentiality request, by clicking on the "Yes" box next to the desired motivation(s). Explanations of when to tick a condition are available right under each condition.

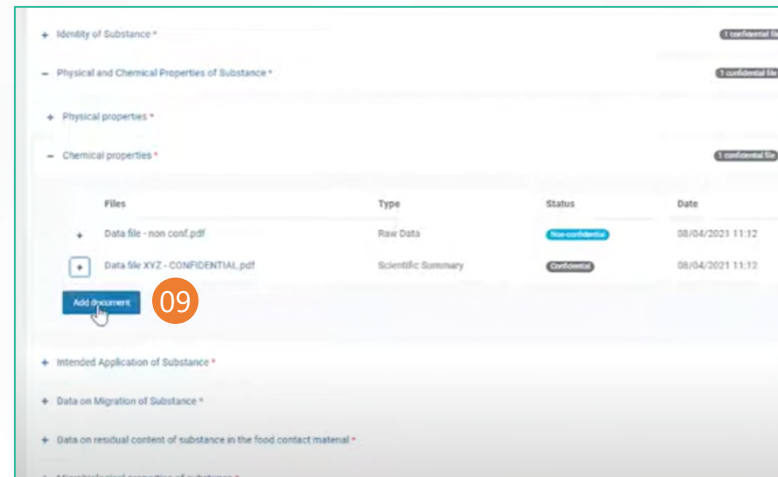
## 08. ADD THE NON-CONFIDENTIAL VERSION



Now upload the non-confidential version of your confidential document, with any confidential elements digitally redacted and irreversibly blackened. Note that the mere use of highlights, black shapes or any other way of hiding information may be not be permanently masking the content you wish to redact. Ensure that you have applied such functionality in an irreversible manner.

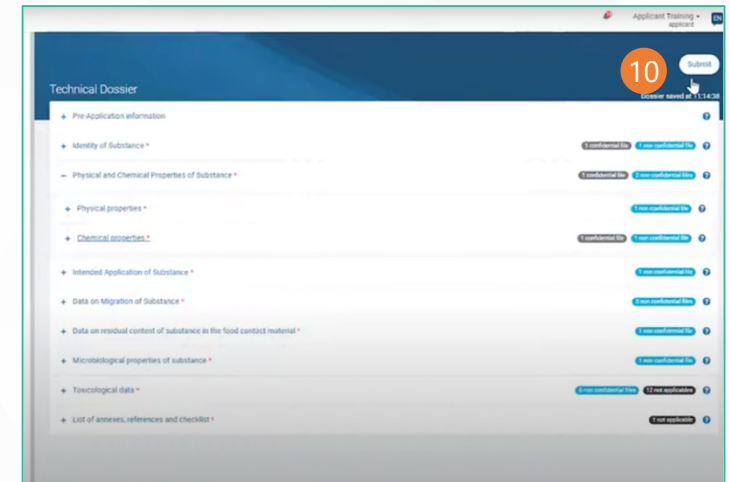
Click on "Choose file" in the "Non confidential file" section. Remember that this will be disseminated after dossier validation.

## 09. ADD A NEW DOCUMENT



If you want to add a new document, click on the "-" next to the uploaded file name to minimize the corresponding tab, click on "Add document" and follow the same procedure.

## 10. SUBMIT THE DOSSIER



Once the dossier is ready, submit it by clicking on "Submit" at the right top angle of the page.

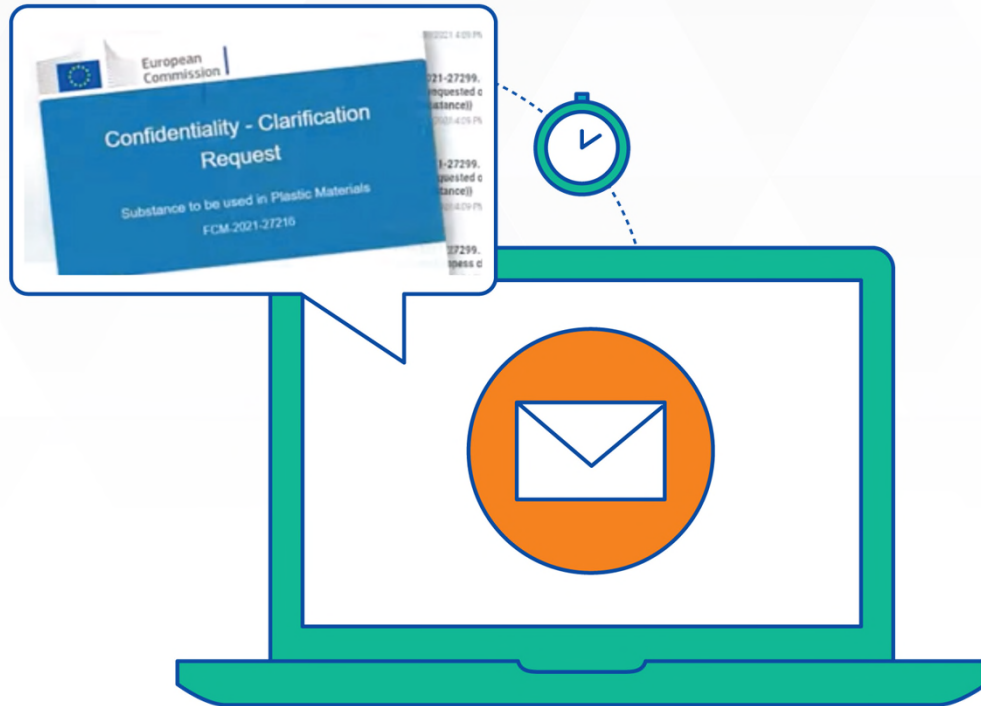
The dossier will be first received by the Commission or Member State competent authority depending on the food sector and it will be forwarded to EFSA for risk assessment.

As an Applicant, you will be informed by email when the dossier is valid. At that moment, EFSA can start the confidentiality request review.



# Chapter 04

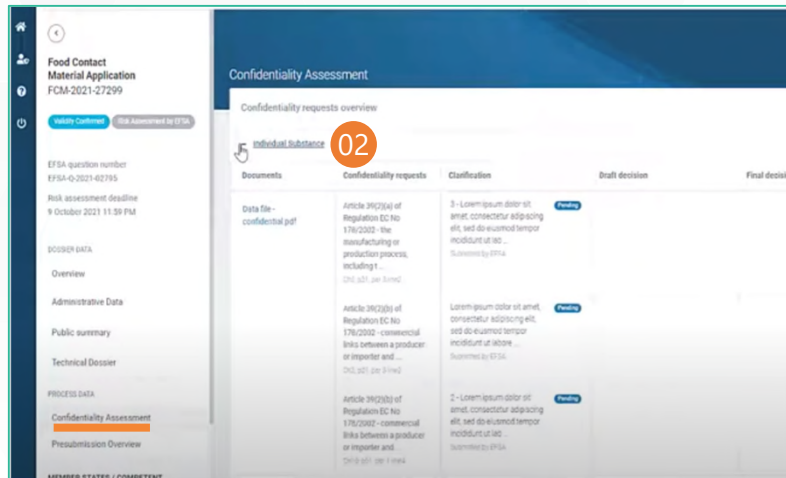
## How EFSA receives confidentiality requests, and when the confidentiality assessment process starts



### 01. FURTHER INFORMATION REQUIRED

If EFSA requires further information in order to make a decision, they may send you a request for clarification via the ESFC platform. Remember that, in case of this optional request for clarification, you will only be given limited time to reply. You will receive a notification of the clarification request by email. When (and only if) a clarification request was sent, a "Confidentiality Assessment" tab appears in the item list on the left of ESFC Platform.

