WEBINAR ON NOVEL FOOD APPLICATIONS

26 OCTOBER 2023

EUROPEAN FOOD SAFETY AUTHORITY

WELCOME AND INTRODUCTION

OBJECTIVES

- To help applicants better understand the procedure for novel food applications and the support activities provided by EFSA during the pre-submission phase
- To present the most common issues identified during the suitability check of a novel food application, based on two years of experience with implementing the Transparency Regulation
- To address questions from participants regarding EFSA's procedures and common issues related to novel food applications

WHO WE ARE

- Presenters

  Patricia Romero Fernandez, Silvia Federici
- Contributors

  Federico Morreale, Irene Baratto, Ellen Van Haver, Costanza Casiraghi, Catalina Manieu, Sara De Berardis, Ilaria Mangerini, Oscar Gonzalez, Maja Gorgieva
- Moderator: **Goran Kumric**
- Event organizer: **Carolina Vastola**
- Event producer: **Marina Canale**
- Technical support: **Margherita Olivieri**

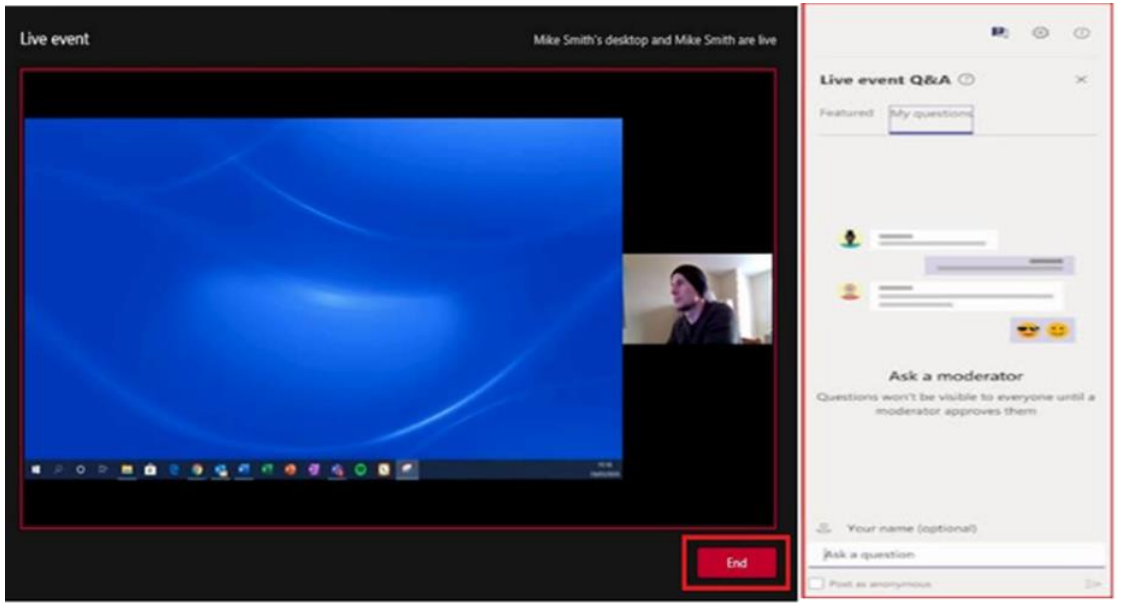
AGENDA

Time	Topic	Speaker
10.30-10.35	Introduction and outline of the webinar	Goran Kumric
10.35-10.55	Overview of the procedure for novel food applications and EFSA support activities	Silvia Federici
10.55-11.20	Most common issues identified during the suitability check	Patricia Romero Fernández
11.20-11.40	Q&A session	
11.40-11.45	Conclusion	Goran Kumric

HOUSE KEEPING RULES

- You are **automatically connected** to the audio broadcast. One-way audio (**listen only** mode).
- The **event is in English. Questions** should be submitted **in English** via the **Q&A chat;**
- This event is **being recorded** and recordings will be published on EFSA's website
- After the event, attendees will receive a **link to a survey** to evaluate EFSA's event & services

Presentation window



Q&A box: For any questions related to the topic or unexpected IT issues

Novel Food Application Procedure

IS YOUR PRODUCT A NOVEL FOOD?

- Under EU Regulations, a novel food is **any food that was not consumed to a significant degree within the Union prior to May 1997**
- As a first step, you should first verify whether or not the product you want to place on the EU market, falls under the scope of **Regulation (EU) 2015/2283**
- You can consult the **Union list** of novel foods on the European Commission website, to see whether your product is an already authorised novel food
- **If you are unsure whether your product is a novel food or not**, you can contact the Competent Authority of the Member State where you first intend to place the food on the market. EFSA is not in charge of deciding whether a food is novel or not

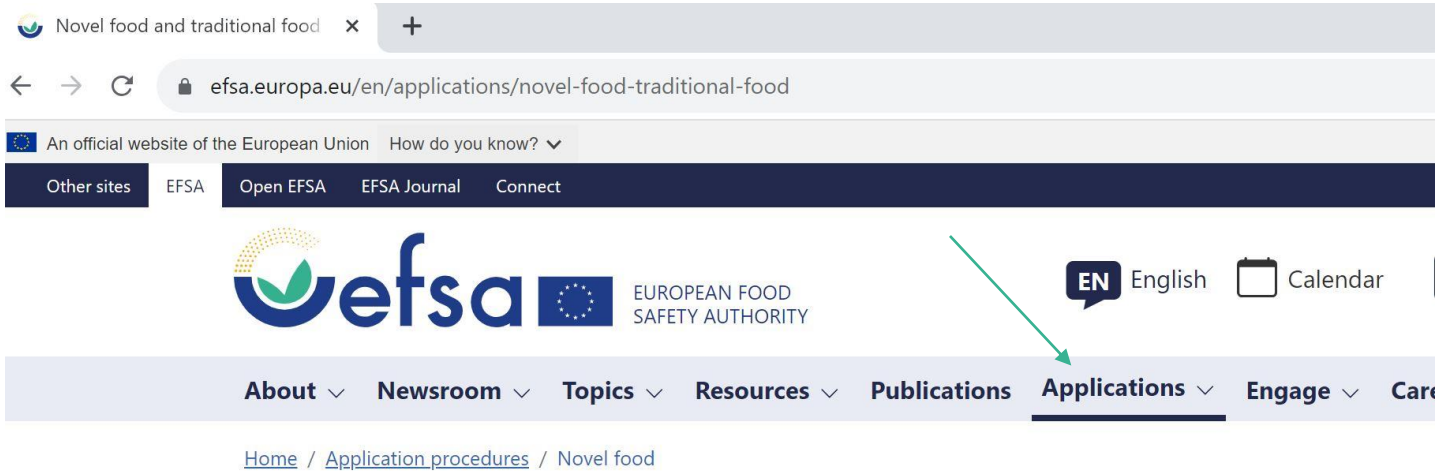
NOVEL FOOD APPLICATION

- If your product qualifies as novel food, you must **submit an application to the European Commission**, complying with Regulation (EU) 2015/2283 and Regulation (EU) 2017/2469
- The application must be submitted through the **e-submission food chain platform (ESFC)**
- **No fees** will be charged for the submission and the scientific assessment of an application
- The application must fulfil the **data requirements** described in the **EFSA guidance documents**

ESFC

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

NOVEL FOOD OVERVIEW AND PROCEDURE



Novel food and traditional food applications

Share:

