MECHANICAL PET RECYCLING PROCESSES FOR PLASTICS USED IN FOOD CONTACT MATERIALS: NAVIGATING THE APPLICATION PROCEDURE

Front-Desk & Workforce Planning Unit

25 June 2025

EUROPEAN FOOD SAFETY AUTHORITY

WHAT'S ON THE MENU

1. FCM-Recycling application process
2. Support to applicants
3. Submission and completeness check
4. Lessons learnt during the completeness check

THE ROLE OF EFSA

European Commission, Member States and European Parliament are the **risk managers**. They take decisions to ensure the **safety of the food chain** for the interest of the EU citizens.

Authorisation of a recycling process and regulatory decisions.

Request of scientific advice

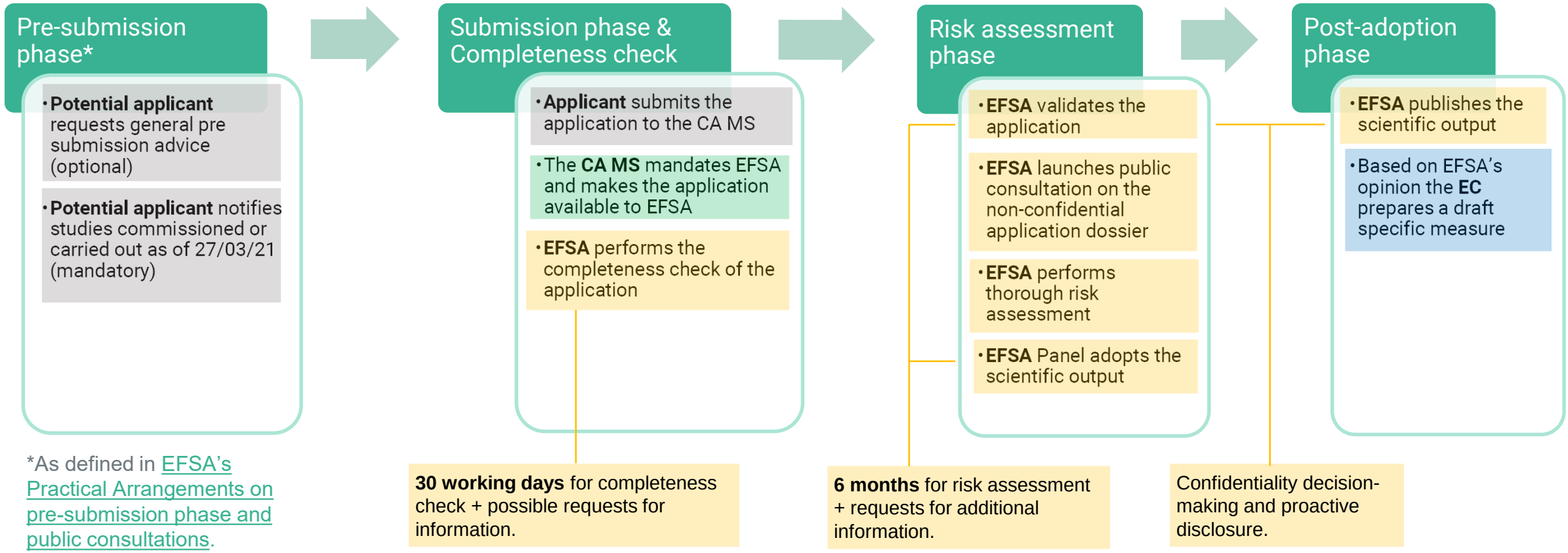
Scientific opinion

EFSA is a **risk assessor** and provides risk managers with the **sound scientific advice** they need to take the final legislative or regulatory decision.

Reference: Risk Assessment Vs Risk Management: What's The Difference?

FCM-RECYCLING APPLICATION PROCESS

FCM-RECYCLING APPLICATION PROCESS



*As defined in EFSA's Practical Arrangements on pre-submission phase and public consultations.

Reference: Application procedure for food contact materials

NOTIFICATION OF STUDIES (NOS)

Key points from Article 32b of the General Food Law (GFL)

- Potential applicants are **required to notify the studies** carried out or commissioned **in support of their applications** under the EU law **without delay, i.e. before the starting date.**
- **Only studies carried out as of 27 March 2021 require a notification.**
- **Any deviation** from the requirements set by Article 32b **needs to be justified**.
- **Justifications** are to be submitted with the corresponding application in the e-submission food chain platform (**ESFC**) and will be evaluated by EFSA at the suitability check.

Notify studies on the **Connect.EFSA** portal upon registration

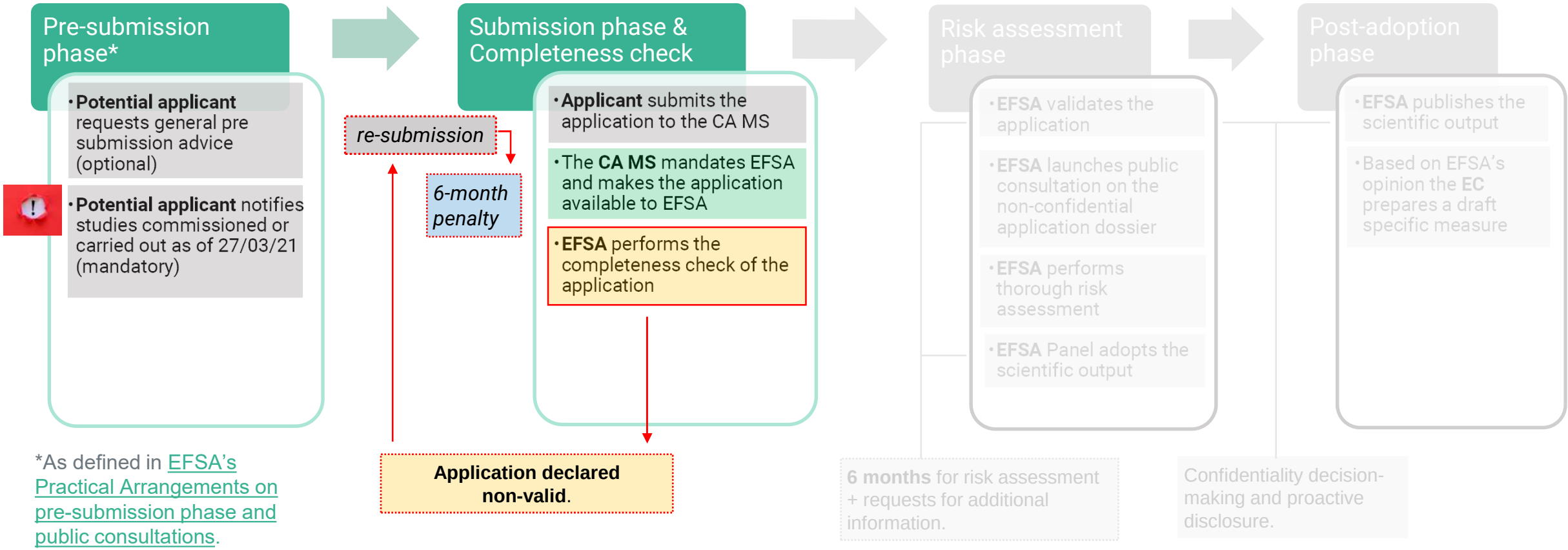
Question 4, Part B of **Q&A on EFSA's practical arrangements** provides indications on:

- studies for which the notification is required (e.g. challenge test)
- analyses exempted from the notification of studies obligation

No feedback on the study is foreseen upon the notification. EFSA checks the compliance with NOS obligations at the submission phase

Reference: Section 2.2 of the Administrative guidance for individual recycling processes

NON-COMPLIANCE WITH NOS OBLIGATIONS



*As defined in EFSA's Practical Arrangements on pre-submission phase and public consultations.

Reference : Section 2.2. of the Administrative guidance for individual recycling processes

CONFIDENTIALITY REQUIREMENTS

Key points

- The Transparency Regulation introduced **a principle of proactive disclosure and transparency** of information, studies and data submitted to EFSA for scientific evaluation.
- **Confidentiality requests** may be submitted by the applicant only for certain elements (**Section 2.6.3**).
- EFSA **may grant confidentiality status to those elements**.
- **When the application is declared valid, the application dossier is made publicly available** with the exception of the information that has been claimed confidential by the applicant and acknowledged by EFSA.

Confidentiality requests should be **submitted via the EFSC platform.** Hands-on instructions are provided in Section 11 of the **ESFC User guide**.

For each confidentiality request a **verifiable justification should be provided.**

Applicants should provide **a confidential and a non-confidential** version of the dossier.

Reference: Section 2.6 of the Administrative guidance for individual recycling processes & EFSA's Practical Arrangements concerning transparency and confidentiality

Enhanced User Guide on Confidentiality

NOW LIVE!

Your **go-to resource on confidentiality** just became even more user-friendly:

- Revamped General Requirements
- Simplified content

Check it out and navigate confidentiality smoothly!

IT PLATFORMS

Engage

Connect

Bringing together EFSA and its stakeholders

This portal gives you the possibility to **engage with EFSA** on a variety of topics. You can **perform pre-submission activities (i.e. GPSA and NOS)**, take part in public consultations, **request information** and browse frequently asked questions.

Submit

ESFC

The **e-submission Food Chain platform** (ESFC) is a web-based application used by applicants to **create, submit and manage their applications.**

Follow

OpenEFSA

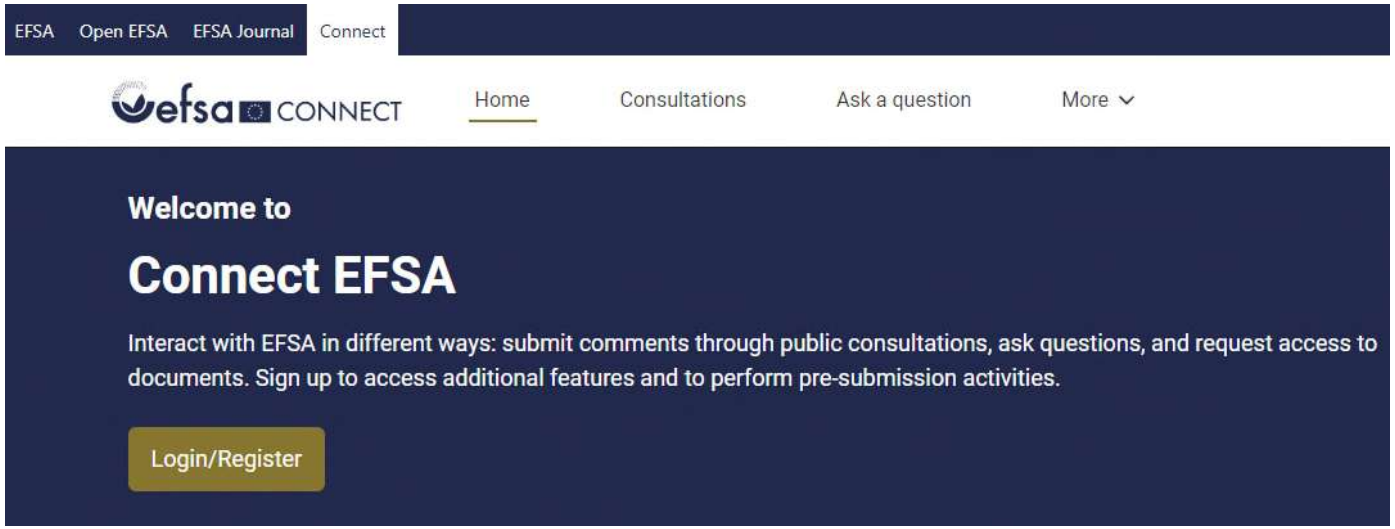
All you need to know about our risk assessments

This portal hosts information on scientific assessment work, allowing you **to follow the lifecycle of the risk assessment process, from reception to adoption**, and to access public documents related to it.