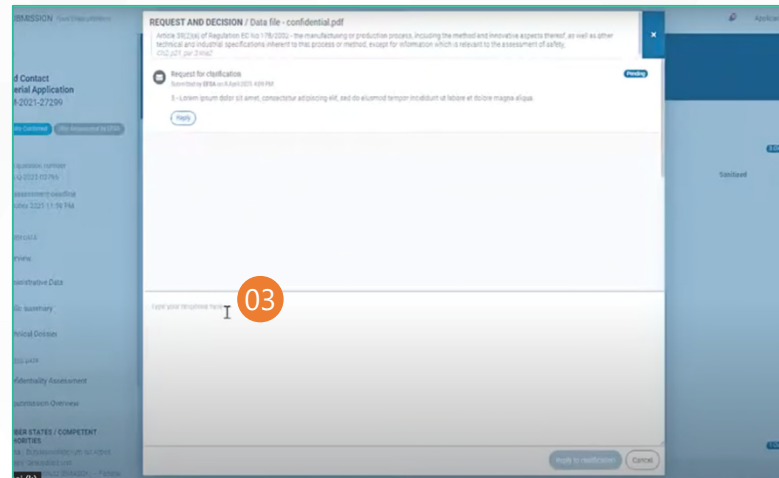
## 02. ACCESS THE SECTION



In case you receive a request for clarification, enter the "Confidentiality Assessment" tab by clicking on the corresponding item in the list.

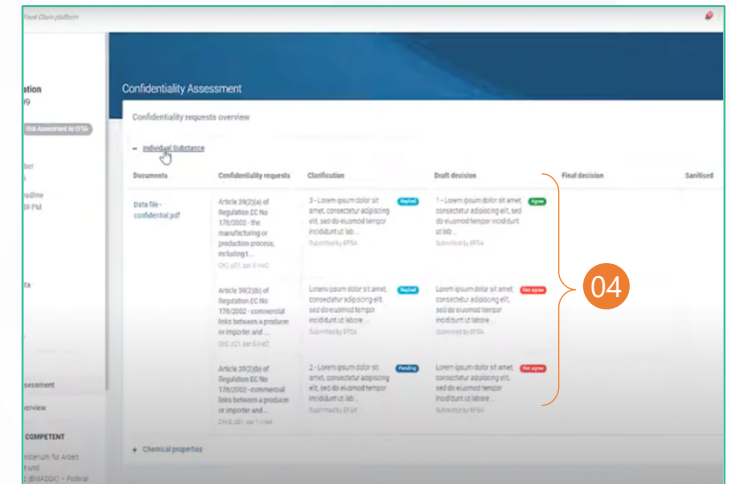
Click on the "+" next to the category/topic for which a clarification request has been made, to see the details of the request and of the follow-up of the confidentiality process.

## 03. READ AND REPLY



By clicking on a clarification, you will see a pop-up containing the text of the request for clarification. Read the request and click on "Reply" to respond. You can only respond with free text, no files can be uploaded. Click on "Reply to clarifications" to send your reply to EFSA.

## 04. DRAFT DECISION

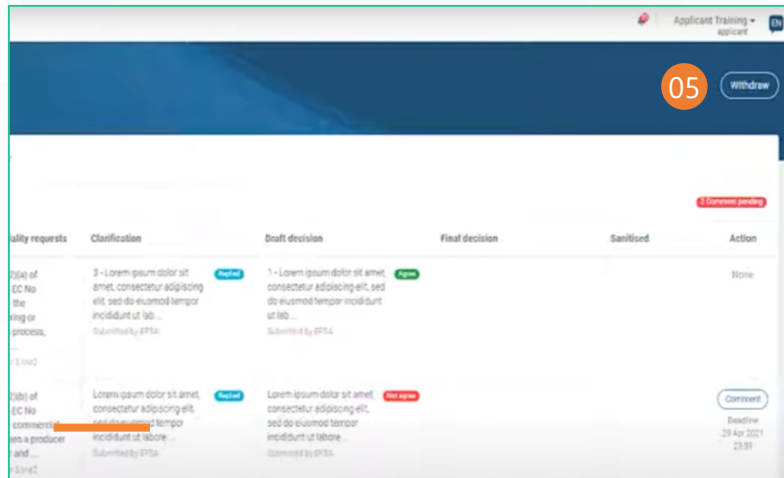


EFSA will consider if your reply is suitable and make a draft decision for that confidentiality request. If you do not reply to the request for clarification, EFSA will send the draft decision without having your input.

You will see the draft decision in the column "Draft decision" of the Dashboard, together with the badge "Agree" or "Not agree".

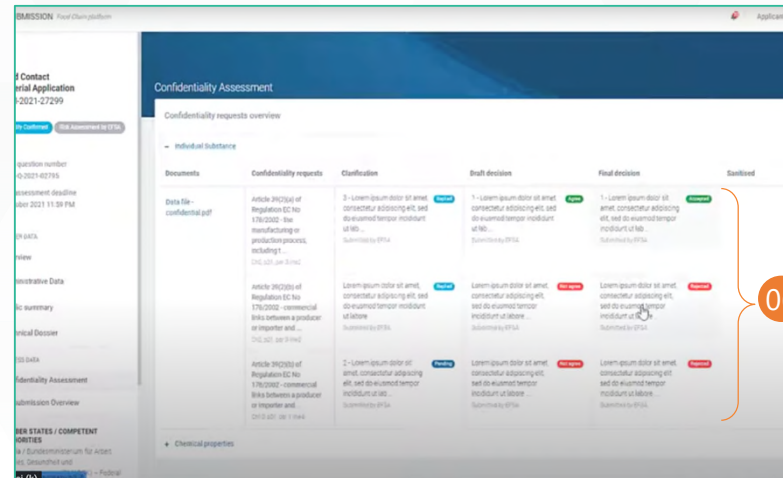
The badge 'Not agree' also covers cases where the request is partially not accepted.

### 05. WITHDRAW



You have two weeks from the reception of the draft decision, to state a view on each not agreed decision. After that, the opportunity to comment is lost and the process continues. You have also the possibility of stating agreement with EFSA's draft decision. During the same period, you can also withdraw the entire dossier. This will prevent the disclosure of elements claimed confidential but will also terminate the evaluation procedure of the dossier.