Overview and procedure

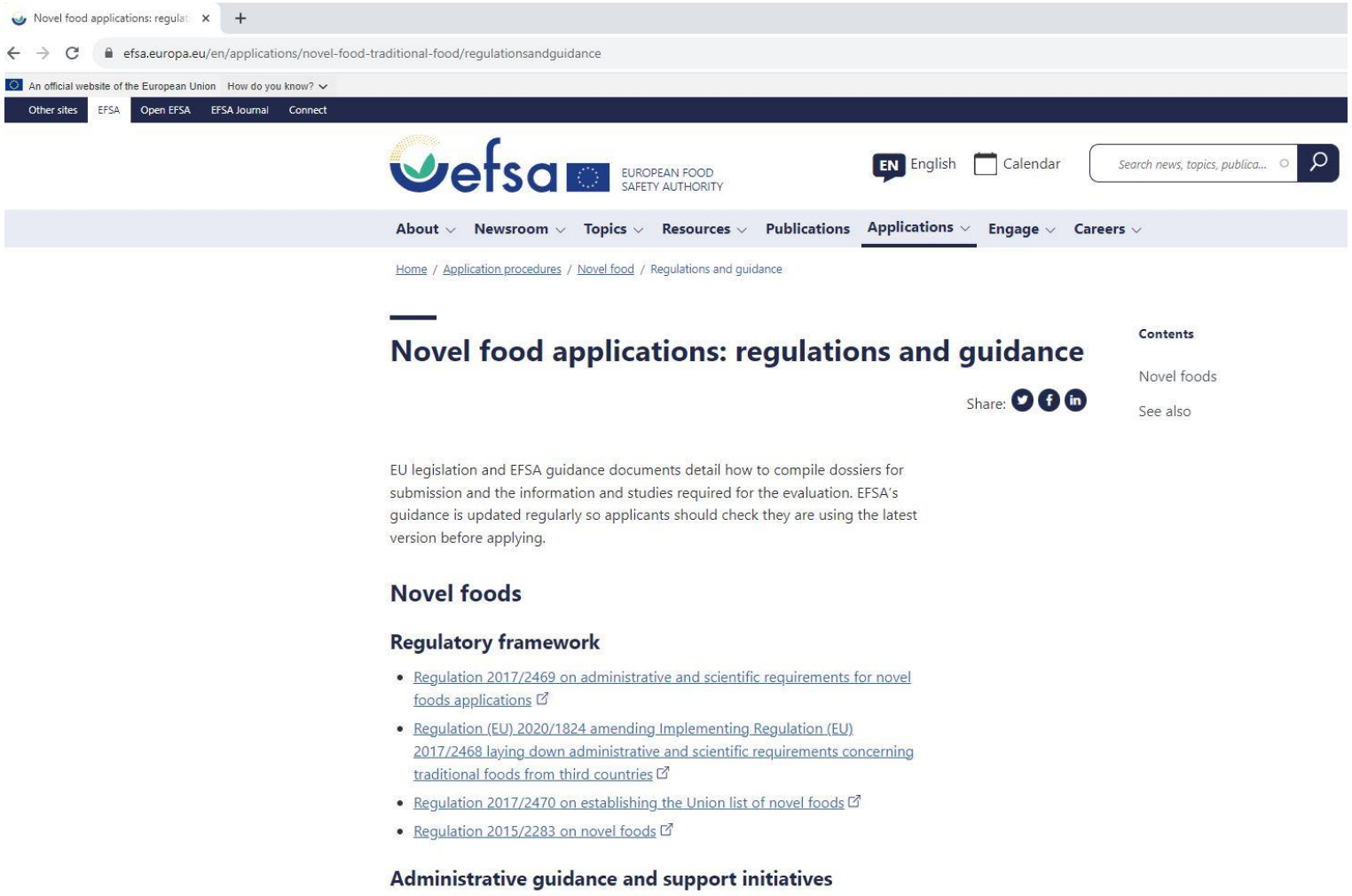
The authorisation and use of novel foods and food ingredients have been harmonised in the European Union since 1997 when Regulation EC 258/1997 on novel foods and novel food ingredients was adopted. In 2013, the Commission presented a proposal for a new regulation on the matter. The co-legislators the European Parliament and the Council have reached an agreement with the new Regulation EU 2015/2283.

Regulations and guidance

Legal framework, administrative and technical guidance

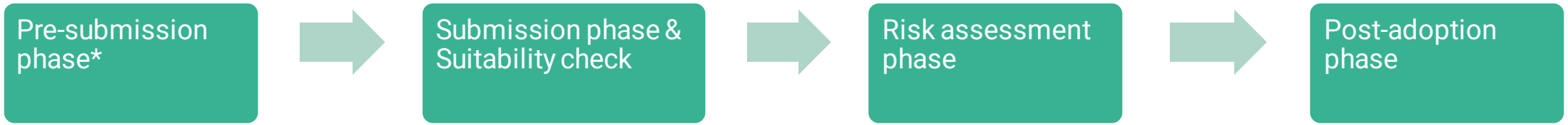
Information on how to compile dossiers for applications

NOVEL FOOD GUIDANCE DOCUMENTS



- **Administrative guidance**: with detailed description of the procedure for a novel food application
- **Scientific guidance**: with detailed description of the data requirements for a novel food application

NOVEL FOOD APPLICATION PROCEDURE IN A NUTSHELL



Legend:

- Potential applicant / applicant
- EC: European Commission
- EFSA: European Food Safety Authority

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

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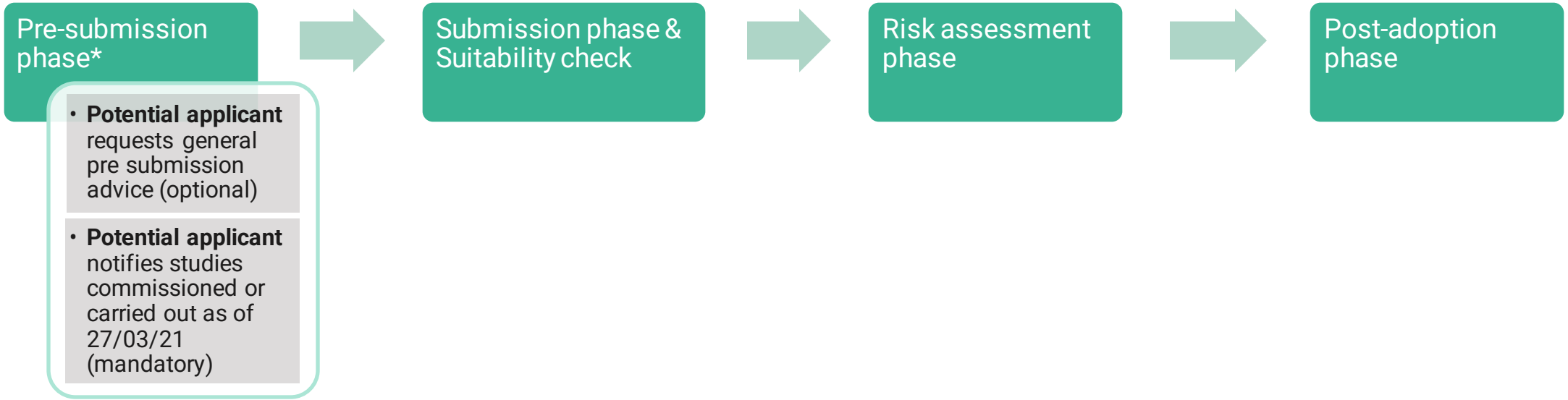