EFSA's toolkit page

CONNECT.EFSA PLATFORM

Register in the Connect.EFSA platform



Dedicated **IT platform** for engaging with EFSA and performing different activities, including:

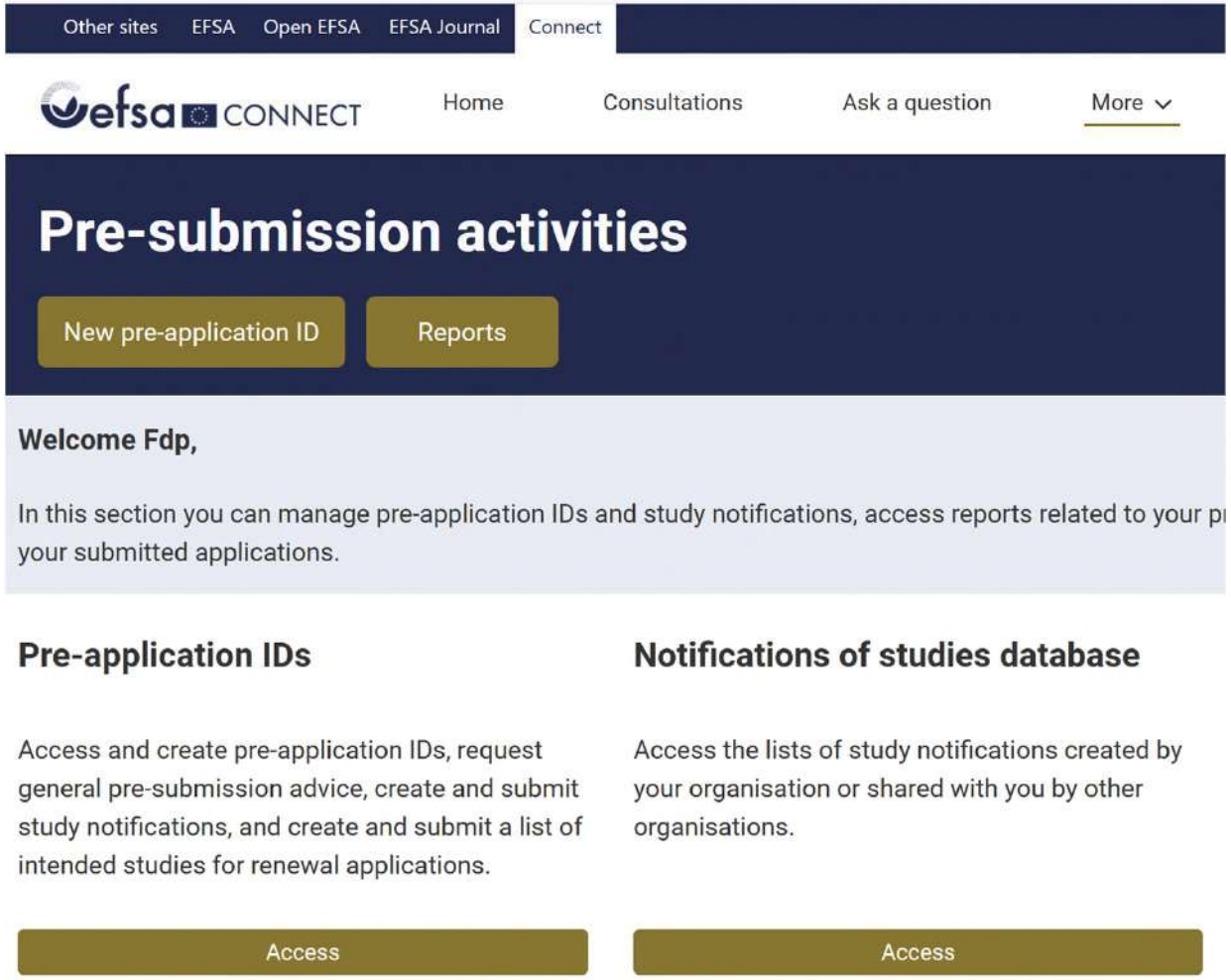
- Notification of studies
- Request General pre-submission advice
- Ask a Question to EFSA
- Participate in public consultations

Some useful documents:

- How to register on Connect.EFSA
- User guides on how to perform pre-submission activities: user guide on pre-application ID and user guide on notification of studies

Important **to register in advance** to Connect.EFSA to be ready to perform activities. Registration will **require a verification step by EFSA** and may take a few days

CONNECT.EFSA: CREATION OF PA-ID



Once registered to Connect.EFSA and prior to initiating any pre-submission activity, a **potential applicant must create a pre-application ID (PA-ID)** to link all pre-submission activities to the future application

Useful resources

Connect EFSA registration manual

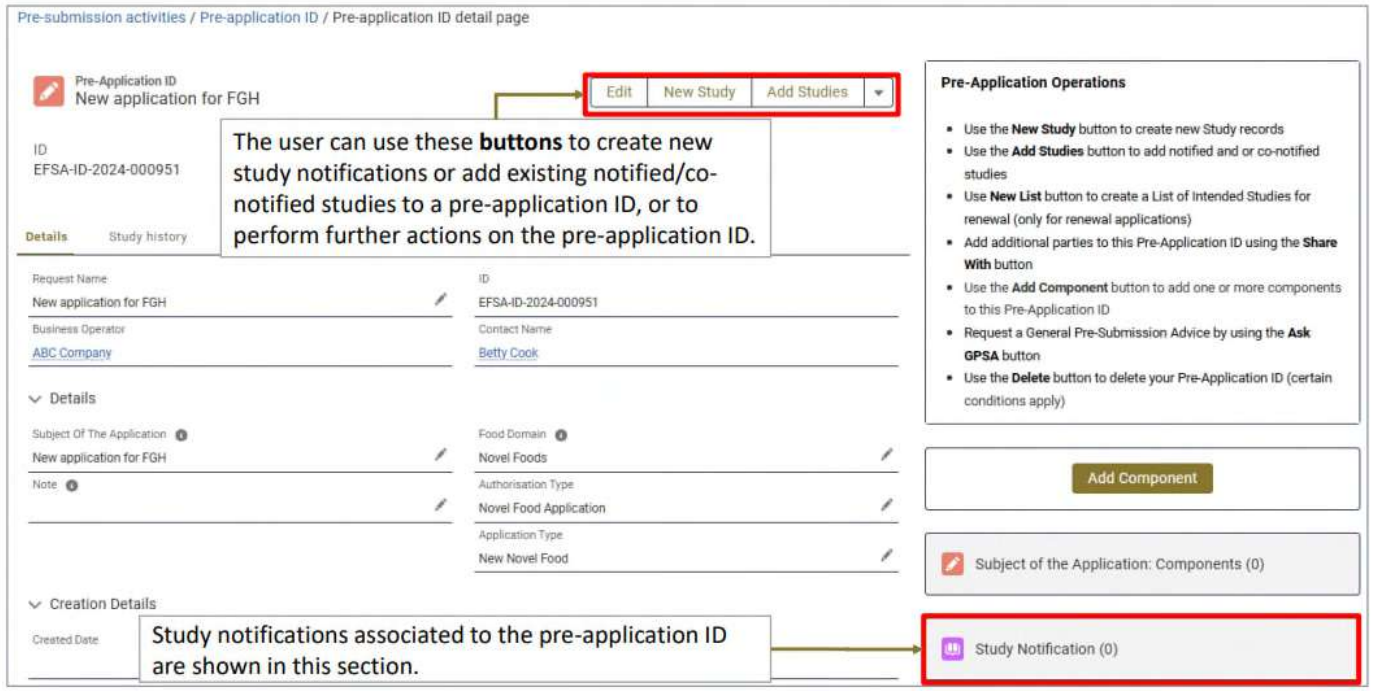
User guide on pre-application ID

User guide on notification of studies

EFSA's catalogue of services for applicants

CONNECT.EFSA: CREATION OF STUDY NOTIFICATION (NOS)

3.1 Study creation (from *pre-application ID*) – Account type: Applicant



Useful resources

Connect EFSA registration manual

User guide on pre-application ID

User guide on notification of studies

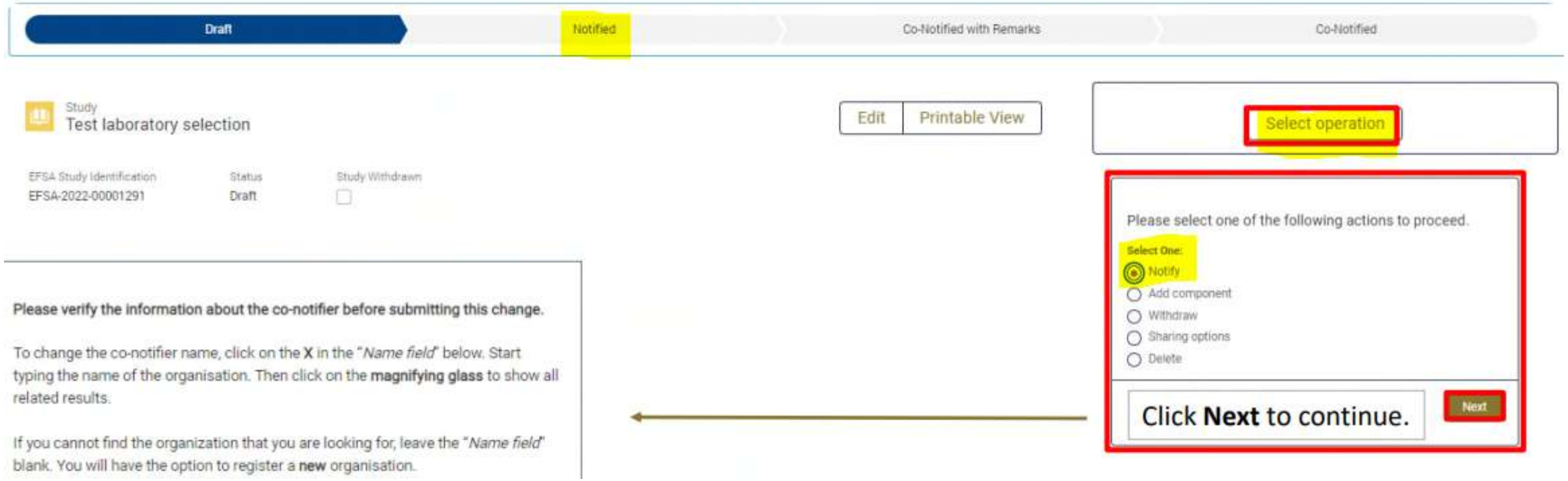
EFSA's catalogue of services for applicants

Mandatory fields indicated with * (Study title, Study starting date, Study planned completion date, Business Operator/applicant(s), Laboratory/ies, Study type, Intended Study area, International standard certification, Study objective and Test item)

Reference: Annex II of EFSA's Practical Arrangements on pre-submission phase and public consultations