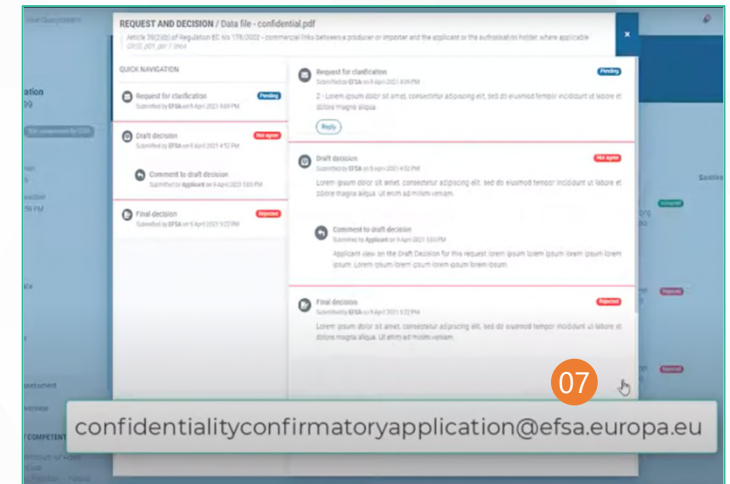
### 06. FINAL DECISION



If the dossier has not been withdrawn, EFSA takes a final decision for the confidentiality request, taking into account your comments on the draft decision, if any.

You will see the final decision in the column "Final decision" of the Dashboard.

### 07. CONFIRMATORY APPLICATION



If you do not agree to the final decision, you have two weeks in which you can submit a confirmatory application through the tool.

# Chapter 05

## How EFSA informs you of the dissemination of the (updated) sanitised version of confidential documents?

### THE NOTIFICATION

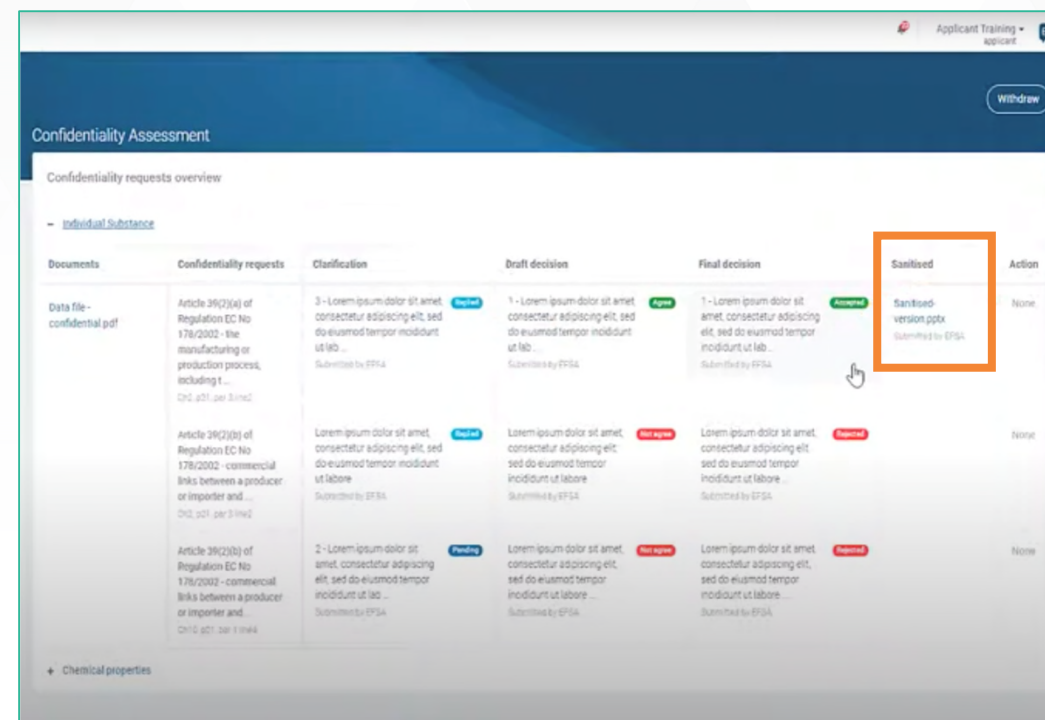
You will receive an email notifying the sanitisation of the confidential document by EFSA. The sanitised document will be accessible in the dossier, under the section "Confidentiality treatment" of the corresponding file, and in the "Confidentiality Assessment" Dashboard, in the column "Sanitised".

### IF A CONFIDENTIALITY REQUEST IS NOT ACCEPTED

If a confidentiality request is not accepted by EFSA, then the version of the document you provided is sanitised by EFSA, so the corresponding information from the confidential version of the document for that specific confidentiality request will be revealed. The document sanitised by EFSA will appear on the OpenEFSA portal and will replace the initial con-confidential version you provided.

### IF ALL CONFIDENTIALITY REQUESTS ARE ACCEPTED

If all confidentiality requests within one document are accepted, then the non-confidential version of the document you provided will remain published on the OpenEFSA portal.



# How to submit confidentiality requests via IUCLID



## Content Overview

**Chapter 1** → Sources

**Chapter 2** → About IUCLID

**Chapter 3** → The Dissemination preview functionality

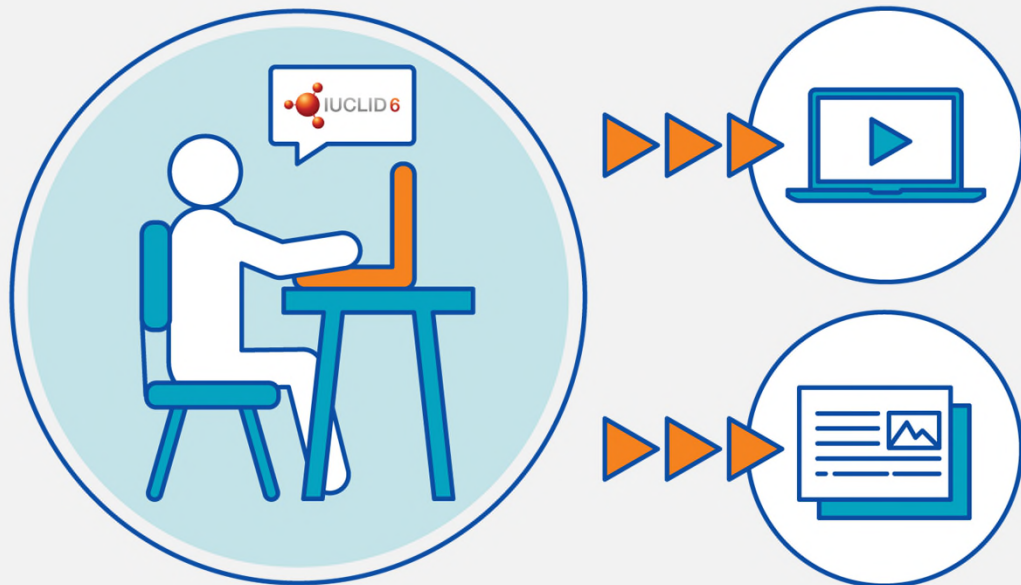
**Chapter 4** → Submitting confidentiality requests

**Chapter 5** → How confidentiality requests submitted via IUCLID are assessed

**Chapter 6** → Best practices

# Chapter 01

## Sources



**WATCH THIS USEFUL VIDEO**

[Confidentiality for applicants/business operators \(38:13 to 45:43\)](#)

or

**READ THE INSTRUCTIONS IN THE FOLLOWING PAGES**

And note that from now on, we will refer to the applicant as "you"

# Chapter 02

## About IUCLID



### WHAT IS IUCLID?

IUCLID is the tool used for **managing pesticide submissions**. More specifically, it is used for the following application types:

- Active substances (both new active substances and renewals, including micro-organisms);
- Basic substances;
- MRL applications.