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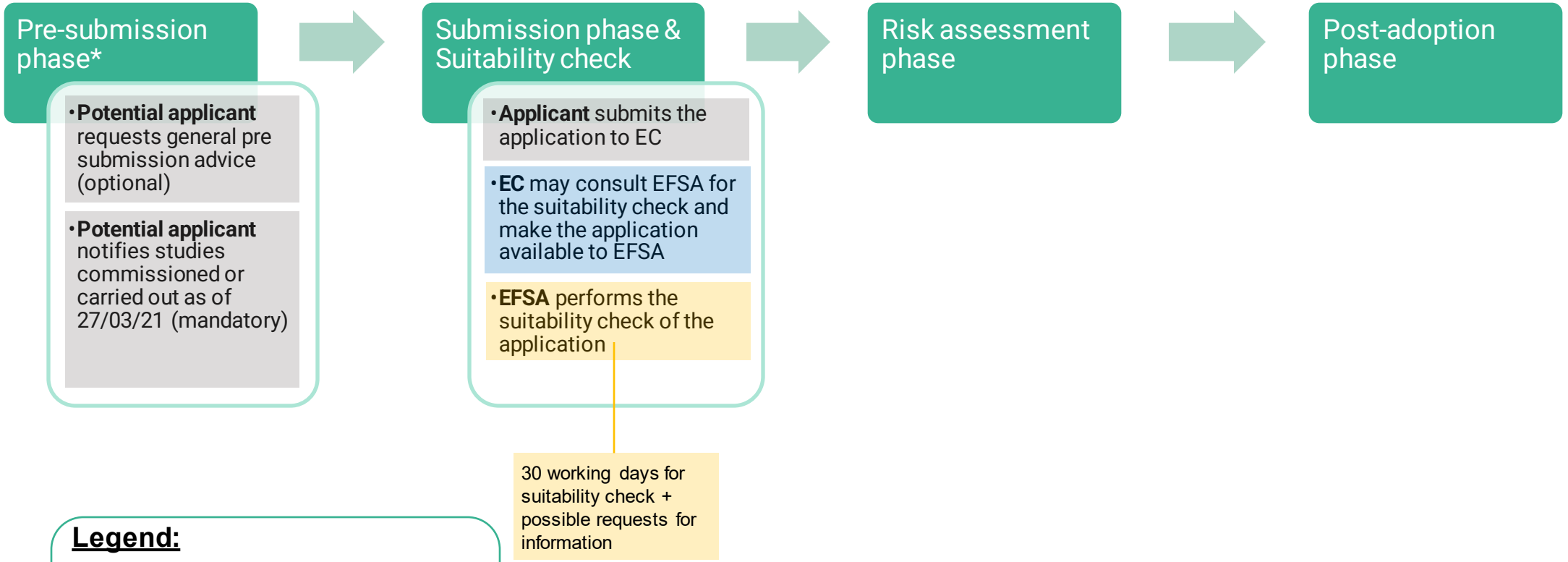

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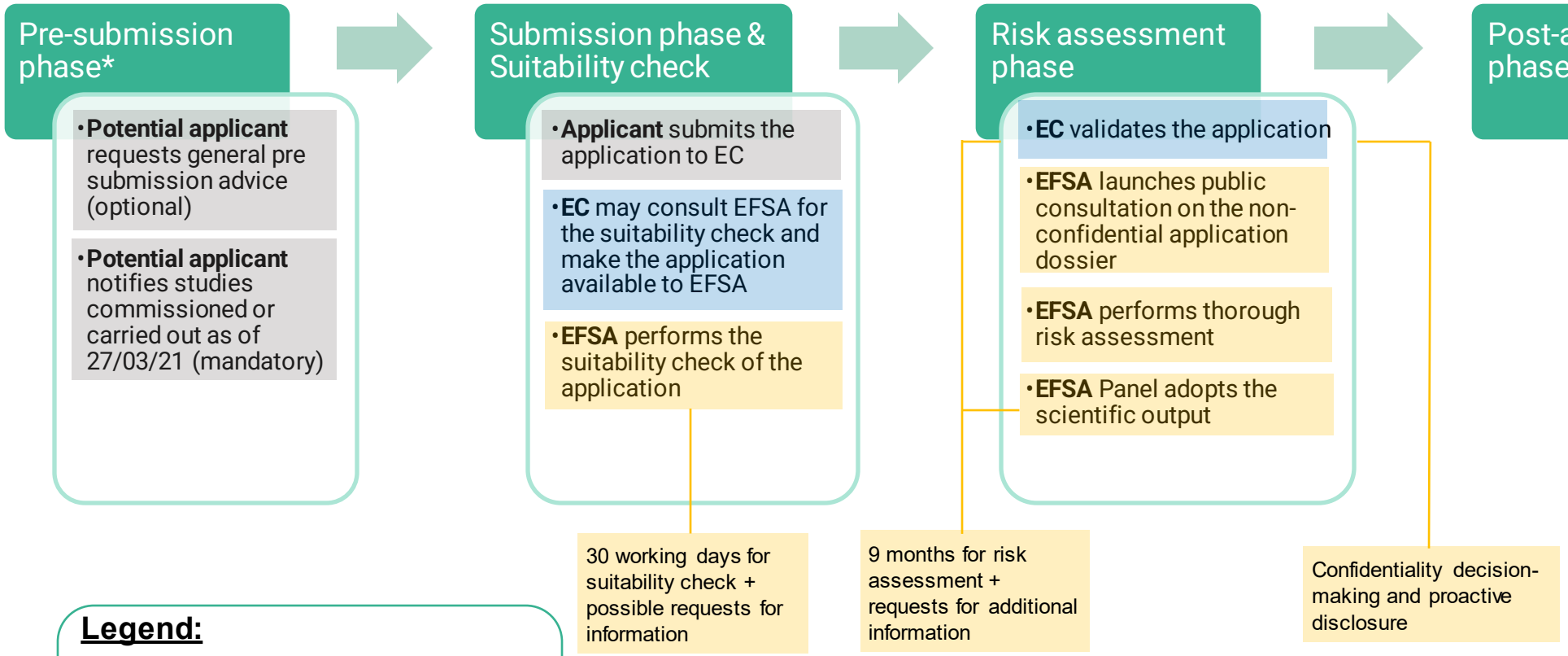

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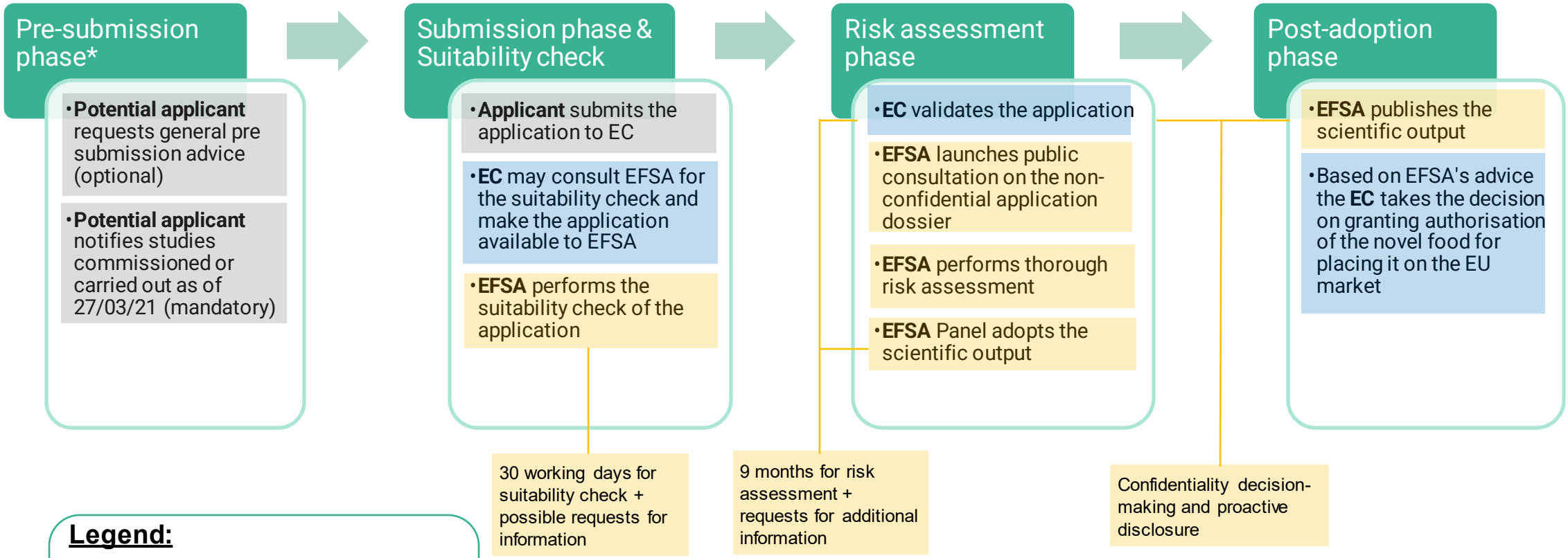