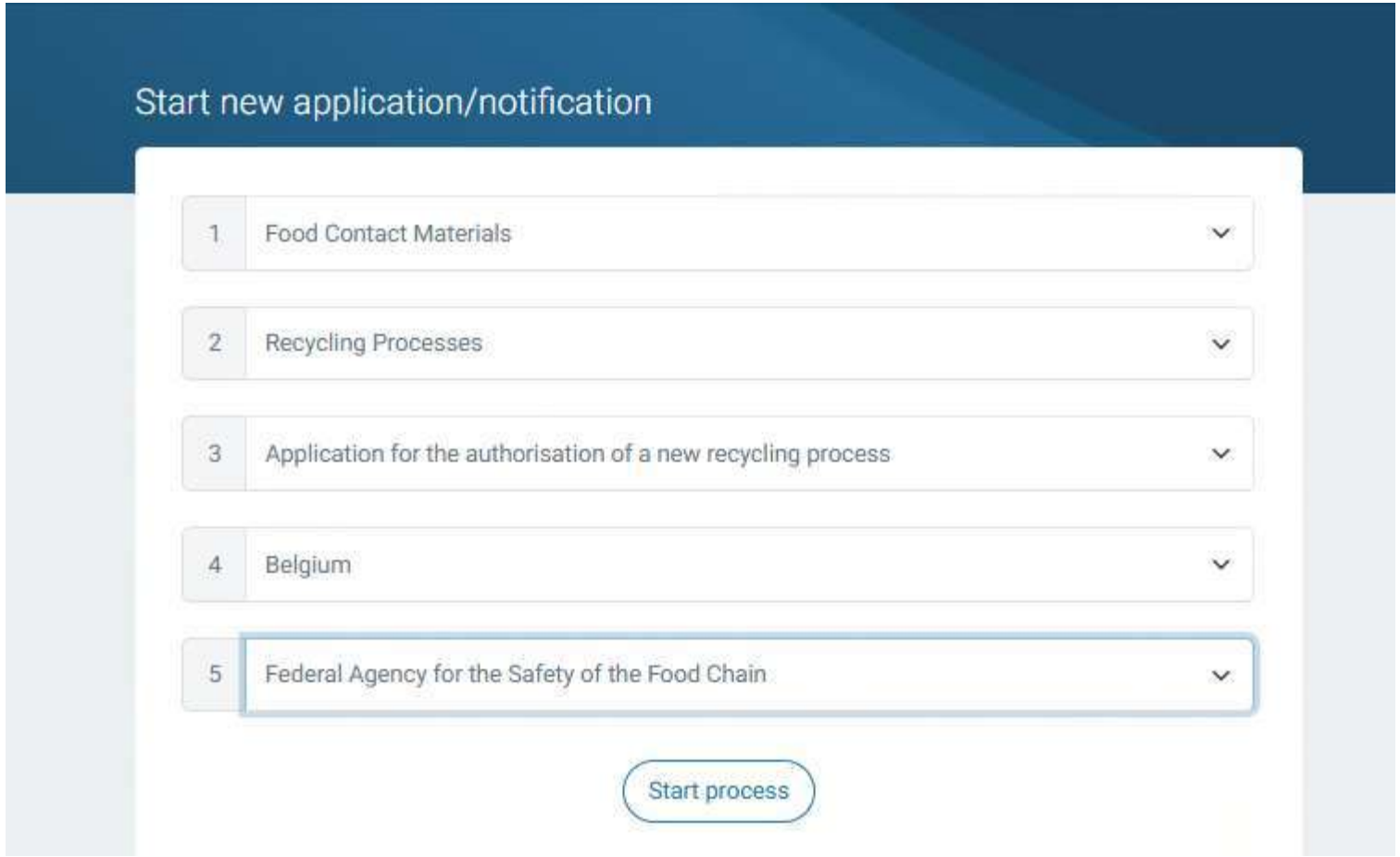
CONNECT.EFSA: DRAFT NOTIFICATION TO BE NOTIFIED

To notify a draft study the user needs to click on **Select Operation** and then on the picklist value **Notify**.
The following instructions are valid also in case the laboratory starts the notification process.



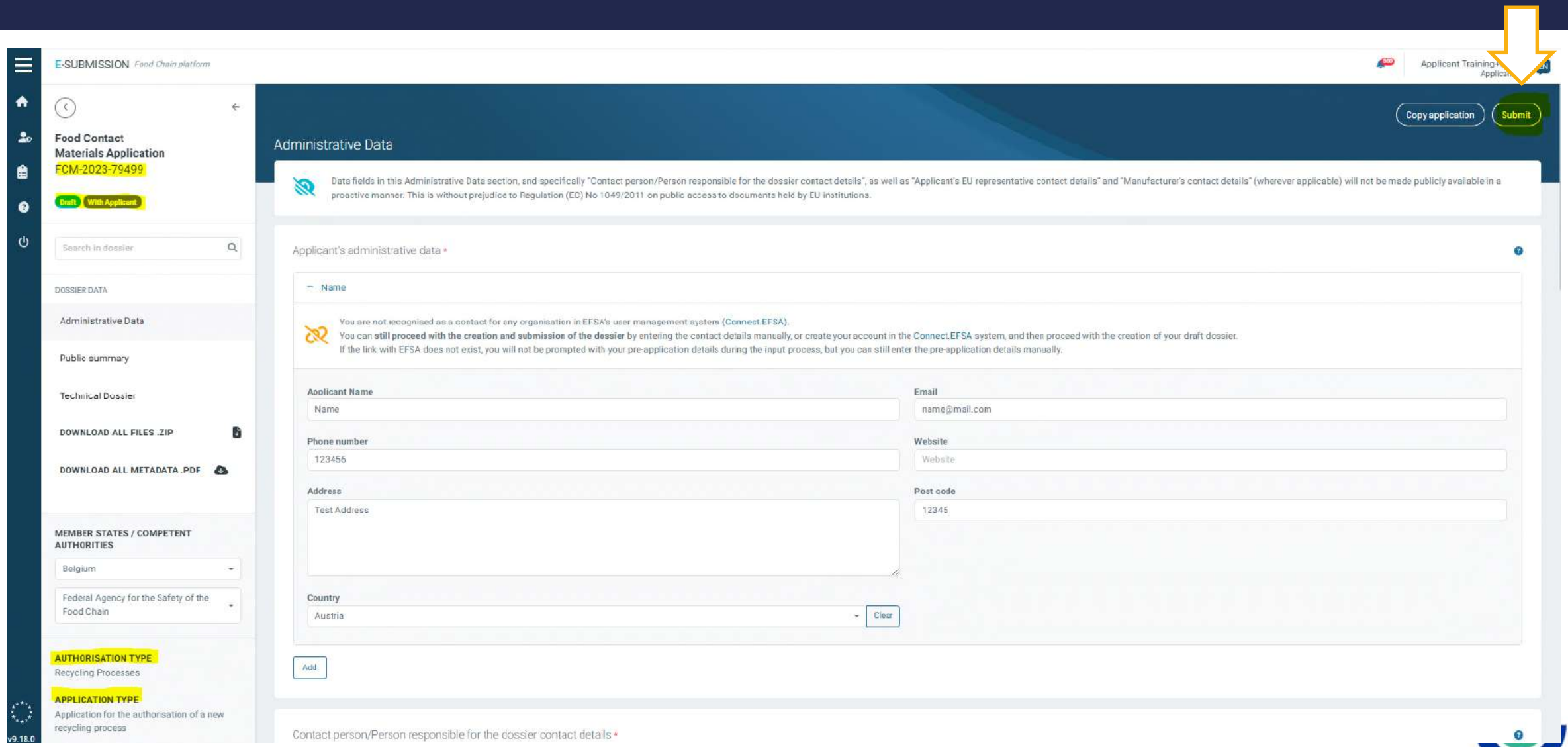
Important to Notify a draft study notification as the date of this operation corresponds to the date of the notification that is verified by EFSA during the compliance check with the NoS obligations (i.e. notification before the starting date)

ESFC: START THE APPLICATION PROCESS



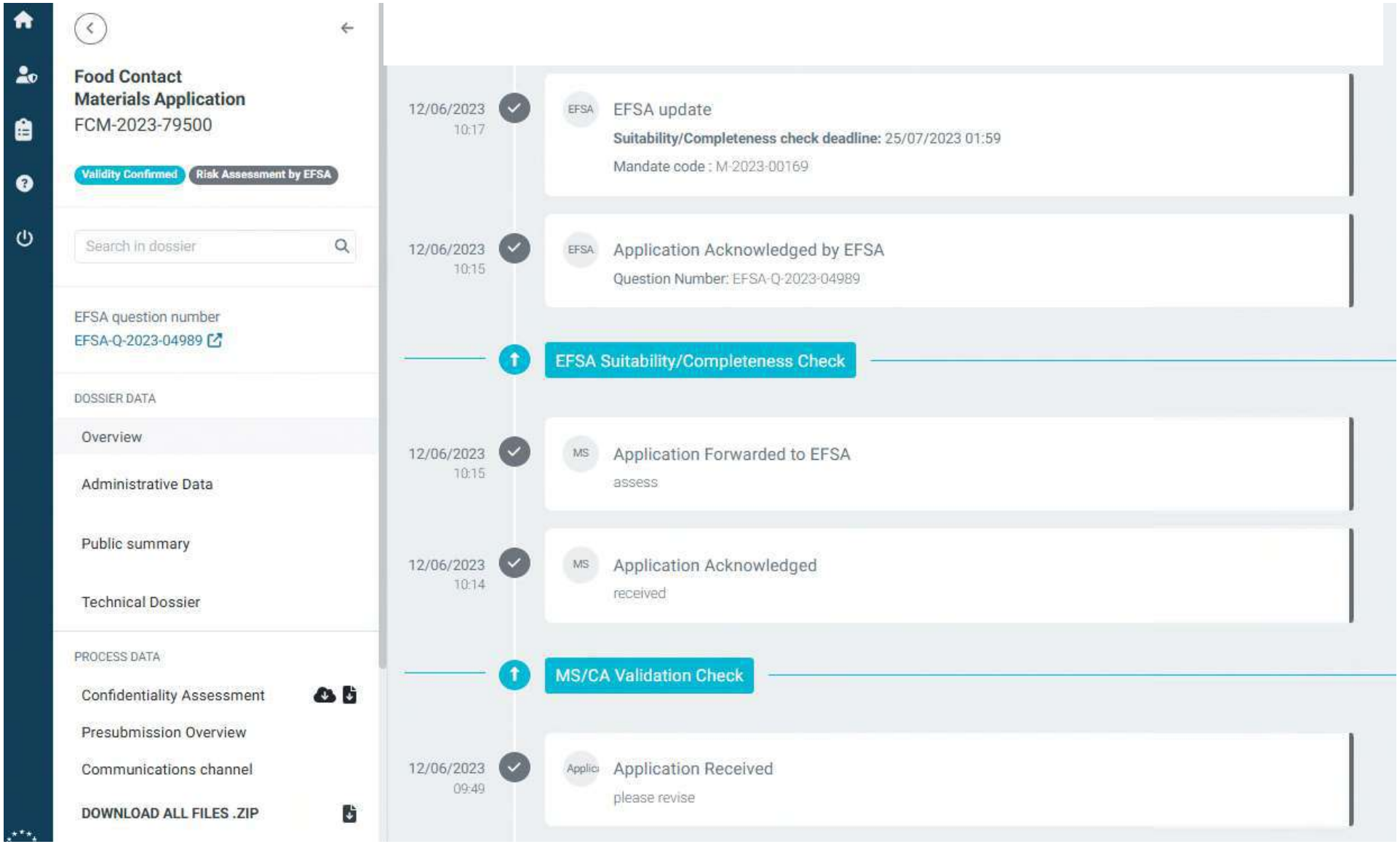
IMPORTANT: this selection cannot be changed once the process is started, the applicant should make sure that the selection has been done correctly before starting

ESFC: SUBMISSION OF APPLICATION ONCE ALL INFORMATION IS PROVIDED



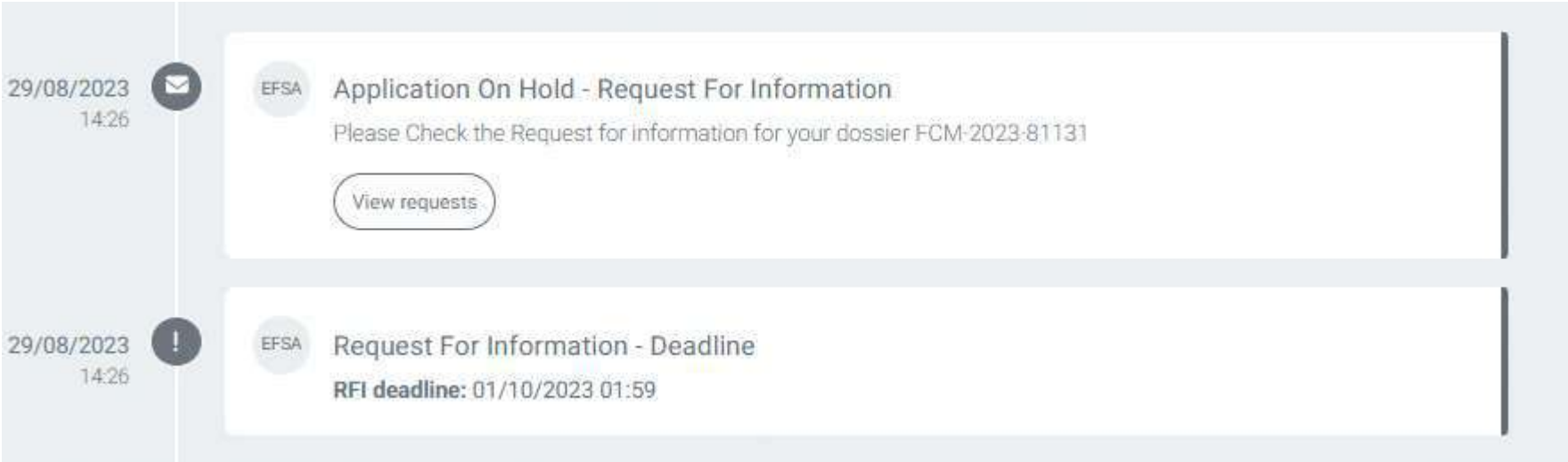
ESFC: MONITOR THE APPLICATION STATUS AFTER SUBMISSION (1)