### ABOUT IUCLID

**Publishing from IUCLID is a semi-automated process.**

It is based on the principle that every field used in pesticide submissions 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.

### THE FILTER RULES IN IUCLID

The **main filter rules** are:

- PUBLISHED: it is the default rule; implies publication of the data;
- UNLESS\_CONF: it implies that the information is published unless claimed confidential; if claimed confidential, the information will not be published pending the outcome of the confidentiality assessment; if the claim is rejected, the flag must be removed and the data will be published;
- NOT\_PUBLISHED: it is exceptionally applied to certain attachments where a sanitized version is provided.

Before submission of your dossier, use the latest version of the filter configuration file available [here](#) to verify the applicable filter rules.

# Chapter 03

## The Dissemination preview functionality

The **dissemination preview** is a IUCLID functionality which enables you to simulate which information from your dossier is likely to be made publicly available by EFSA.

The dissemination preview is run from a dossier, not a dataset.

It is strongly recommended to use this functionality before submitting a dossier.

In order to run the dissemination preview, **you must:**

- Go to the IUCLID Dashboard and select the dossier
- Click on the three dots at the right from the upper right-hand corner
- Select "Dissemination preview" from the drop-down menu (01)
- The dissemination preview will be generated in Excel format. (02)

Dashboard > Mixtures / Products > M1

Mixture 1  
398fce9f-7806-436b-b876-c16504d3a34b

EU PPP Active substance application (product)

M1

View Dossiers

Export to i6z  
Export annotations to i6z  
Create component PDF  
Compare  
Generate report  
Dissemination preview

01

sectionName	documentName	field	outcome	path
1.1 Identity of the plant protection produc	Clodinafop-propar Mixture / Legal entity flags		Published	MIXTURE.OwnerLegalEntityProtection
1.1 Identity of the plant protection produc	Clodinafop-propar Mixture / Legal entity owner		Published	MIXTURE.OwnerLegalEntity
1.1 Identity of the plant protection produc	Clodinafop-propar Mixture / Role in the supply chain		Published	MIXTURE.RoleInSupplyChain.RoleProtection
1.1 Identity of the plant protection produc	Clodinafop-propar Mixture / Role in the supply chain		Flagged confidential – Not published	MIXTURE.RoleInSupplyChain.Manufacturer
1.2.1 Location of manufacturing plant(s)	Location of manuf Sites		Published	FLEXIBLE_RECORD/Sites.DataProtection
1.2.1 Location of manufacturing plant(s)	Location of manuf Sites / Site		Flagged confidential – Not published	FLEXIBLE_RECORD/Sites.ReferenceSite
1.2.1 Location of manufacturing plant(s)	Location of manuf Sites / Remark		Flagged confidential – Not published	FLEXIBLE_RECORD/Sites.Remarks

02



## Chapter 04

# Submitting confidentiality requests: CBI - 1

For claims concerning confidential business information ('CBI') you must:

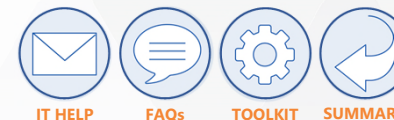
- i) **set a CBI flag**; and
- ii) **provide a justification** supporting your CBI flag in the justification box.  
You can claim confidential both a) **IUCLID fields** subject to the filter rule 'UNLESS\_CONF' and b) certain information in **attachments** uploaded in the IUCLID record/summary or linked in the IUCLID record/summary as literature reference.

You can set a **confidentiality flag** (in the upper left-hand corner) in the corresponding IUCLID entity, record/summary or section thereof by picking the value 'CBI' from the confidentiality picklist. **If you set a flag, it is marked in red. (01)** Depending on the IUCLID document, the flag can be **field-specific** or can refer to a **section**. When the flag refers to an entire section, the flag and the associated justification will apply to all the fields within that section for which the **filter rule is set to UNLESS\_CONF. (02)**

The screenshot displays the IUCLID interface for a record titled 'FormulationHyper100'. A red 'CBI' flag is visible in the upper left corner of the record header, with a circled '1' and an arrow pointing to it. Below the header, the 'Administrative data' section is highlighted with a blue box and a circled '2', with an arrow pointing to it. Under 'Administrative data', the 'General information' section is expanded, showing 'Mixture/product name' as 'Hypercare 100' and 'Trade names' as '+ New item'. A circled '1' points to the 'Country' field, which is set to 'New Zealand' with a checkmark. Below 'Country', the 'Trade name' is listed as 'HYPER'.

## Chapter 04

## Submitting confidentiality requests: CBI - 2



As a general rule, always select the **specific confidentiality flag** covering the information you would like to keep confidential.

For example, if you wish to submit a confidentiality request regarding **some specific components** of the mixture, **do not use** the confidentiality flag at the top of the IUCLID document or linked to the administrative data section of the IUCLID document. If the flag is only set at the top/administrative data section your confidentiality request will merely cover the following fields under the "General information" header subject to the filter rule "UNLESS\_CONF" (see latest version of the filter configuration file available [here](#)):

- FLEXIBLE\_RECORD.MixtureComposition.GeneralInformation.TradeNames.Country
- FLEXIBLE\_RECORD.MixtureComposition.GeneralInformation.TradeNames.TradeName
- FLEXIBLE\_RECORD.MixtureComposition.GeneralInformation.Description

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

NB: 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).

Composition (mixture).001  
 UUID: 6da359db-6d80-4b20-8871-457dc0eacd28

~~IT~~ ~~CONF~~

Administrative data | General information | Components

Administrative data ~~IT~~ ~~CONF~~

General information

Mixture/product name  
 xyz mixture

Trade names + New item Import file

Brief description

Formulation type

Components

+ New item Import file

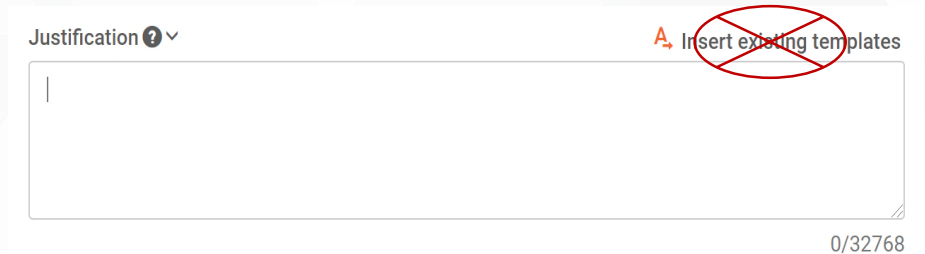
#	Component ...	Name	Function	Typical con...
1	<del>IT</del> <del>CONF</del> CBI	xyz component 2	wetting agent	
2	<del>IT</del> <del>CONF</del> CBI	xyz component 1	antifoaming agent	

## Chapter 04

# Submitting confidentiality requests: CBI - 3

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.

**In principle, the justification must be provided in the corresponding justification box.** Justifications inserted in other places will normally not be considered. **It is only in exceptional circumstances where the justification is so long that it cannot fit in the character limit that an attachment can be used.** The justification attachment 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 box must also expressly refer to the attachment, with the name of the attachment and the field where it can be found.