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Pre-submission activities

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

- 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
- Important to get familiar with the user guides on how to perform pre-submission activities: user guide on pre-application ID and user guide on notification of studies

PRE-SUBMISSION ACTIVITIES

Connect

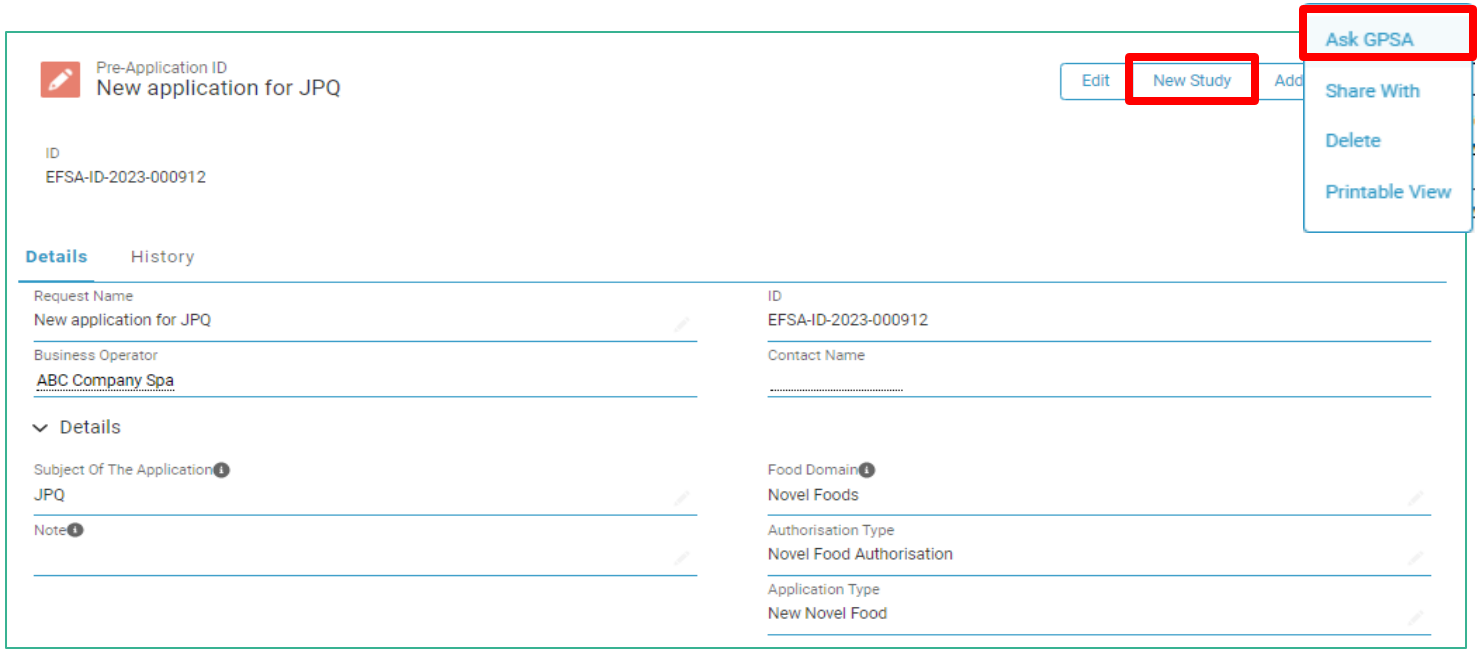
Bringing together EFSA and its stakeholders

Need to ask us about pre-submission advice, public consultations, public access to documents, notification of studies or other similar issues? The Connect platform is where you will find the answers.

Prior to initiating any pre-submission activity, **applicants must request a pre-application ID.**

Pre-submission activities can be performed from the pre-application ID:

- **Notification of studies**
- **Request for general pre-submission advice (GPSA)**



NOTIFICATION OF STUDIES (NOS)

Article 32b of the General Food Law

- Potential applicants **must notify without delay the studies** carried out or commissioned to laboratories and other external testing facilities for regulatory purposes and for which, pursuant to Union law, EFSA may or shall be requested to provide a scientific output, including a scientific opinion

Obligations

- Studies must be notified **before their starting date.** Delayed notification or non-notification must be justified
- **All notified studies** must be **included in the application.** Non-inclusion of notified studies must be justified
- **A justification is needed for studies** that have been notified and then **withdrawn** from the database

Compliance with NoS obligations

- **No response** is foreseen from EFSA after the submission of a study notification. **Compliance is verified** during suitability check
- In case of **non-compliance** with NoS obligations, the application is declared **non-valid**
- If the non-valid application is resubmitted, the suitability check will start after 6 months from the resubmission

NOTIFICATION OF STUDIES (NOS)

Update of the Q&A on EFSA Practical Arrangements

- After two years' experience of the notification obligation of Article 32b of the General Food Law*, it is understood that **some analytical measurements should be exempted** from the NoS obligations (Question 4, Part B of updated Q&A)

Studies exempted with the updated Q&A

- Analysis to assess the **identity/composition of a product**, including the determination of its impurities and whole genome sequencing
- Analysis to determine **physico-chemical properties**
- **Method validation** studies

Applicability

- **Ongoing applications**
- **Future applications**

* Regulation (EC) No 178/2002

SUPPORT TO APPLICANTS – GENERAL PRE-SUBMISSION ADVICE

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 and in this video tutorial

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

SUPPORT TO APPLICANTS – INITIATIVES FOR SMES

Already in place - **Ask a Question fast processing:**

- responses within 7 working days instead of 15

Under development / pilot - **General pre-submission advice:**

- **fast processing**: 15 working days instead of 30

- responses in **tele-meeting** instead of in writing

Most common issues in suitability check

MOST COMMON ISSUES IDENTIFIED IN SUITABILITY CHECK

- Missing or incomplete information
- Notification of studies (NOS)
- Metadata of files in support of an application
- Confidentiality and Sanitization
- Replying to Request For Information (RFI)
- Administrative issues

MISSING OR INCOMPLETE INFORMATION

Production process

- Description of steps are not detailed enough
- When different productions process are used not all of them are completely described
- Quality control and safety assurance are not properly described

Compositional data

- Number of batches analysed is not enough (according to the EFSA GD should be preferably at least 5 batches)
- Information on batches in main text does not match with the certificates of analysis included or certificates are not provided
- Description and validation of “in house” methods are often not provided

MISSING OR INCOMPLETE INFORMATION

History of use of the novel food

- Literature review not provided
- Search strategy of literature review not provided

Proposed uses and use levels

- Information does not match with what is included in Cover letter and/or in section “Proposed entry in the Union list”

Quality and certifications

- Laboratory accreditation or justifications are missing
- GLP certifications are not properly signed or not included

NOTIFICATION OF STUDIES (NOS)