MS/CA and EFSA validity check



ESFC: MONITOR THE APPLICATION STATUS AFTER SUBMISSION (2)

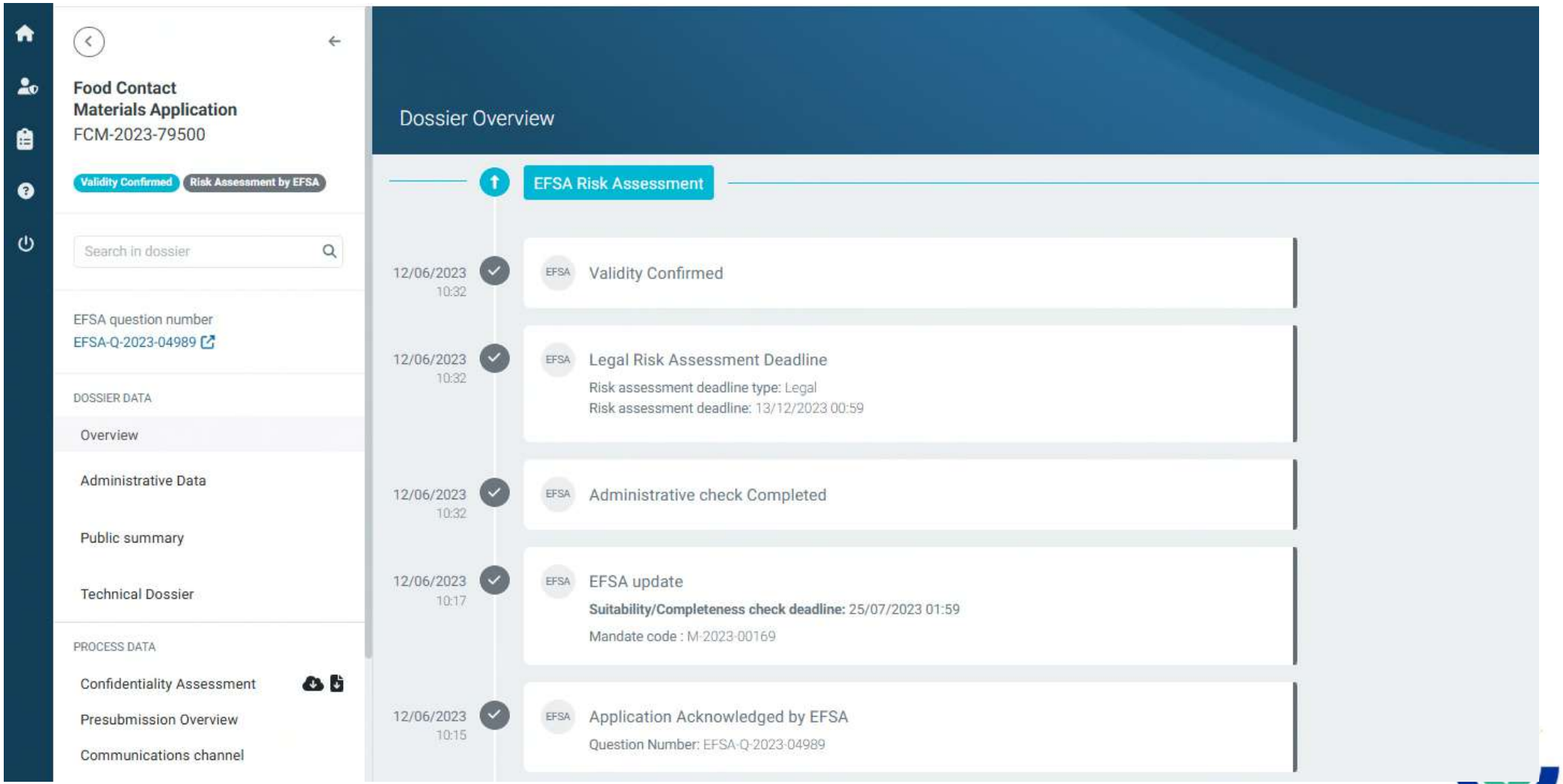
Request for information (RFI) by EFSA



ESFC is sending automatic reminders a week before the deadline to reply to EFSA

ESFC: MONITOR THE APPLICATION STATUS AFTER SUBMISSION (3)

Validity confirmed and start of Risk assessment



OPENEFSA

efsa OPEN

QUESTIONS | PUBLIC CONSULTATIONS | EXPERTS

Search entire site

Questions

Search by: question no., food domain, description, question type, substance, mandate no., dossier no., output no., appli...

361 results found Export (361) questions to CSV

Sorting: Relevance

Food domain

Search food domains

- [x] Food Contact Material (361)
- [ ] Administrative and Technical Support
- [ ] Animal Health
- [ ] Animal Welfare
- [ ] Assessment and Methodological Support

Show All

Authorisation type

- [x] Recycling Processes (361)
- [ ] Active and Intelligent Materials (53)
- [ ] Food Additives (3)
- [ ] Substance to be used in plastic materials (386)

Type

- [ ] Application (358)
- [ ] Art 29 - Scientific opinion (3)

Substances

Search substances

Status

Food Contact Material EFSA-Q-2023-00467

Application for the authorisation of the recycling process Gneuss_5 to produce recycled plastic for food contact uses

Last updated on: 18/06/2025
Status: Published

Food Contact Material EFSA-Q-2023-00731

Application for the authorisation of the recycling process Sunwell Global IRD Crystallizing and Drying System to produce recycled plastic for food contact uses

Last updated on: 13/06/2025
Status: Intake

Food Contact Material EFSA-Q-2023-00419

Application for the authorisation of the recycling process Zhejiang BORETECH Environmental Engineering_brtCOMBIPET to produce recycled plastic for food contact uses

Last updated on: 12/06/2025
Status: Ongoing Risk Assessment

Clockstop expected until 12/09/2025

Food Contact Material EFSA-Q-2025-00227

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FOOD CONTACT MATERIAL

Recycling Processes

EFSA-Q-2024-00670 | Status: Ongoing Risk Assessment

Last updated: 13/05/2025

Subject

Application for the authorisation of the recycling process EREMA_VACUREMA Basic to produce recycled plastic for food contact uses

Output

No Output has been formed yet for this question.

Supporting documents

All files

Document Type	Publish Date	Download file
Mandate	26 Nov. 2024	PDF (150.0KB)

Timeline

13-11-2025
Risk Assessment Deadline

13-05-2025
Dossier Valid

2025

20-11-2024
Dossier Received

2024

General Info

Dossier number

FCM-2024-29770

The non-confidential version of the dossier is publicly available once the application is declared valid.

SUPPORT TO APPLICANTS

SUPPORT TO APPLICANTS

"EFSA is committed to engage with its stakeholders and to increase understanding of its scientific risk assessment work."

Services for applicants

Share:

As part of EFSA's ongoing commitment to engage with its stakeholders and to increase understanding of its scientific *risk assessment* work, EFSA has developed a customer-oriented approach to stakeholders in the area of applications for regulated products. Aiming at an interactive and responsive evaluation process, this approach is centred around a catalogue of services offered to business operators and applicants.

The catalogue provides a list of harmonised support initiatives targeted at applicants. It covers the entire application life-cycle for regulated products, from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's scientific output.

As new possibilities of interaction with EFSA, the catalogue includes general pre-submission advice and renewal pre-submission advice, which were introduced by the Transparency Regulation, as well as tailored services for small and medium-sized enterprises.

Contents

Catalogue of services

SUPPORT INITIATIVES DURING THE LIFE-CYCLE OF APPLICATIONS

EFSA Catalogue of support initiatives

Pre-submission phase
- General pre-submission advice (GPSA)
- Fast-tracking of GPSA submitted **by SMEs**
- Support **to SMEs** on use of IT tools

Submission

Completeness check phase
- Clarification teleconference during completeness check (**>2 if SME**)

Validation

Risk assessment phase
- Clarification teleconference during scientific assessment
- Applicants' hearing

Opinion

Post-adoption phase
- Notification on adopted scientific output
- Pre-publication notification of adopted scientific output
- Post-adoption teleconference

- Info session and webinars on applications
- Ad-hoc meeting with food and feed business representatives
- Scientific workshops and conferences

- **EFSA web form - Ask a Question**
- Follow-up teleconference on web form query
- Fast processing of web form queries **by SMEs**

+ 'beyond the Catalogue' initiatives
LinkedIn group 'Support to applicants', mass mailing, IT tools campaign, conference attendance with EFSA info point

GENERAL PRE-SUBMISSION ADVICE (GPSA)

Do you have questions, while preparing your application, regarding the applicable **rules and the content** in guidance documents?

General Pre-Submission Advice (GPSA)

- **Non-mandatory (but highly recommended)**
- **Non-committal for the applicants nor for EFSA and its Scientific Panels**
- **Available for all kind of applications**
- **Can be requested any time before sending the application**
- **Written advice given within 30 working days (35, if the advice is given in a telemeeting)**
- **Only a succinct summary of the advice is published together with the application upon its validation**

More information on how to request a GPSA can be found in section 3.11 of the User guide on pre-application ID

SUPPORT TO APPLICANTS – ASK A QUESTION

Do you have questions regarding the **status of applications, procedural steps, administrative/ scientific requirements and/or IT tools***?

Ask a Question

- **Not necessarily related to an application**
- **Can be submitted anytime, not only during the pre-submission phase**
- **Questions out of scope are those related to rules and content for a future application and to risk management and interpretation of EU legislation**
- **Replies given within 15 working days**

* Requests for technical assistance on ESFC should be addressed to sante-e-submission-food-chain@ec.europa.eu

SUBMISSION AND COMPLETENESS CHECK

PREMISE - REGULATION (EU) 2022/1616

(25) Since this Regulation requires the individual authorisation of recycling processes in certain cases, a procedure should be laid down to this end. This procedure should be similar to the procedure for authorisation of a new substance laid down in Regulation (EC) No 1935/2004, adapted as necessary for the individual authorisation of recycling processes. In particular, since preparing an application for authorisation requires of the applicant an intricate knowledge of the recycling process concerned, and in order to avoid that several applications for the same recycling process are submitted, it is appropriate to lay down that only the business operator who developed the recycling process, and not any recycler using it, may apply for authorisation. Furthermore, as authorised recycling processes may be subject to minor and major technical and administrative changes over their life-cycle, this Regulation should ensure clarity over the procedures applicable to changes to authorised recycling processes.

Intricate knowledge as the basis for the preparation of an application

→ **only the developer** of the decontamination process of a recycling process **can apply for authorisation**

CHAPTER V

PROCEDURE FOR THE AUTHORISATION OF INDIVIDUAL RECYCLING PROCESSES

Article 17

Application for the authorisation of individual recycling processes

1. To obtain authorisation of an individual recycling process, the natural person or legal entity that developed the decontamination process of the recycling process, either exclusively for its own purposes as a recycler or for the sale or licensing of recycling or decontamination installations to recyclers, 'the applicant', shall submit an application in accordance with paragraph 2.