Justification ?

~~Insert existing templates~~

0/32768

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.

# Chapter 04

## Submitting confidentiality requests: CBI - 4 (justification template -1)

**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 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. NB: if one justification in the justification field covers several fields/attachments pertaining to the same IUCLID record/summary, you must clearly identify each single field and/or attachment, 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. "information about the identity of a manufacturing site whose disclosure may reveal commercial links between a producer and the applicant", and insert the legal basis under which you would like to request the item of information concerned to be kept 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.]

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 EFSA will perform a detailed individual examination of the justification provided and will reject any confidential request that does not meet all 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.

### NOTES

The parts of the template marked in red can be copy-pasted into the justification field, while the parts in blue are to be filled in by the applicant. In case different elements are claimed confidential in the same document based on the same legal basis and justification, it is recommended to group these together.

# Chapter 04

## Submitting confidentiality requests: CBI - 5 (justification template – 2)

Example of a filled in CBI justification template for a CBI confidentiality request concerning IUCLID fields

Set Flags

Confidentiality ⓘ

CBI

Justification ⓘ

Insert existing templates

I. IDENTIFICATION OF THE RELEVANT ITEM: The item claimed confidential can be found in the fields with IUCLID path 'SITE.GeneralInfo.SiteName' and 'SITE.GeneralInfo.OwnerLegalEntity'.

II. LEGAL BASIS: The item claimed confidential concerns information about the identity of a manufacturing site whose disclosure may reveal commercial links between a producer and the applicant within the meaning of Article 39(2)(b) of Regulation (EC) No 178/2002.

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 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.

1151/32768

Use restricted to selected regulatory programmes ⓘ

# Chapter 04

## Submitting confidentiality requests:

### CBI - 6 (justification template – 3)

**Example of a filled in CBI justification template for a CBI confidentiality request concerning an attachment**

**Set Flags**

**Confidentiality** ⓘ

CBI

**Justification** ⓘ

[Insert existing templates](#)

I. IDENTIFICATION OF THE RELEVANT ITEM: The item claimed confidential can be found in the file "Batch analysis study for substance xyz" in the following locations:

- on electronic page no. 8, table 4 (non-relevant impurity);
- on electronic page no. 8, table 5 (non-relevant impurity);
- on electronic page no. 8, table 7 (non-relevant impurity);
- on electronic page no. 9, figure 24 (results of production batches);
- on electronic page no. 11, summary, table, (results of production batches).

II. LEGAL BASIS: The items claimed confidential concern the specifications of impurities which are not toxicologically, ecotoxicologically or environmentally relevant within the meaning of Article 63(2)(b) of Regulation (EC) No 1107/2009 and the results of production batches in the 5-batch analysis within the meaning of Article 63(2)(c) 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:

- it is not publicly available;
- it is eligible or worthy legal protection and has not been acquired in an unlawful manner ;
- it does not constitute environmental information within the meaning of Article 2(1)(d) of Regulation (EC) No 1367/2006; and
- its disclosure would be liable to cause potential harm to a significant degree because:
  - it would result in financial damage corresponding to at least 5% of my gross annual turnover/earnings, and
  - the information is not older than 5 years.

1573/32768

**Use restricted to selected regulatory programmes** ⓘ

# Chapter 04

## Submitting confidentiality requests:

### PD - 1

For claims concerning personal data ('PD') you must **ONLY provide a justification** supporting your PD request in the justification box. **No CBI flag must be set** (this mean you should NOT select any value from the confidentiality picklist) – see screenshot. You can only claim confidential PD in an attachment uploaded or linked in an IUCLID record/summary.



**Set Flags**

**Confidentiality** ⓘ  
Please select

**Justification** ⓘ A. Insert existing templates

I would like to request confidential treatment for personal data contained in the file "Acute Dermal Toxicity Study of substance xyz in Rats" and in the file "Acute Inhalation Toxicity Study in the Rat for substance xyz".

**IDENTIFICATION OF THE PERSONAL DATA:**

1) Acute Dermal Toxicity Study of substance xyz in Rats:

- electronic page 1: name of test facility, names of natural persons, signatures;
- electronic page 3: name and address of test facility;
- electronic page 11: names of natural persons;
- electronic page 13: name of natural person, signature, initials of natural person.

2) Acute Inhalation Toxicity Study in the Rat for substance xyz:

- electronic page 2: names of natural persons, signatures, personal contact details;
- electronic page 4: name and address of test facility;
- electronic page 9: initials of test facility;
- electronic page 12: initials of test facility;
- electronic page 21: initials of test facility;
- electronic page 22: name and address of test facility;
- electronic page 23: names of natural persons;
- electronic page 24: personal contact details, name of natural person, signature, initials of natural person.

1159/32768

**Use restricted to selected regulatory programmes** ⓘ

**Important:** a **functional mailbox** address and the number of a **switchboard** must be provided in the 'Legal entity' since this is always published. Personal contact details should be included in the 'Contact' entity. The IUCLID field concerning author name in the 'Literature' entity is subject to the filter rule 'STUDY\_REF\_AUTH\_PPP', which implies that author names are **automatically removed** from the literature reference. The 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 unpublished tox/ecotox studies and for unpublished studies involving vertebrate testing.

# Chapter 04

## Submitting confidentiality requests: PD - 2 (justification template – 1)

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

### NOTES

The parts of the template marked in red can be copy-pasted into the justification field, while the parts in blue are to be filled in by the applicant. Note that categories 7) – 17) should be only claimed confidential insofar as they qualify as personal data on account of the limited number of employees in the legal entity concerned (except for legal entities involved in testing on vertebrate animals or in obtaining toxicological information which may be presumed confidential pursuant to Article 39e(2) of Regulation (EC) No 178/2002 regardless of the number of employees).







# Chapter 04

## Submitting confidentiality requests: PD - 3 (justification template – 2)

**Example of a filled in PD justification template for a PD confidentiality request concerning attachments**

Set Flags

Confidentiality    
Please select 

Justification  Insert existing templates 

I would like to request confidential treatment for personal data contained in the file "Acute Dermal Toxicity Study of substance xyz in Rats" and in the file "Acute Inhalation Toxicity Study in the Rat for substance xyz".


IDENTIFICATION OF THE PERSONAL DATA:



1) Acute Dermal Toxicity Study of substance xyz in Rats:

- electronic page 1: name of test facility, names of natural persons, signatures;
- electronic page 3: name and address of test facility;
- electronic page 11: names of natural persons;
- electronic page 13: name of natural person, signature, initials of natural person.

2) Acute Inhalation Toxicity Study in the Rat for substance xyz

- electronic page 2: names of natural persons, signatures, personal contact details;
- electronic page 4: name and address of test facility;
- electronic page 9: initials of test facility;
- electronic page 12: initials of test facility;
- electronic page 21: initials of test facility;
- electronic page 22: name and address of test facility;
- electronic page 23: names of natural persons;
- electronic page 24: personal contact details, name of natural person, signature, initials of natural person.