General information on NoS and tools

- **Notification** should be done **before the starting date of the study**
- **Studies** commissioned/performed **before 27 March 2021 do not require a notification,** still they **can be used** in support of an application **with simple justification** referring to the commission date
- **Notification** can be done **even if the laboratory is not registered** in Connect.EFSA

One study – One notification

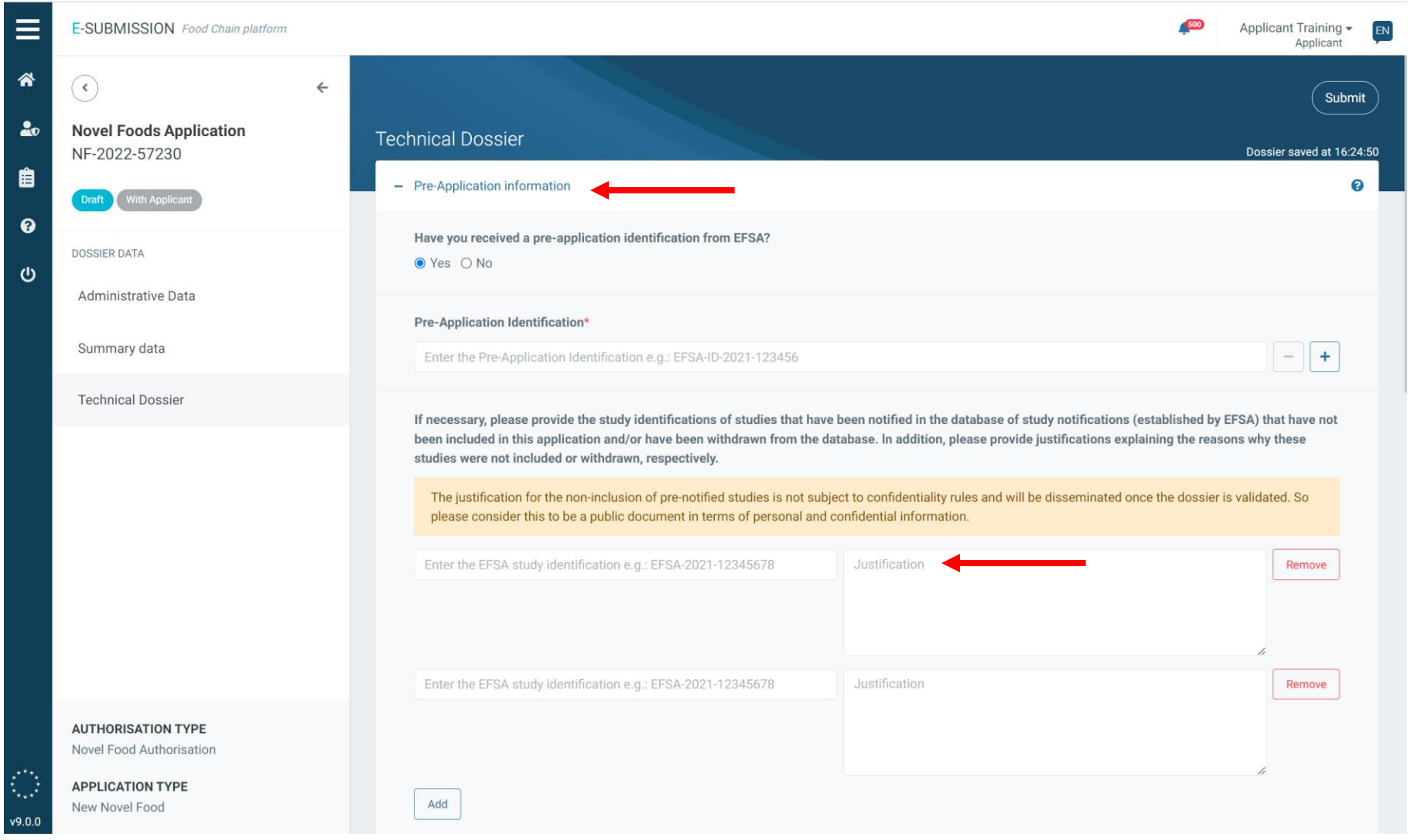
- **Timepoints** part of a study **do not need a separate notification** (*E.g.* In Stability studies no need to notify each timepoint separately)

Justifications

- **Justifications** for non-notification, non-inclusion, withdrawal, delayed notification of studies or any deviation should be provided **as detailed as possible**
- Provide **all the supporting evidences for any justification** as part of the submission of the application (*E.g.* proof that EU was not the original market by providing evidence of the submission of the specific study to another regulatory agency)

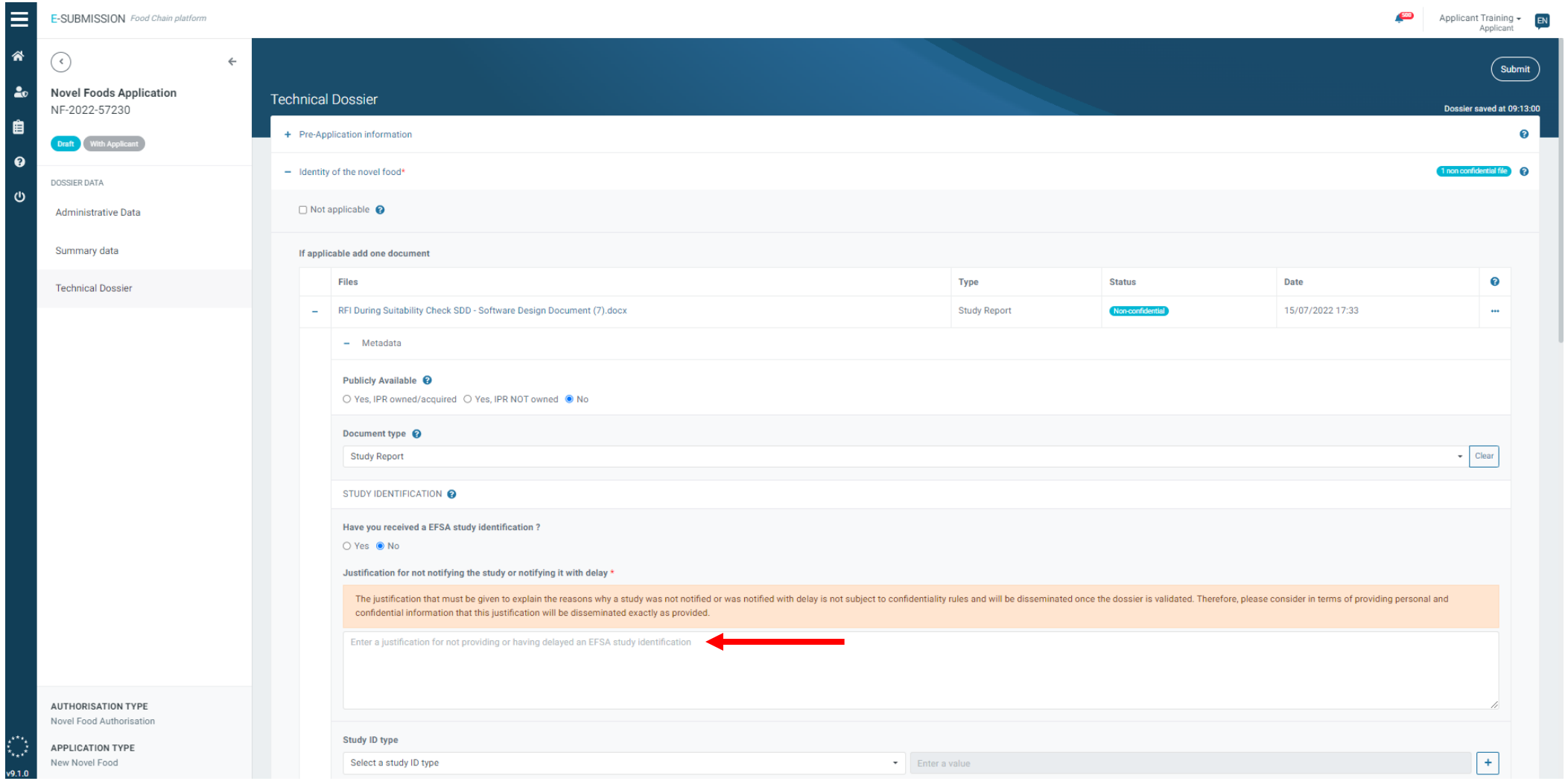
NOTIFICATION OF STUDIES (NOS)