MANDATE FOR THE PREPARATION OF THE EFSA GUIDANCE

- → EFSA internal mandate for the preparation of a **scientific and administrative guidance** on **post-consumer mechanical PET recycling** processes intended to be used for manufacture of materials and articles in contact with food

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Recycling technology number	Technology name	Polymer type (detailed specification in Table 2)	Short description of the recycling technology (detailed specification in Table 3)	Specification of plastic input	Specification of output	Subject to the authorisation of individual processes
1	Post-consumer mechanical PET recycling	PET (2.1)	Mechanical recycling (3.1)	Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.	Decontaminated PET, final materials and articles not to be used in microwave and conventional ovens; additional specifications may apply to output from individual processes	Yes

FCM REGULATION AND EFSA GUIDANCE DOCUMENTS

Regulatory framework

- Regulation (EC) No 1935/2004 on FCM
- Commission Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods

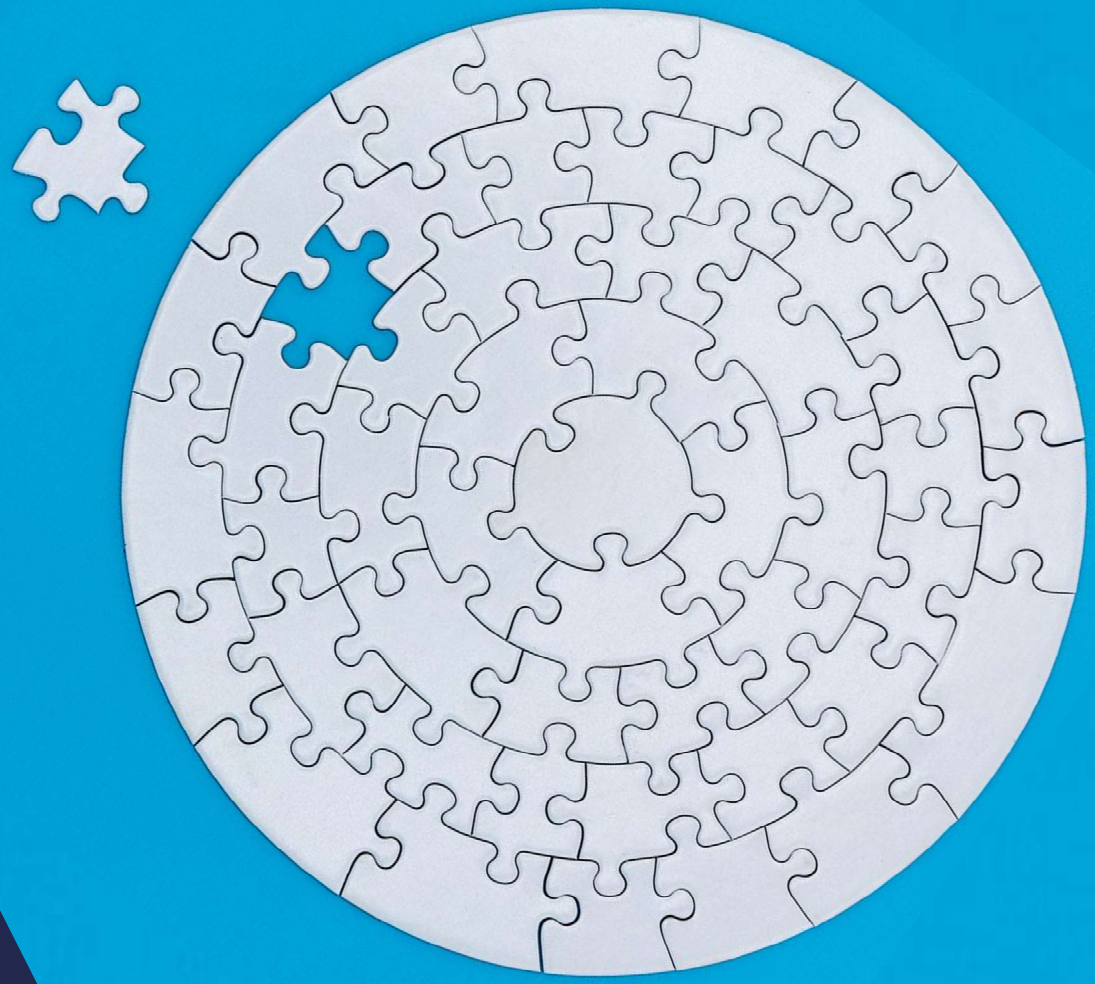
Administrative and Scientific guidance on Recycling process to produce recycled plastic – UPDATED in July 2024

- **Administrative guidance** for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food
- **Scientific Guidance** on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

✓ **Additional material**

Info session : Guidance on mechanical PET recycling

LESSONS LEARNT PERFORMING COMPLETENESS CHECKS



COMPLETENESS CHECK

- After receipt of the application, EFSA checks the completeness of the application and confirms its validity when it fulfils the legal requirements, including those on notification of studies, and the requirements set in EFSA's guidance document on recycling processes
- Compliance with Article 17(1) of Regulation (EU) 2022/1616 shall also be ensured and therefore EFSA checks if the applicant can be considered the **developer** of the **decontamination process**. To this aim, various considerations will be applied, including taking into consideration any past EFSA opinions regarding similar decontamination processes

COMPLETENESS CHECK

GUIDANCE

efsa JOURNAL

Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of post-consumer mechanical PET recycling processes intended to be used for manufacture of materials and articles in contact with food

The table of content has been updated in the e-submission food chain platform (ESFC) in July 2024

If some of the data stipulated in the guidance are not considered by the applicant as relevant to a particular case, they may be omitted **provided that the omission is fully scientifically justified**.

The dossier must be consistent

APPENDIXES TO BE INCLUDED IN THE DOSSIER

efsa SUPPORTING PUBLICATIONS OPEN ACCESS

Individual recycling processes – Administrative guidance | Open Access

Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food[1]

European Food Safety Authority (EFSA)

First published: 30 July 2024 | https://doi.org/10.2903/sp.efsa.2024.EN-8968

[1] This document is subject to the formal agreement of the European Commission as per Article 20(1) of Regulation EU 2022/1616. It is therefore provisional in nature and may be subject to further modifications until the finalised administrative guidance will be published, following receipt of the formal agreement of the European Commission. This provisional document is published for the benefit of the applicants preparing an application under Regulation EU 2022/1616, however it cannot result in any binding obligations and cannot give rise to any legitimate expectations of future conduct. Only the finalised version that will be published in the future can be considered as the applicable administrative guidance document.

‡ **Requestor**: European Food Safety Authority

§ **Question number**: EFSA-Q-2023-00175

¶ **Correspondence**: Ask a Question

† **Appendices A, B are available as separate files under the** supporting information section

†† Amended: 13 August 2024

PDF TOOLS SHARE

Abstract

This document provides guidance to applicants submitting applications for the authorisation of individual recycling processes that use a suitable technology to produce recycled plastic materials and articles intended to come into contact with food, which are to be evaluated by EFSA. Currently post-consumer mechanical PET recycling is the only suitable technology listed in Annex I to Commission Regulation (EU) 2022/1616 that requires individual authorisation. Consequently, this guidance describes the administrative requirements for the preparation and online submission of the dossier to support applications, submitted to the competent authority of a Member State for a new authorisation or for the modification of an authorisation of an individual recycling process based on post-consumer mechanical PET recycling as technology. It does not apply to novel technologies developed in accordance with Chapter IV of Commission Regulation (EU) 2022/1616. The Transparency Regulation amended the General Food Law by introducing new provisions in the pre-submission phase and in the application procedure: general pre-submission advice, notification of information related to studies commissioned or carried out to support an application, public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process, public consultation on submitted applications. These new requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in this guidance. The guidance describes the procedure and the associated timelines for handling applications on individual recycling processes that use a suitable technology, the different possibilities to interact with EFSA and the support initiatives available from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's scientific opinion.

Supporting Information

References

Individual recycling processes – Appendix A

efsa SUPPORTING PUBLICATIONS

Appendix to: Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food. doi:10.2903/sp.efsa.2024.EN-8968

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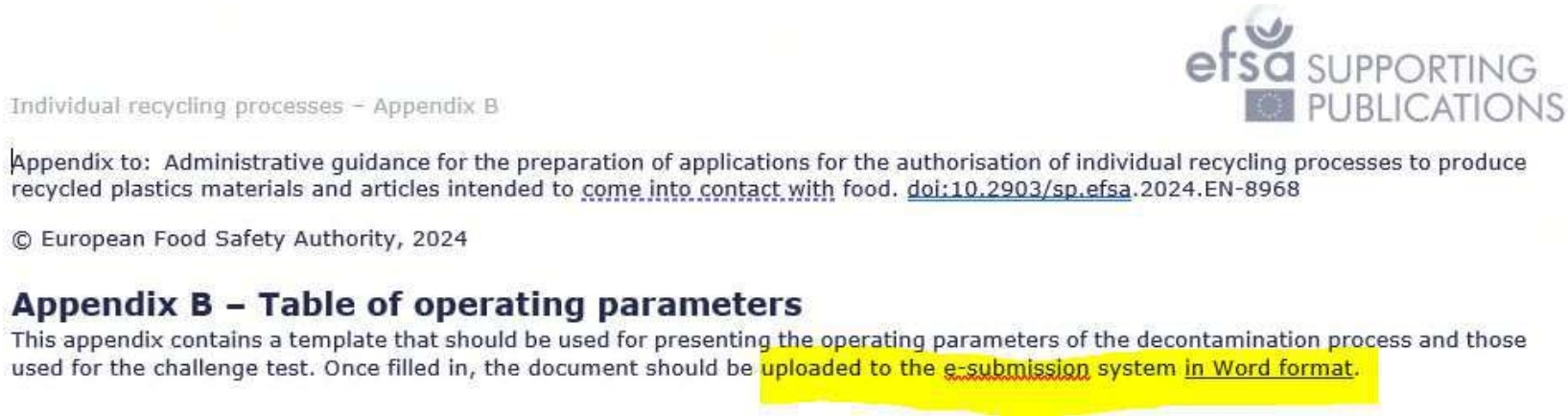
Appendix A – Completeness checklist



Individual recycling processes – Appendix B

efsa SUPPORTING PUBLICATIONS

Appendix to: Administrative guidance for the preparation of applications for the authorisation of individual recycling processes to produce recycled plastics materials and articles intended to come into contact with food. doi:10.2903/sp.efsa.2024.EN-8968

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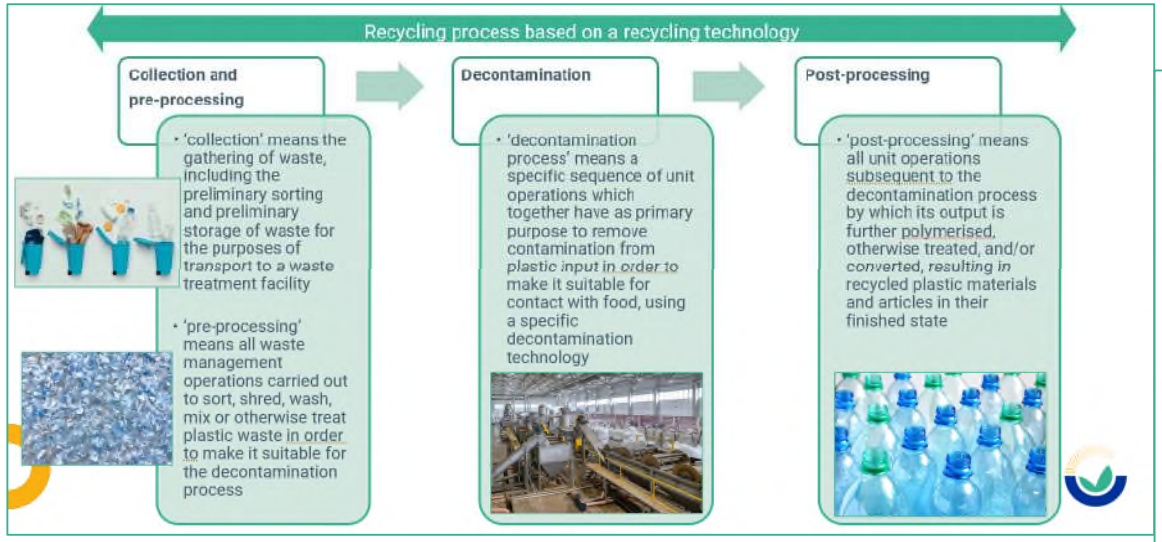
Appendix B – Table of operating parameters

This appendix contains a template that should be used for presenting the operating parameters of the decontamination process and those used for the challenge test. Once filled in, the document should be uploaded to the e-submission system in Word format.