1159/32768 

Use restricted to selected regulatory programmes    


# Chapter 05

## How confidentiality requests submitted via IUCLID are assessed

- a EFSA will contact you by email in case of optional request for clarification
- b EFSA will send the draft decision by email as an encrypted document
- c You must provide your comments on the draft decision
- d After the final decision is communicated to you by EFSA, you will have 2 weeks to implement EFSA's decision

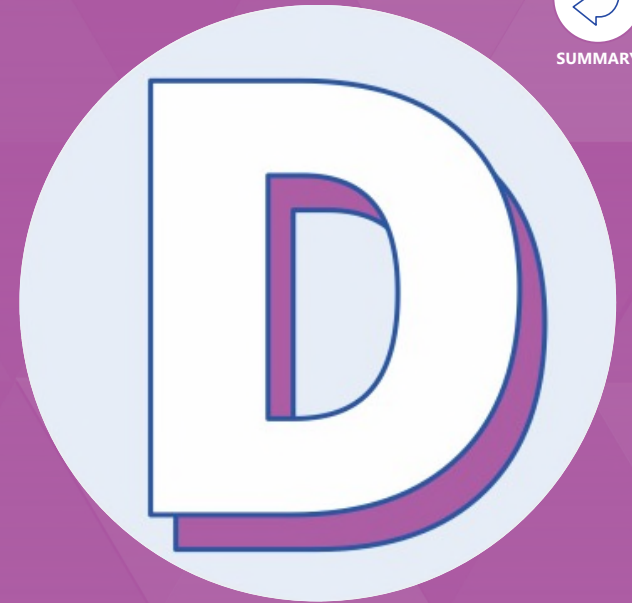


# Chapter 06

## Best practices

- 01 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 dossier, including for the confidentiality assessment and implementation.
- 02 In case of doubts about confidentiality assessment, **engage with EFSA at pre-submission stage**, using the '[ASK a question](#)' form.
- 03 **Make sure personal data and information deemed commercially sensitive 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 by the applicant.
- 04 **Reasonable recourse to confidentiality requests on CBI:** before submitting a confidentiality request on CBI, carefully reflect on 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 -> if you consider your claim will not meet these requirements do not submit it as it will be rejected.
- 05 **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/blacken whole pages if only a specific element – e.g. name of an impurity – is what reveals CBI, etc.).
- 06 **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).
- 07 In case you use the **same literature reference as other applicants, (e.g. in a joint submission) make sure that you submit the same confidentiality requests** in relation to it, so as to avoid inconsistencies.
- 08 **Engage with EFSA during the confidentiality assessment:** make effective use of the engagement opportunities, i.e. i) the request for clarification (optional) regarding your confidentiality requests and ii) the consultation of the applicant on the EFSA draft decision (mandatory).

# How to submit confidentiality requests via Portalino



## Content Overview

**Chapter 1** → Sources

**Chapter 2** → About Portalino

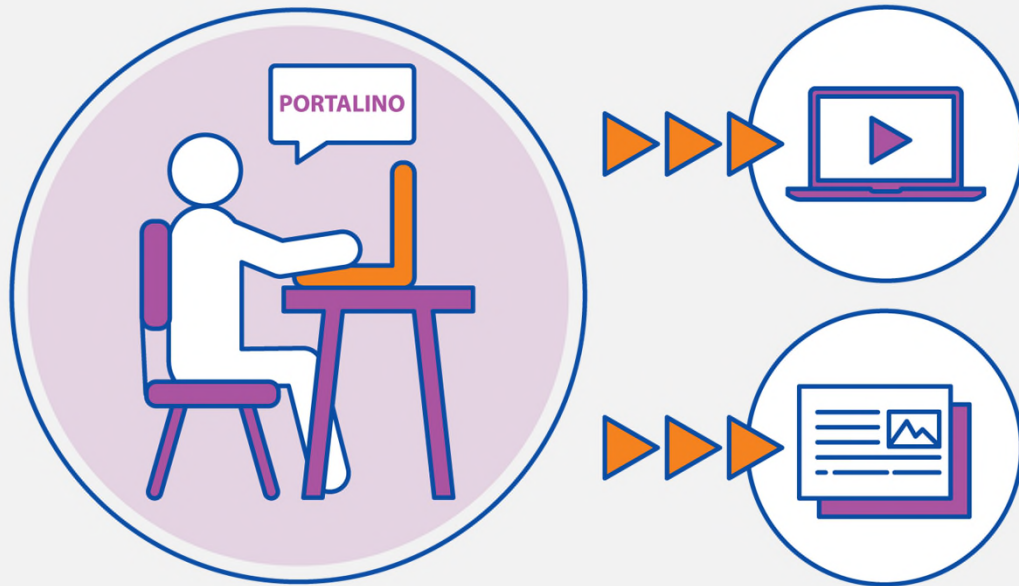
**Chapter 3** → How to submit applications and confidentiality requests via Portalino

**Chapter 4** → Template examples for Portalino

**Chapter 5** → How confidentiality requests submitted via Portalino are assessed

# Chapter 01

## Sources



### WATCH THIS USEFUL VIDEO

[The Portalino - Confidentiality requests](#)

[Confidentiality for applicants/business operators \(45:44 to 52:56\)](#)

or

### READ THE INSTRUCTIONS IN THE FOLLOWING PAGES

And note that from now on, we will refer to the applicant as "you"

# Chapter 02

## About Portalino

### WHAT IS PORTALINO?

Portalino is an EFSA tool that enables applicants and business operators to **request confidentiality for applications, data sets or scientific supporting documents** that are out of scope of the ESFC Platform or IUCLID.

### CONFIDENTIALITY REQUESTS IN SCOPE OF PORTALINO:

- Animal by products (ABPs) and fertilizers
- Feed detoxification for chemical contaminants
- Stunning methods
- High risk plants
- Additional datasets for inconclusive options
- Food additives re-evaluation
- Addition of vitamins and total diet
- Approval of active substances (ad-hoc requests)
- Calls for data
- Contaminants data in the context of Data Collection Framework (DCF)
- Other information supporting mandates as per Article 29 of the Regulation 178/2002
- DAR/RAR (also for confirmatory information) & Renewal Conclusion under Regulation (EC) No 1107/2009

### ORPHAN DOSSIER

An Orphan Dossier is a kind of application in relation to which confidentiality requests must be managed via Portalino, as for the moment it is not supported by the two other platforms: ESFC and IUCLID.

### NOTES

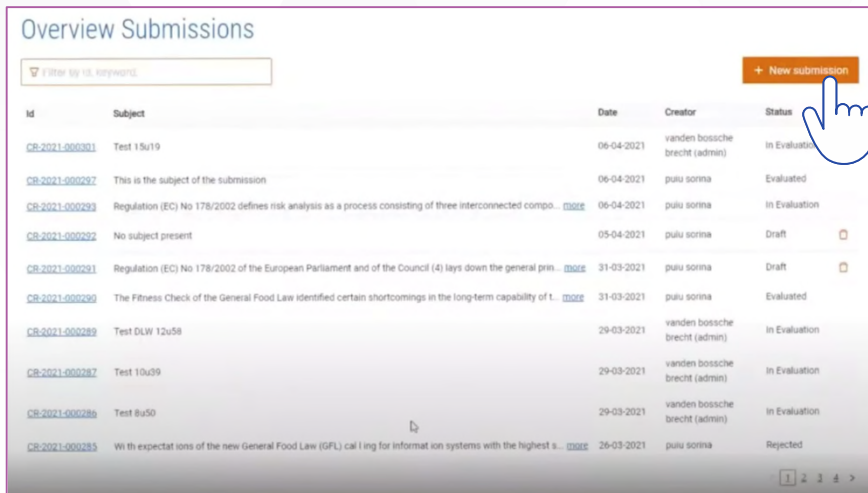
**Applicants submitting application dossiers neither covered by the ESFC managed by the Commission nor by IUCLID, must submit their confidentiality requests using Portalino.** Failure to do so will result in their dataset or application dossiers being made proactively available in their entirety to the public by EFSA, as soon as the application is deemed valid by EFSA.