- **Justifications for <u>non-inclusion of studies</u> notified or justifications for study withdrawn**



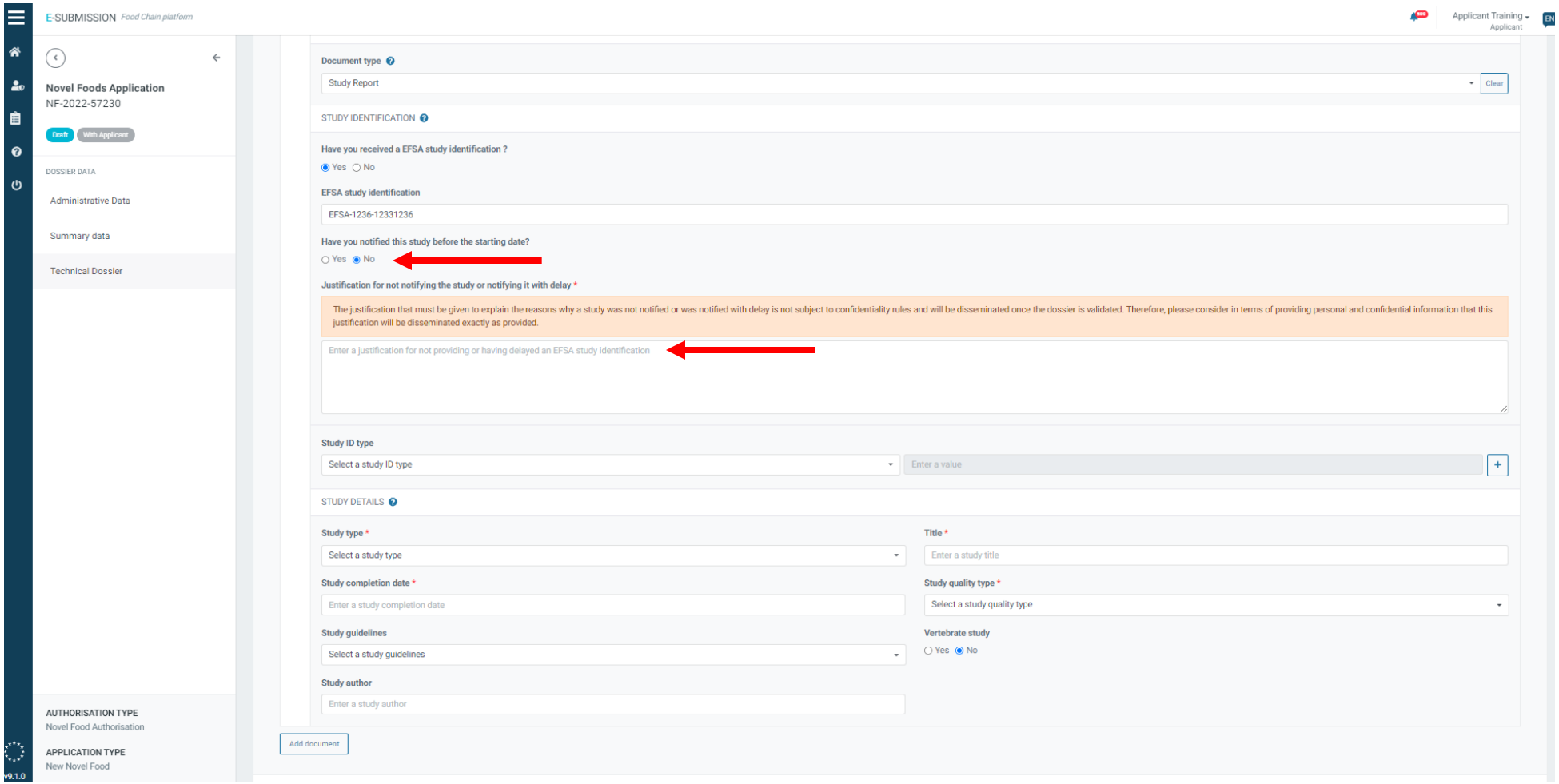
NOTIFICATION OF STUDIES (NOS)

- **Justifications for <u>non-notification of studies</u> submitted in the dossier**



NOTIFICATION OF STUDIES (NOS)

- **Justifications for <u>delay notification of studies</u> submitted in the dossier**



EXAMPLES OF JUSTIFICATIONS NOT ACCEPTED

- Studies are not notified/notified with delay due to lack of knowledge of applicable NoS obligation requirements (Article 32b(2) of the General Food Law)
- Studies are not notified/notified with delay because they were performed after EC/EFSA request for information
- Self-declaration for non-notification/notified with delay of a study as EU was initially not considered as a potential market (additional supporting evidence should be provided)
- Studies not notified/notified with delay as initially performed for research purposes only when conducted according to OECD test guidelines and/or GLP

NOTIFICATION OF STUDIES (NOS)

Resubmission of an application after non-validity due to NoS

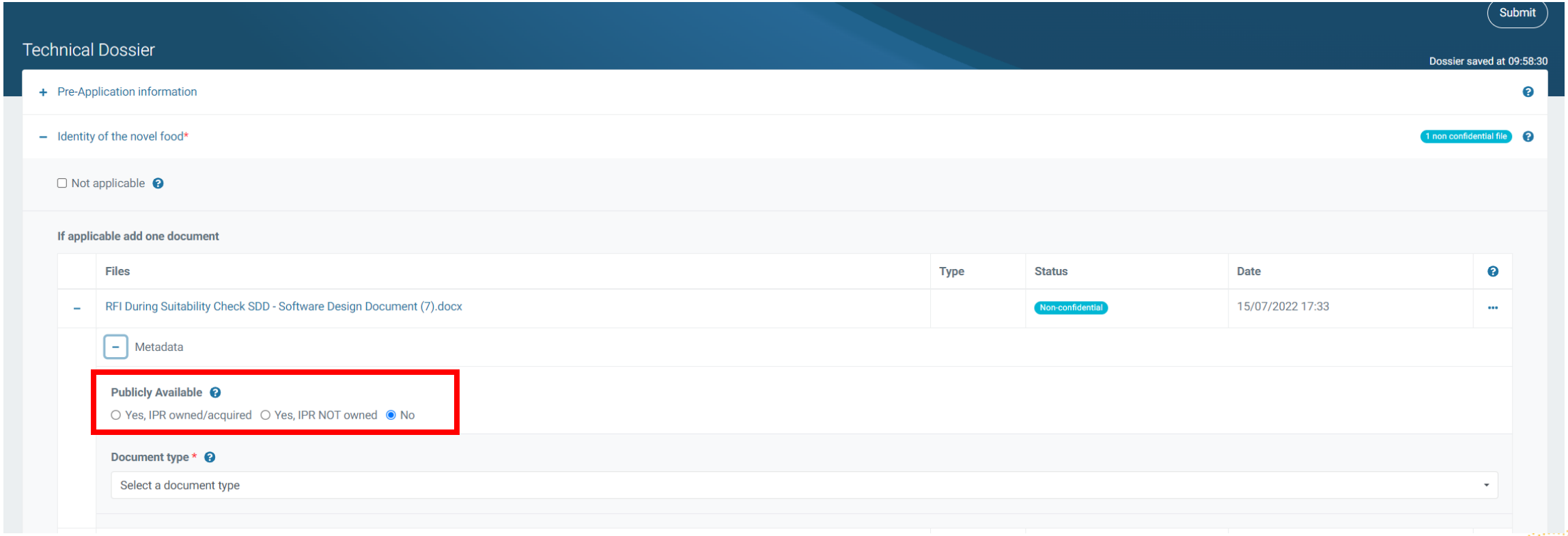
- Resubmit a new application in ESFC as soon as all issues have been solved providing the dossier/question number of the previous application declared non-valid
- **6 months penalty starts from the moment of the resubmission of the application and not the declaration of non-validity**