REGULATORY REQUIREMENTS



- **Article 17.5** of Regulation (EU) 2022/1616 sets out the information to be provided by the applicant in the technical dossier

5. The technical dossier shall contain the following information:

(a) any information required in the detailed guidance published by the Authority in accordance with Article 20(2);

(b) a description of the pre-processing carried out to produce plastic input suitable for being entered into the decontamination process and of the specific quality control procedures applied during collection and pre-processing, including a detailed specification of the pre-processed plastic input;

(c) a description of any required post-processing of the recycled plastic and of the intended use of the resulting plastic materials and articles and of uses for which it would not be suitable, including relevant instructions and labelling to be provided to convertors and to end-users of the recycled plastic materials and articles;

(d) a simple block diagram of all unit operations used in the decontamination process, that provides a reference to the input, output and quality control procedures applied by each operation;

(e) a piping and instrumentation diagram of the decontamination process in accordance with section 4.4 of ISO 10628-1:2014, showing only the instrumentation relevant for decontamination;

(f) a description of the quality control procedures applied at each unit operation of the decontamination process, including:

(i) the values of monitored parameters such as operating temperatures, pressures, flowrates and concentrations, and acceptable ranges thereof;

(ii) laboratory analysis and its frequency; if any,

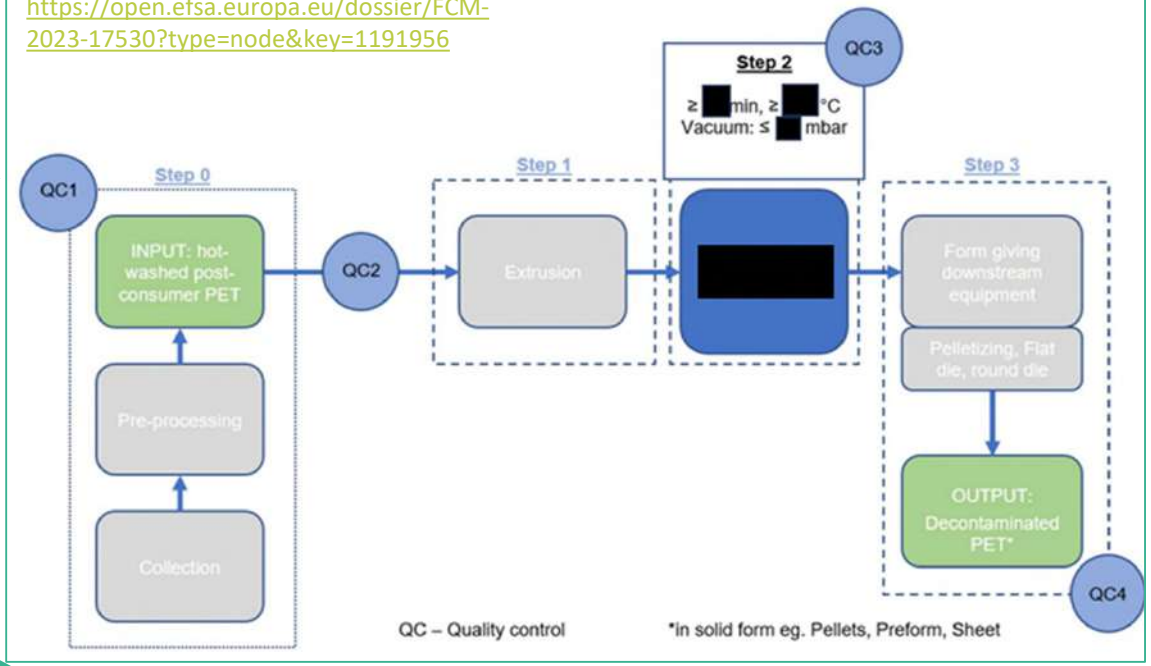
(iii) correction and record keeping procedures; and

(iv) any other information the applicant deems relevant to fully describe its quality control procedures.

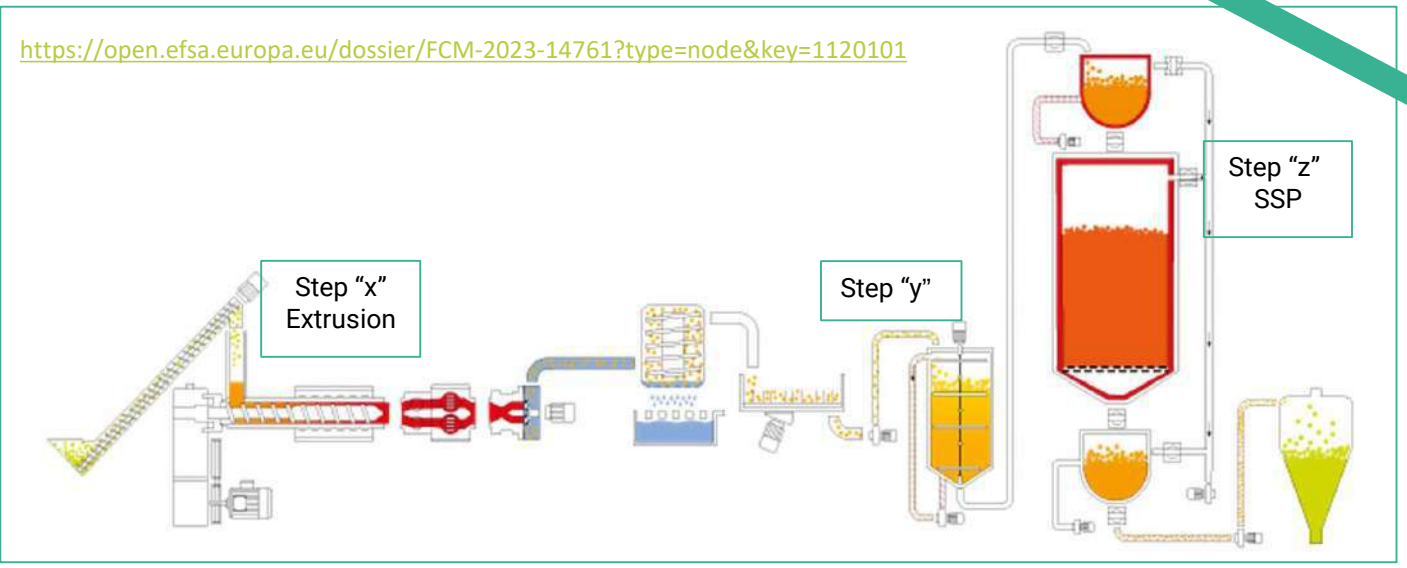
DECONTAMINATION PROCESS - DIAGRAMS

- Simple **block diagram** with unit operations and quality control points
- **Process flow diagram** with distinct unit operations and their schematic set-up
- **Piping and instrumentation diagram** (ISO 10628-1:2014, section 4.4)

https://open.efsa.europa.eu/dossier/FCM-2023-17530?type=node&key=1191956



https://open.efsa.europa.eu/dossier/FCM-2023-14761?type=node&key=1120101



Regulation (EU) 2022/1616:

Specific mention of possibility of claiming confidentiality for this diagram

TECHNICAL DETAILS ON EQUIPMENT AND OPERATIONS ARE REQUIRED

More and detailed information on the equipment and the operating parameters are now required in comparison with the previous EFSA guidance

a. Equipment

The technical dossier shall contain a description of the equipment used in the unit operations (steps) of the decontamination process, with a clear identification and distinction of the steps from input to output. The design and assembly of the main and auxiliary equipment pieces (e.g. reactors, stirring systems, vessels, extruders, crystallisers, preheaters, pelletisers) should be described in detail and supported by technical drawings and photos.[12] Design details that may affect the parameters relevant for the decontamination efficiency should be specified.

In particular, the following aspects should be clearly addressed, and supported by data, where relevant:

- Brand name if any, version and date of introduction of the decontamination installation
- Principal function of the decontamination equipment part(s) (e.g. SSP reactor, extruder, preheater), type of reactor (e.g. stirring tank, fluidised bed, plug-flow), type of special extruders (e.g. extruders with planetary sections, satellite screws), type of special melt-polymerisation installations;
- Design and position of stirring tools; set-up of stirring system, including number and type of rotating tools, if any;
- Heating/cooling systems, vacuum or flowing gas, position and design of gas and vacuum ports, purification of circulated gases;
- Size of the equipment: dimensions and capacity for a given recyclate density for the various sizes brought to the market
  - A non-exhaustive list of examples of dimensions is shown below:
    - For a conventional reactor or vessel: e.g. cross section surface and height, stirrer length (if any).
    - For an extruder type reactor: e.g. screw(s) length and diameter, position of vacuum ports along the length of the extruder, as well as shape and dimensions of the die(s).
  - For a melt-polymerisation installation: e.g. diameter and number of any melt orifices (dies) as well shape and dimensions of any melt tanks used and of any moving blades into the melt.
  - In case other types of reactors/systems are used, the corresponding parameters should be provided.

b. Operation

The technical dossier shall contain information on the operation of all equipment parts belonging to the same process. It should also be provided for different installation sizes, if applicable. In particular, the following aspects should be clearly addressed in the technical dossier, and supported by data, where relevant:

- Operating parameters (e.g. residence time, temperature, pressure, gas flow rate);
- Operation mode (e.g. batch, continuous);
- Capacity, load and filling level;
- Throughput/discharge rate;
- Rotation parameters (e.g. rotation speed of stirrer, screw of special extruders, blades or drums in special installations);
- Geometrical dimensions (i.e. length and thickness) of the pellets formed and/or treated within the decontamination process;
- Temperature gradient along the axes of the reactor;
- Melt surface area exposed to the decontamination conditions;
- Considerations on the degree of mixing in the equipment.

The operating parameters of the steps of the decontamination process should be provided following the instructions laid down in the administrative guidance document (EFSA, 2024).

An identification of the critical steps of the decontamination process should be provided, together with an analysis of the possible consequences of an incidental failure of compliance of some critical parameters with pre-established values.

REQUIREMENTS FOR THE DESIGN OF THE CHALLENGE TEST

The new EFSA guidance includes specific requirements for the design of the challenge test, in comparison with the previous EFSA guidance, in terms of:

- Contamination procedure
- Number of samples to be analysed
- Detailed information required on equipment and parameters if the test is not performed in the industrial installation

INTENDED USES AND EVALUATION OF THE RECYCLING PROCESS

The applicant should choose between one of the 3 scenarios for the intended uses included in the EFSA guidance in appendix C

The appropriate Cmod values, as provided in appendix D, should be used for the evaluation of the process

Surrogate	Mr (Da)	Cmod (mg/kg PET) scenario A	Cmod (mg/kg PET) scenario B	Cmod (mg/kg PET) scenario C
Toluene	92.1	0.04	0.13	0.51
Chlorobenzene	112.6	0.05	0.15	0.60
Chloroform	119.4	0.05	0.16	0.63
Methyl salicylate	152.2	0.12	0.40	1.60[a]
Phenylcyclohexane	160.3	0.13	0.42	1.69[a]
Benzophenone	182.2	0.15	0.49	1.96
Lindane	290.8	0.28	0.92	3.67[a]
Methyl stearate	298.5	0.29[a]	0.95[a]	3.82[a]

MOST COMMON ISSUES FOUND DURING COMPLETENESS CHECK (AND HOW TO AVOID THEM)

- Deviations from notification of studies obligations are not justified

Read paragraphs 2.2; 2.3 and 2.5 of the administrative guidance

- Confidential and non-confidential version of the documents are not provided according to the EFSA requirements

Read paragraphs 2.6 and 2.11.4 of the administrative guidance and the user guide on confidentiality

- Documents are not provided in the correct format
- Intellectual property rights are not indicated correctly