Applicants sharing information with EFSA in the context of public calls for data or to support mandates submitted by the Commission, the Parliament or the Member States must use Portalino, if they wish to remove some parts of this information from the scope of proactive disclosure in application of the Transparency Regulation (EU) 2019/1381.

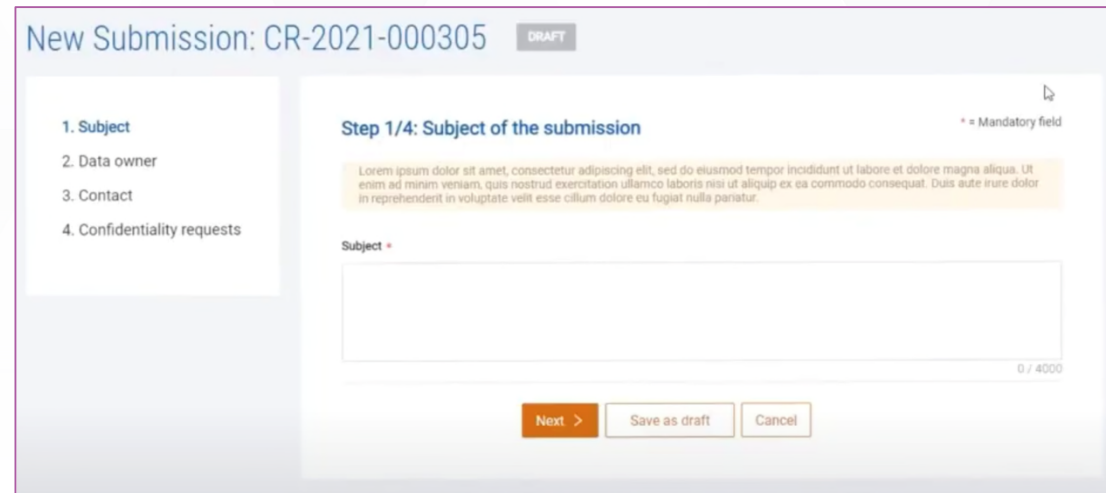
The Applicants and their contacts intending to submit confidentiality requests need to register in the **EFSA Connect Portal** before accessing Portalino.

# Chapter 03

## How to submit applications and confidentiality requests via Portalino



ID	Subject	Date	Creator	Status
CR-2021-000301	Test 13u19	06-04-2021	vanden bossche brecht (admin)	In Evaluation
CR-2021-000297	This is the subject of the submission	06-04-2021	puu sornia	Evaluated
CR-2021-000293	Regulation (EC) No 178/2002 defines risk analysis as a process consisting of three interconnected compo...	06-04-2021	puu sornia	In Evaluation
CR-2021-000292	No subject present	05-04-2021	puu sornia	Draft
CR-2021-000291	Regulation (EC) No 178/2002 of the European Parliament and of the Council (4) lays down the general prin...	31-03-2021	puu sornia	Draft
CR-2021-000290	The Fitness Check of the General Food Law identified certain shortcomings in the long-term capability of t...	31-03-2021	puu sornia	Evaluated
CR-2021-000289	Test DLW 12u58	29-03-2021	vanden bossche brecht (admin)	In Evaluation
CR-2021-000287	Test 10u39	29-03-2021	vanden bossche brecht (admin)	In Evaluation
CR-2021-000286	Test 8u50	29-03-2021	vanden bossche brecht (admin)	In Evaluation
CR-2021-000285	With expectations of the new General Food Law (GFL) call ing for information systems with the highest s...	29-03-2021	puu sornia	Rejected



New Submission: CR-2021-000305 DRAFT

1. Subject
2. Data owner
3. Contact
4. Confidentiality requests

Step 1/4: Subject of the submission \* = Mandatory field

Subject \*

Next >    Save as draft    Cancel

Enter the Portalino platform and log-in. You will see the "Overview Submissions" page, containing all the submissions previously created.

Click on "New submission" on the right upper corner to start the creation of a submission and the confidentiality requests linked to it.

## STEP 1/4 → SUBJECT OF THE SUBMISSION

You must fill in the "Subject" field with a brief description of the content of the submission.

Click on the "Next" button to continue.

### Step 1/4: Subject of the submission \* = Mandatory field

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur.

**Subject \***

For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.

333 / 4000

Next >Save as draftCancel



## STEP 2/4 → DATA OWNER

You must specify the organization owning the data contained in the submission, choosing it from the drop-down list. All the information related to the selected organization will be automatically filled in.

Click on the “Next” button to continue.

### Step 2/4: Data owner \* = Mandatory field

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur.

Company or organisation *	<input type="text" value="ABC Company"/>
E-mail	<input type="text" value="gmorandin@gmail.com"/>
Phone number	<input type="text" value="+49 214 30 1"/>
Street Address	<input type="text" value="Kaiser-Wilhelm-Allee 1"/>
Postal code	<input type="text" value="51373"/>
City	<input type="text" value="Leverkusen"/>
Country	<input type="text" value="Germany"/>
Website	<input type="text"/>

[< Previous](#)    **Next >**    [Save as draft](#)    [Cancel](#)

### STEP 3/4 → CONTACT

You must choose the contact person from the drop-down list. The selected person will receive via email all the communications related to the confidentiality decision-making process triggered upon submitting the request.

Click on the “Next” button to continue.

#### Step 3/4: Contact \* = Mandatory field

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat. Duis aute irure dolor in reprehenderit in voluptate velit esse cillum dolore eu fugiat nulla pariatur.

Contacts *	<input type="text" value="Generic Contact"/>
Name contact person	<input type="text" value="Generic Test Contact"/>
E-mail	<input type="text" value="user@testCorporation.eu"/>
Phone number	<input type="text" value="+326540577"/>
Street Address	<input type="text" value="Example address 8"/>
Postal code	<input type="text" value="2600"/>
City	<input type="text" value="Antwerp"/>
Country	<input type="text" value="Belgium"/>
Website	<input type="text"/>

[< Previous](#) [Next](#) [Save as draft](#) [Cancel](#)

## STEP 4/4 → CONFIDENTIALITY REQUESTS

You must provide the details requested by the confidentiality decision-making process.

In the "Full version" field, you must select all the data and files meant to be used during the risk assessment process to which the submission is associated. The excerpts of the text linked with the confidentiality requests need to be earmarked in the documents. All the files composing the full version will be compressed in a zip file prior uploading it.