FILES METADATA

- Publicly available
- Document type
- Study identification

FILES METADATA: PUBLICLY AVAILABLE

Publicly available



FILES METADATA: PUBLICLY AVAILABLE

Publicly available

- **YES** (for all published documents as e.g. publicly available reports, bibliographic references)
  - Yes, IPR owned/acquired – applicant has the rights to disseminate the content
    - ➢ Include a full text copy that will be made available in Open EFSA after validation
  - Yes, IPR NOT owned – applicant does not have the rights to disseminate the content
    - ➢ Include a full text copy that will be used for assessment purposes only
    - ➢ Include the bibliographic citation in the free-text box that will be made available in Open EFSA after validation
- **NO** (when documents are not published)

IPR - Intellectual Property Rights

FILES METADATA: DOCUMENT TYPE

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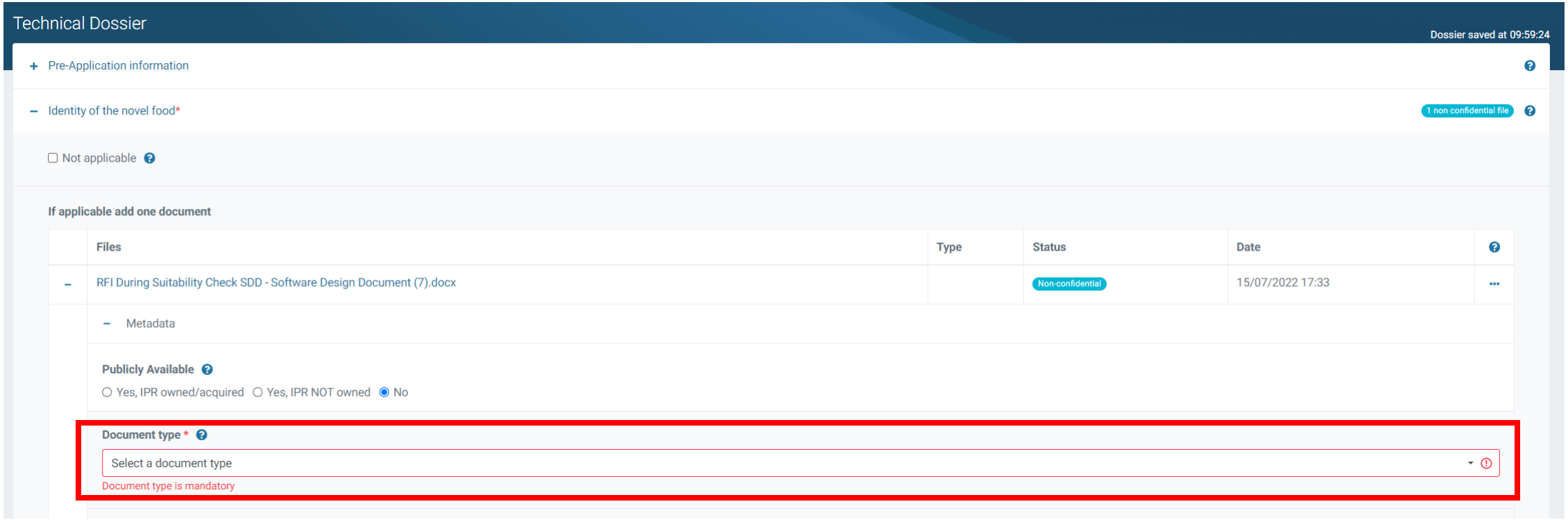


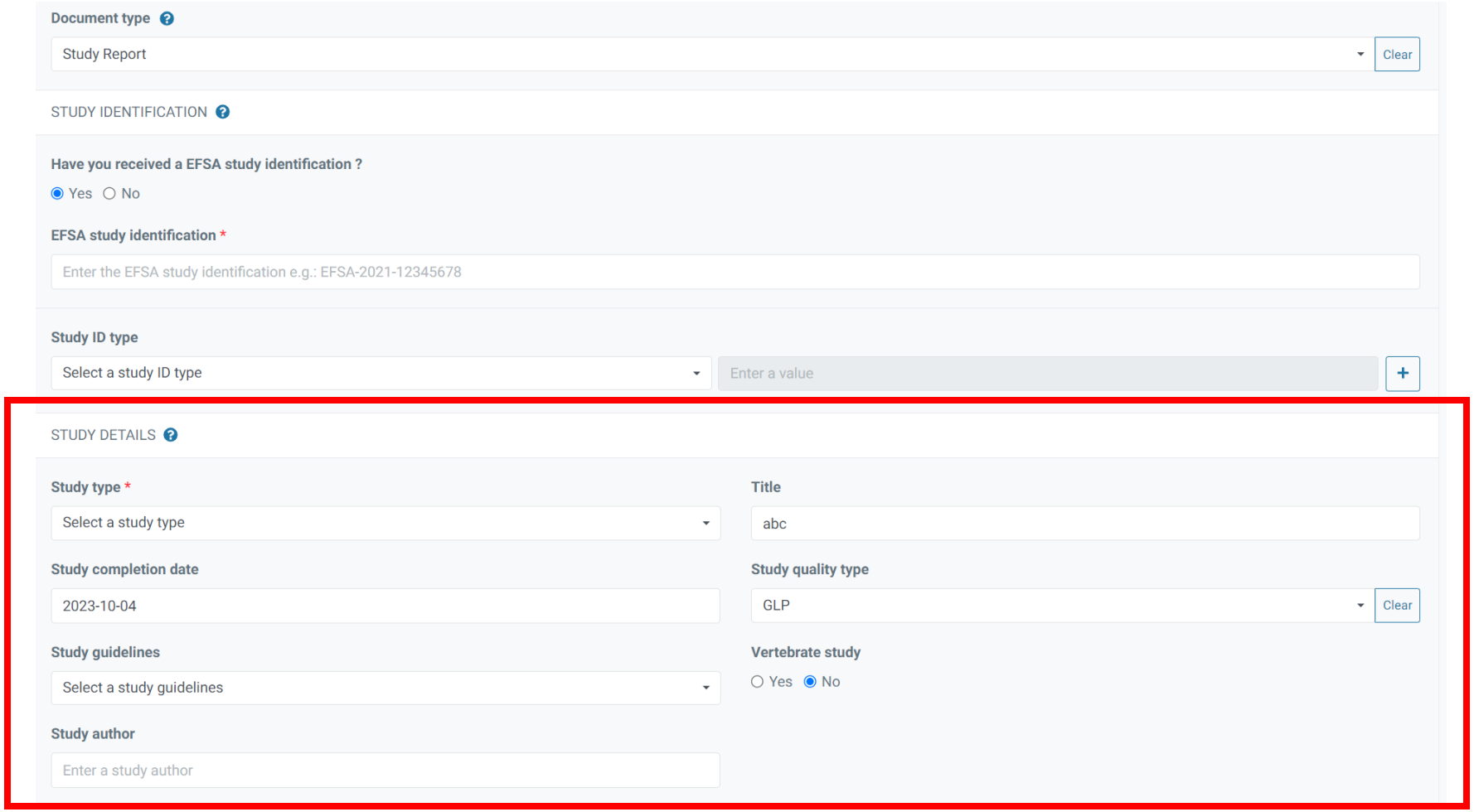
FILES METADATA: DOCUMENT TYPE

Document type

1.Technical dossier
2.Study report
3.Publication
4.Certificate of analysis
5.Laboratory accreditation certificate
6.Scientific summary
7.Raw data
8.Literature search
9.Code for statistical analysis
10.Data sharing agreement/Access letter
11.Copyright licenses
12.Flow charts
13.Graphs/Images
14.Cover letter
15.List of annexes
16.List of references
17.Check list
18.Other supporting documents