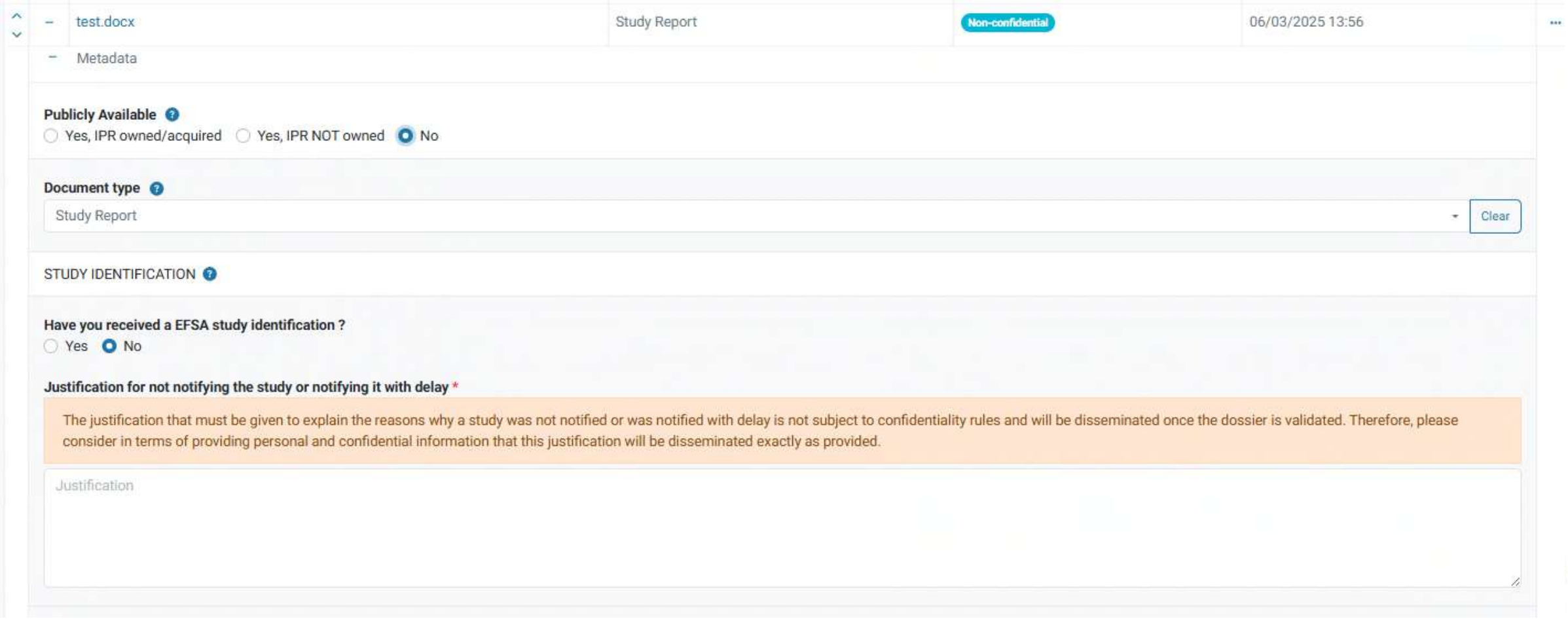
Read paragraph 2.11 of the administrative guidance

- Data omissions are not justified
- Inconsistencies are present between different sections and documents of the dossier

Check the entire dossier carefully and use the checklist included in the administrative guidance

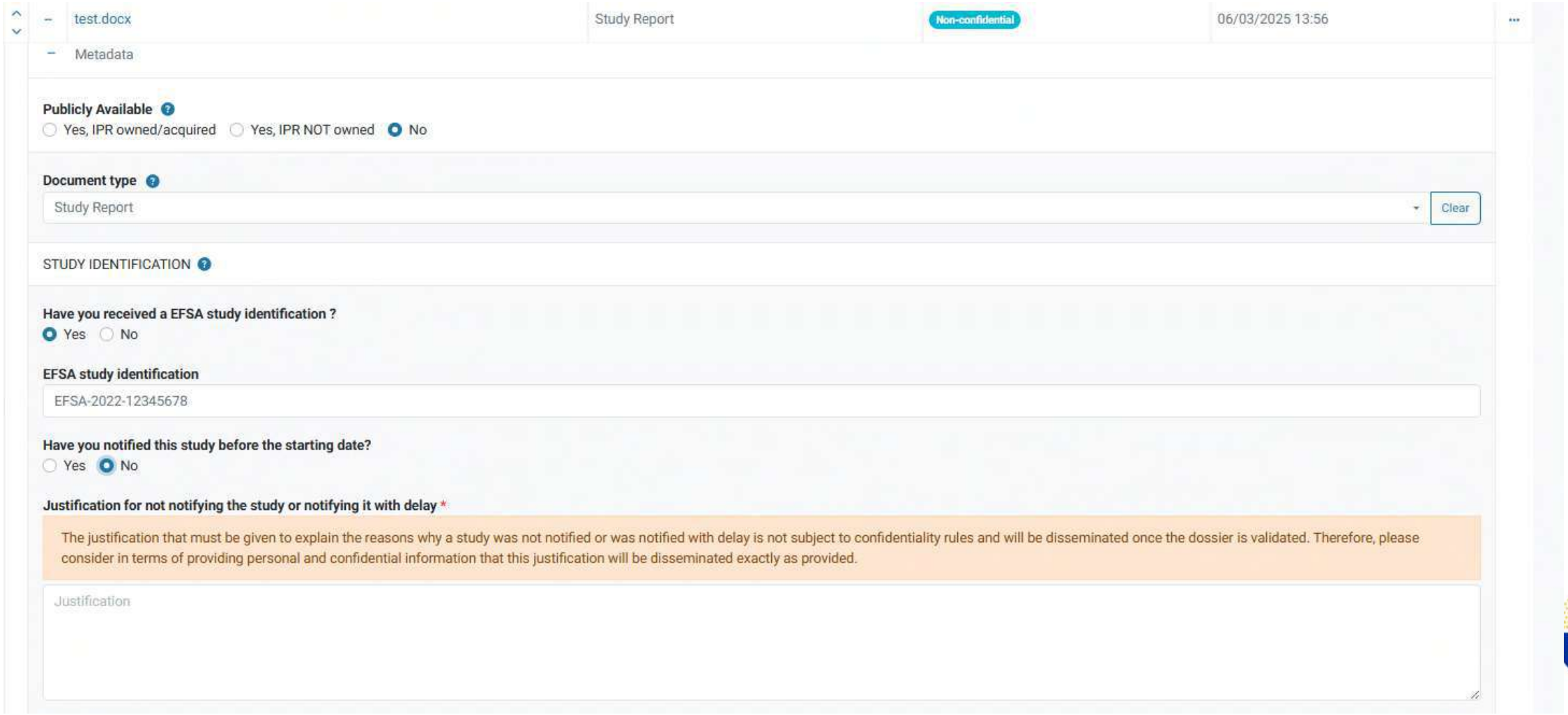
HOW TO CORRECTLY PROVIDE NOS INFORMATION (1)

In case of non-notification of a study (e.g. the challenge test)



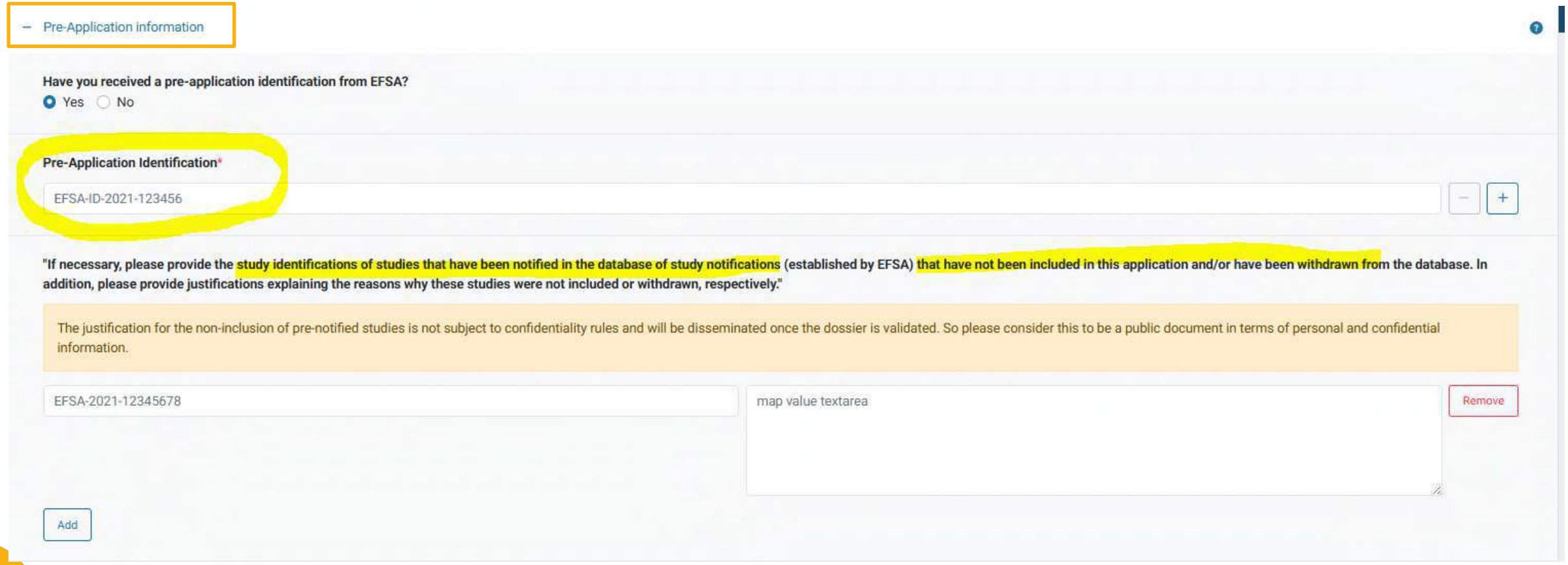
HOW TO CORRECTLY PROVIDE NOS INFORMATION (2)

In case of delayed notification of a study (e.g. the challenge test)



HOW TO CORRECTLY PROVIDE NOS INFORMATION (3)

In case of non-inclusion or withdrawal of a notified study

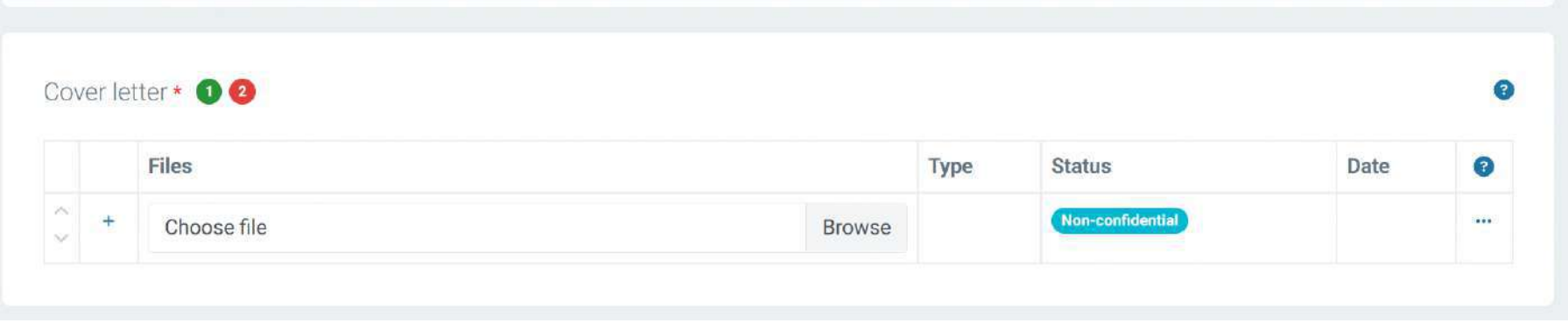


The pre-application ID (PA-ID) must always be indicated, in case studies have been notified and/or a GPSA has been requested.