In the "Non confidential version" field, you must select all the data and files that can be made public. The confidential extracts corresponding to the confidentiality requests must be already irreversibly masked. Ensure that your masking has been done in an irreversible manner.

All the files for the confidential and for the non-confidential version, irrespective of their format, will be compressed in a zip file prior to being uploaded in the tool.

### Step 4/4: Confidentiality requests \* = Mandatory field

Zip files

Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis nostrud exercitation ullamco.

Full version *	<input type="text" value="Full_version Test1.zip"/>	<input type="button" value="Remove"/>
Non confidential version *	<input type="text" value="Non Confidential Test1.zip"/>	<input type="button" value="Remove"/>

## STEP 4/4 → CONFIDENTIALITY REQUESTS

In the "Confidentiality Request" form, you must fill in the details of your confidentiality request:

- File name: the name of the file in the Full version zip in which the request can be found;
- Ground: the confidentiality ground, to be selected from a drop-down list;
- Justification: the justification, explaining clearly the reasons why the information should be granted confidential status;
- Excerpt of the text: the extract to which the confidentiality request is related. It should correspond to an earmarked text in the file included in the Full version;
- Related section: the section of the information with regard to which the confidentiality request is made.
- You must then select the confidentiality conditions by choosing Yes/No for each condition.
- If, within the same document, you claim as confidential **different information items that fall under the same legal ground**, you can may group them all together under the same confidentiality request. In this case, it is possible that the justifications you provide might be different for each item or for some of them.

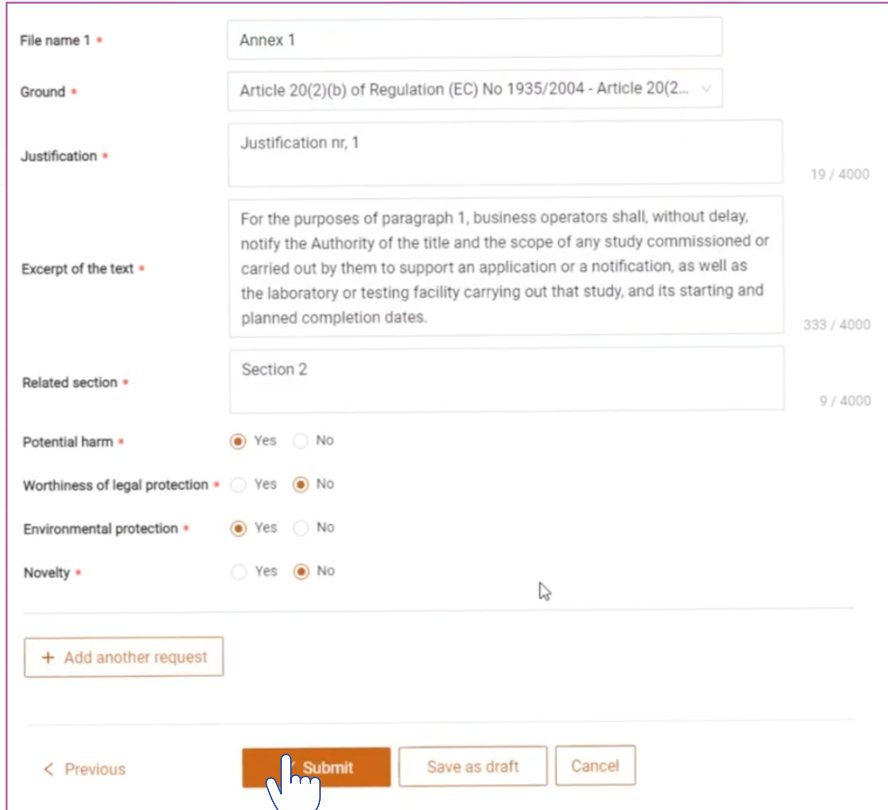
If, within the same document, you claim as confidential **different information items falling under different legal grounds**, you must insert different requests. To do so, click on "Add another request".

If **an information item falls under multiple legal grounds**, it needs to be included repeatedly in different confidentiality requests and accompanied by proper justification as you cannot invoke various legal grounds within the same confidentiality request.

You can save your submission as draft by clicking on "Save as draft".

Once completed, you can send your submission to EFSA by clicking on "Submit".

After sending it, the contact person will receive a notification of the submission.



The screenshot shows a web form for submitting a confidentiality request. The fields are as follows:

- File name 1**: Annex 1
- Ground**: Article 20(2)(b) of Regulation (EC) No 1935/2004 - Article 20(2)...
- Justification**: Justification nr, 1 (19 / 4000 characters)
- Excerpt of the text**: For the purposes of paragraph 1, business operators shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates. (333 / 4000 characters)
- Related section**: Section 2 (9 / 4000 characters)
- Potential harm**:  Yes  No
- Worthiness of legal protection**:  Yes  No
- Environmental protection**:  Yes  No
- Novelty**:  Yes  No

At the bottom, there is a "+ Add another request" button and a navigation bar with "< Previous", "Submit" (highlighted with a hand cursor), "Save as draft", and "Cancel" buttons.

ON THE NEXT PAGE YOU WILL FIND AN EXAMPLE OF HOW TO FILL IN THE CONFIDENTIALITY REQUEST FORM ILLUSTRATED ABOVE.

# Chapter 04

## Template examples for Portalino

### CONFIDENTIALITY REQUESTS **TEMPLATE**

**File Name 1:** DELICIOUS Science Laboratories Certificate of Analysis

**Request:** Request #1

**Ground:**

art\_39\_e\_2\_reg\_178\_2002\_personal\_data\_names\_and\_addresses

**Justification:** This is the name of a natural person involved in testing on vertebrate animals or in obtaining toxicological information. The document concerned is not in the public domain.

**Excerpt:** Name of natural person on the top left side of page 1

**Related Section:** Contact person

**Potential harm:** Yes

**Worthiness of legal protection:** Yes

**Environmental protection:** No

**Novelty:** No

### CONFIDENTIALITY REQUESTS **TEMPLATE**

**File Name 2:** DELICIOUS Science Laboratories Study Report

**Request:** Request #2

**Ground:** art\_39\_2\_a\_reg\_178\_2002\_manufacturing\_production\_process

**Justification:** This information refers to an innovative manufacturing/production process as well as to technical and industrial specifications inherent to that process/method and is not relevant to the assessment of safety. Its disclosure could potentially harm the company's interests to a significant degree given that it would allow competitors to adopt the same methodology without having invested any resources for research. This information is eligible for legal protection and has not been acquired in an unlawful manner. This information does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation. The document concerned is not in the public domain and satisfies the novelty criterion as it was issued on 21 Dec 2020.

**Excerpt:** Page 2 par. 3; page 5 par. 1 and 2; page 7 par. 1, 4, 5 and 7;

**Related Section:** Boiling Methods

**Potential harm:** Yes

**Worthiness of legal protection:** Yes

**Environmental protection:** No

**Novelty:** No

# Chapter 05

## How confidentiality requests submitted via Portalino are assessed

- a EFSA will contact you by email in case of optional request for clarification
- b The draft decision will be uploaded by EFSA directly in Portalino
- c You must submit your comments on the draft decision to EFSA by email
- d The final decision will be uploaded by EFSA in Portalino