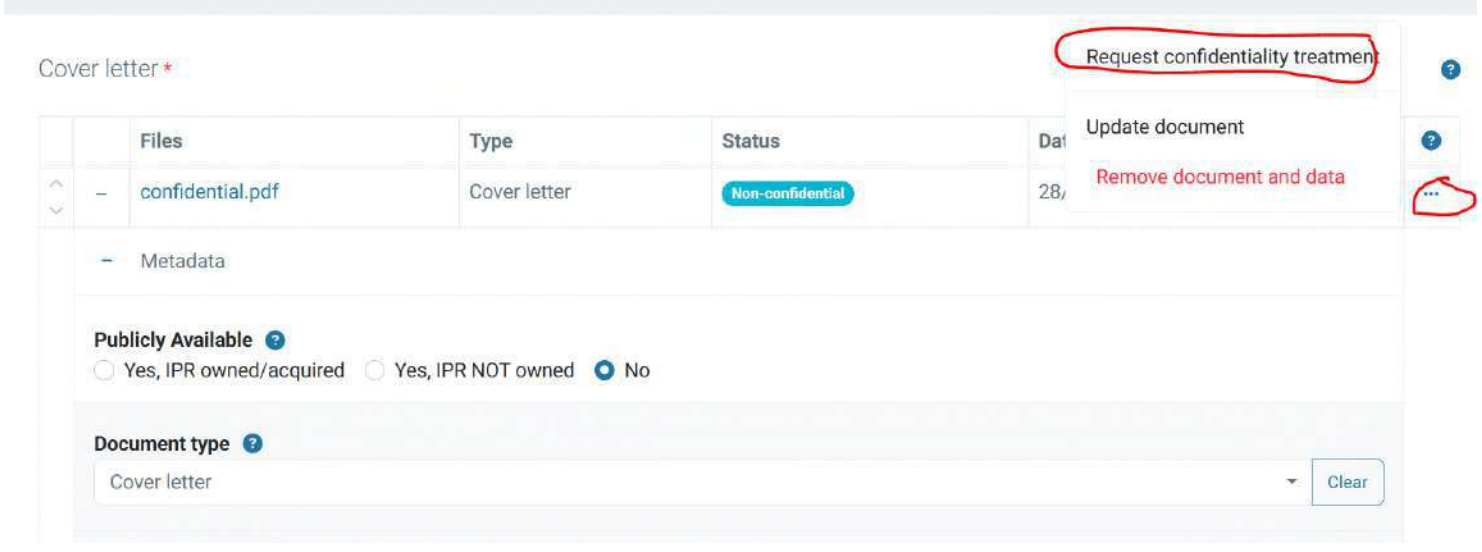
All notified studies must be linked to the PA-ID in connect EFSA **before submission**

HOW TO CORRECTLY INSERT A CONFIDENTIALITY REQUEST IN ESFC (1)

Step 1: to start, upload the confidential version (**confidential info must be earmarked**)

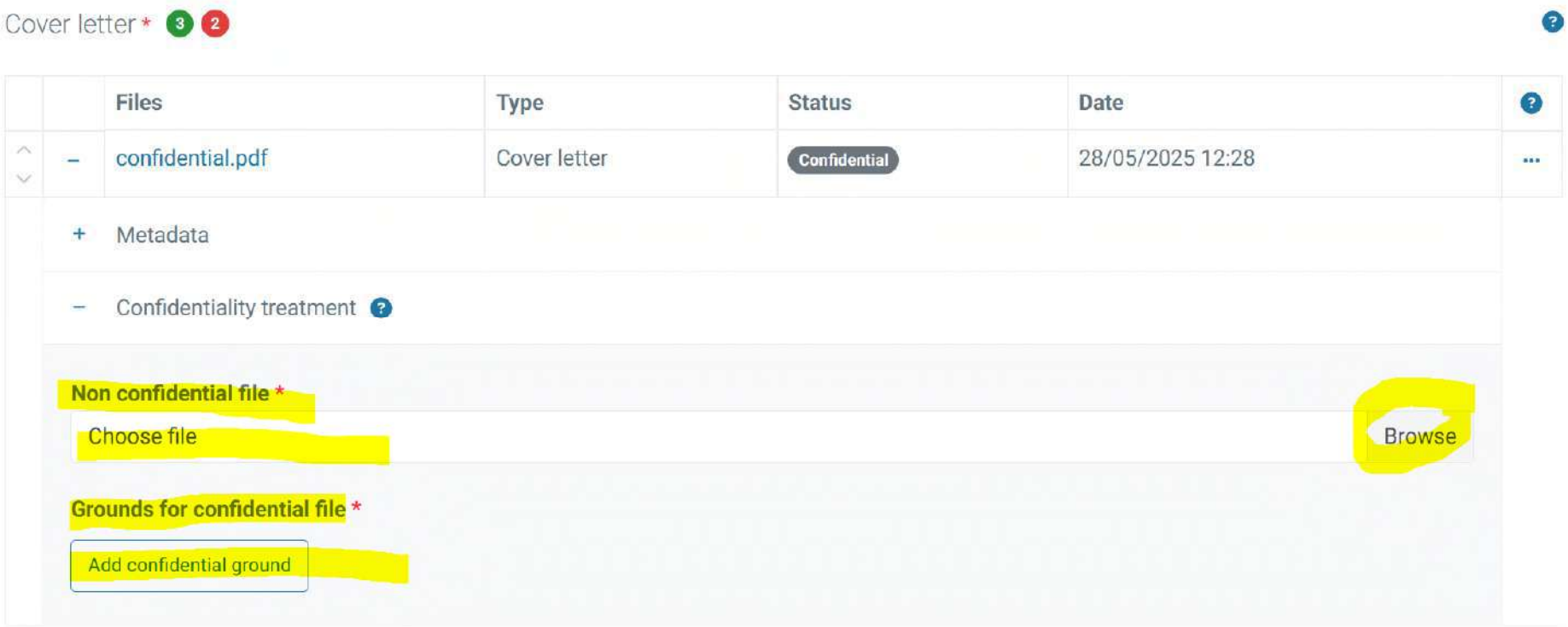


Step 2: once the document is uploaded and the document type is selected, click on the 3 dots to request confidential treatment



HOW TO CORRECTLY INSERT A CONFIDENTIALITY REQUEST IN ESFC (2)

Step 3: the document will turn from non-confidential, to confidential. Now the non-confidential version (**with all confidential info blackened**) can be uploaded and the grounds for requesting confidentiality can be selected



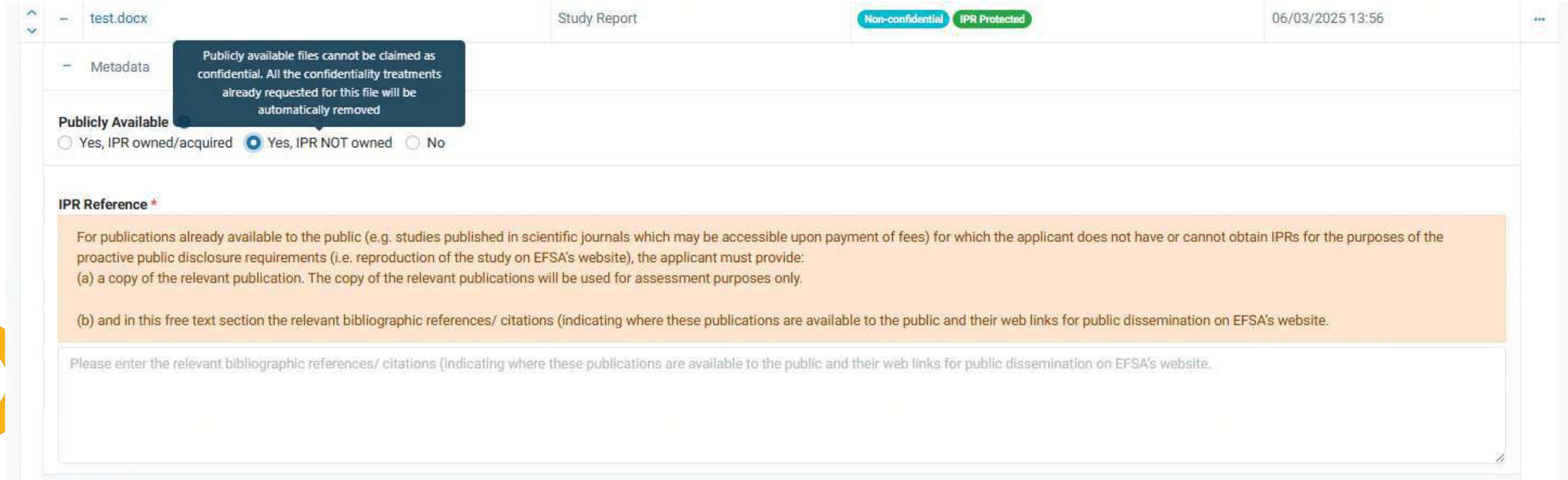
The two versions will remain in the system as one single document

HOW TO CORRECTLY FLAG THE IPR OF EACH DOCUMENT

For each document, to flag if the document is or not publicly available

If publicly available, to indicate if the IPR has been owned/acquired or not

If the IPR is not owned, the full document will not be published in OpenEFSA but only the bibliographic reference indicated will be published



HOW TO REPLY TO AN EFSA REQUEST FOR INFORMATION DURING COMPLETENESS CHECK

- In case of **doubts regarding what EFSA has asked**: to contact FDP@efsa.europa.eu and request a clarification teleconference
- In case of **technical issues in ESFC**: to write to ESFC help desk (sante-e-submission-food-chain@ec.europa.eu) directly
- If case the applicant **needs to update other section(s) of the dossier** that have not been opened: to follow the instructions included in the request for information. If still in doubt, send an email to FDP@efsa.europa.eu
- If **additional time to reply is needed** for the applicant: request an extension of deadline in ESFC directly
- When **ready to reply**:

  - the replies must be integrated in the technical dossier text and/or annexes and/or metadata of the documents, otherwise they will not be considered during risk assessment (no need to highlight the changes)

  - remove obsolete documents

  - do not reply using only the comment/reply box of ESFC

  - check that all the points requested by EFSA have been addressed

MODIFICATION OF AN AUTHORIZATION

Article 22

Request for the modification of an authorisation by the authorisation holder

1. The authorisation holder may apply for a modification of the authorisation of a recycling process.
2. The modification referred to in paragraph 1 shall be subject to the procedure laid down in Articles 17 to 20, unless otherwise provided for in this Article.
3. The application referred to in paragraph 1 shall be accompanied by the following:

(a) the reference to the original application;

(b) a technical dossier containing the information required in Article 17(5), including the information of the technical dossier already submitted during the original application in accordance with Article 17(5) and Article 18(2), updated with the modifications. All modifications (deletions and additions) shall be clearly marked and visible in the technical dossier;

(c) a new complete summary of the technical dossier in a standardised form;

(d) at least one complete compliance monitoring summary sheet related to a decontamination installation operating the authorised process as submitted to a competent authority in accordance with Article 26, and an updated version which includes all changes, if any, expected to be forthcoming from the requested change.

4. In case the modification concerns a transfer of the authorisation of a recycling process to a third party, the authorisation holder shall notify the Commission before the transfer, indicating the name, address and contact information of that third party. At the time of the transfer, it shall provide the notified authorisation, the technical dossier and all documents included therein to the third party. That third party shall contact the Commission without delay by a registered letter, stating that it accepts the transfer, has received all documents and accepts to meet all the obligations arising from this Regulation and the authorisation.

LIST OF USEFUL LINKS

- Risk Assessment Vs Risk Management: What's The Difference?: https://www.efsa.europa.eu/en/discover/infographics/risk-assessment-vs-risk-management-whats-difference
- FCM application procedure: https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowfcm.pdf
- EFSA Practical Arrangements on pre-submission phase and public consultations: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf
- Q&A on EFSA's practical arrangements: https://www.efsa.europa.eu/sites/default/files/2021-03/questions-and-answers-efsa-practical-arrangements.pdf
- EFSA's Practical Arrangements concerning transparency and confidentiality: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf
- EFSA User guide on confidentiality: https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf
- EFSA's toolkit page: https://www.efsa.europa.eu/en/applications/toolkit
- EFSA User guide on pre-application ID : https://www.efsa.europa.eu/sites/default/files/2021-07/user-guide-pre-application-id.pdf
- EFSA User guide on NoS : https://www.efsa.europa.eu/sites/default/files/2021-07/user-guide-notification-of-studies.pdf
- ESFC User manual : https://food.ec.europa.eu/horizontal-topics/general-food-law/training-and-support_en
- Services for applicants' topic page : https://www.efsa.europa.eu/en/applications/about/services
- EFSA's Catalogue of support initiatives : https://www.efsa.europa.eu/en/supporting/pub/en-6472
- Regulation (EC) No 1935/2004 on FCM: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R1935&qid=1747130173290
- Commission Regulation (EU) 2022/1616: https://eur-lex.europa.eu/eli/reg/2022/1616/oj/eng
- **Administrative guidance** on individual recycling processes : https://www.efsa.europa.eu/en/supporting/pub/en-8968
- **Scientific Guidance** on the criteria for the evaluation and on the preparation of applications for PET recycling processes : https://www.efsa.europa.eu/en/efsajournal/pub/8879
- Info session : Guidance on mechanical PET recycling : https://www.efsa.europa.eu/en/events/info-session-guidance-mechanical-pet-recycling-presentations-and-recordings

QUESTIONS & ANSWERS

USEFUL TO KNOW!

https://www.linkedin.com/groups/9083910/

https://www.efsa.europa.eu/en/applications/about/services

https://connect.efsa.europa.eu/RM/s/help

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efsa.europa.eu/en/contact/askefsa

EUROPEAN FOOD SAFETY AUTHORITY