FILES METADATA: STUDY IDENTIFICATION

Study identification



CONFIDENTIALITY AND SANITIZATION

General information for submission of confidential information

Sanitization of confidential information and personal data

CONFIDENTIALITY AND SANITIZATION

General information for submission of confidential information

- Identify parts on which confidentiality is requested in a **clear and consistent manner**
- **Confidential** version and **public** version must **always be submitted and should match**
- Ensure **information claimed confidential in one part is not visible in another part** of the document
- **Do not include watermark 'confidential'** on **parts** of documents that you do **not claim confidential**
- **Properly name documents** to distinguish between confidential and non-confidential version
- **Refer to correct legal basis.** If qualification is not self-evident**, justify why the element falls under that legal basis**
- **No unfounded** confidentiality requests or requests **on publicly available information**

CONFIDENTIALITY AND SANITISATION

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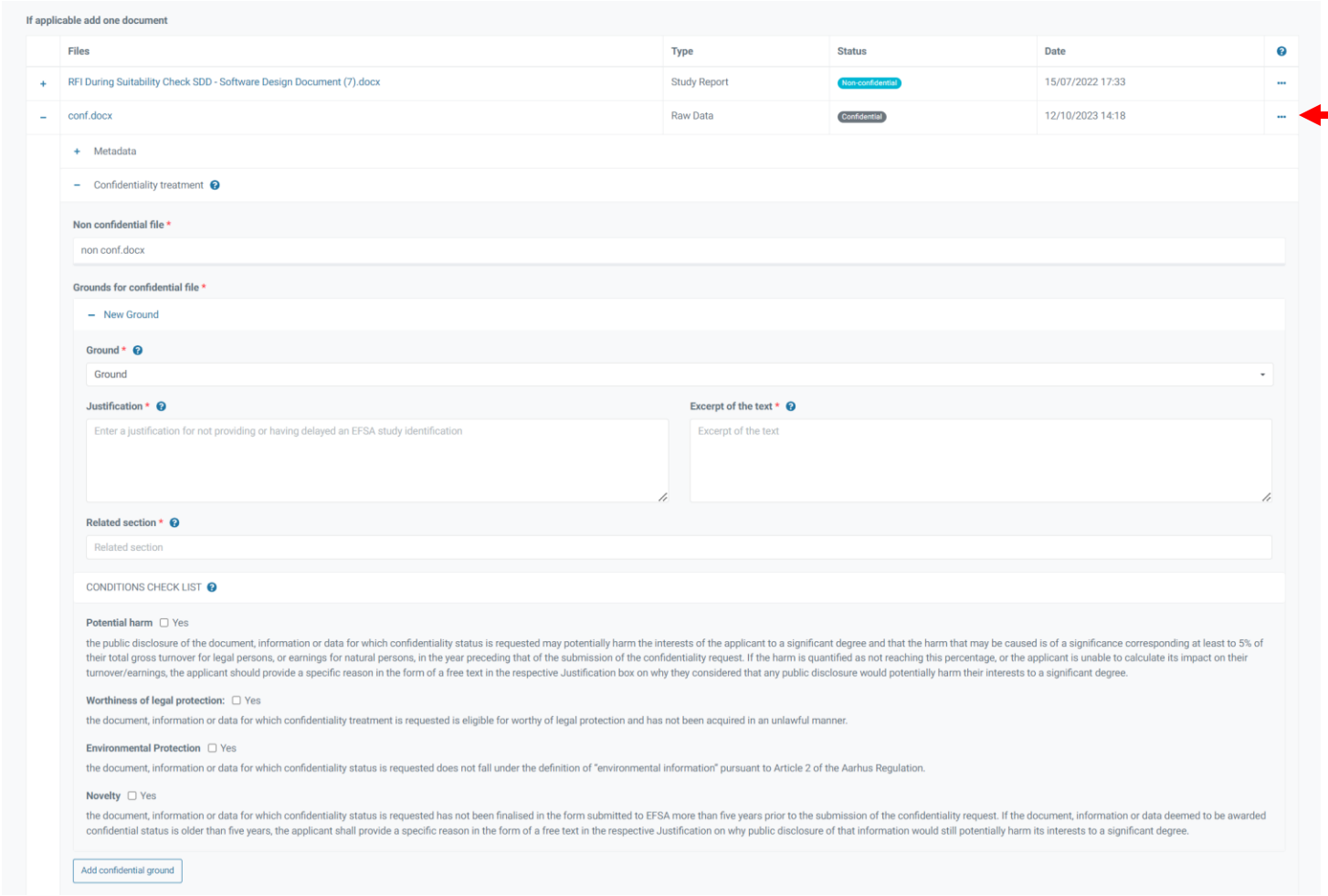


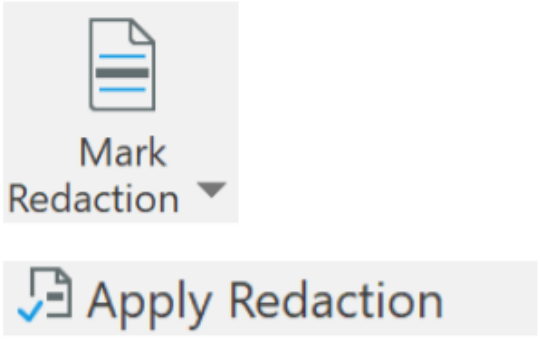
EFSA user guide on confidentiality

CONFIDENTIALITY AND SANITIZATION

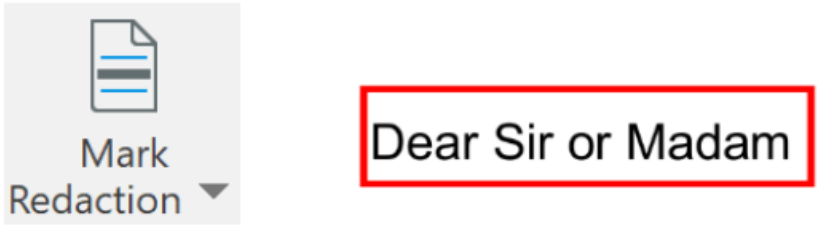
Sanitization of confidential information and personal data

- Use permanent sanitization in non-confidential version of documents for masking confidential information and for personal data
- Earmarking/boxing of confidential information in confidential version of documents

- Non – confidential version



- Confidential version



CONFIDENTIALITY AND SANITIZATION

Sanitization of confidential information and personal data

- Use permanent sanitization in non-confidential version of documents for masking confidential information and for personal data
- Earmarking/boxing of confidential information in confidential version of documents

- **Permanent sanitization does not mean highlighting in different colours, nor masking with a black/white box**
- **Personal data includes names and addresses of natural persons involved in toxicological studies and any other personal data including names, addresses, and/or signatures of natural persons, contained in the different documents (e.g. certificates, studies)**

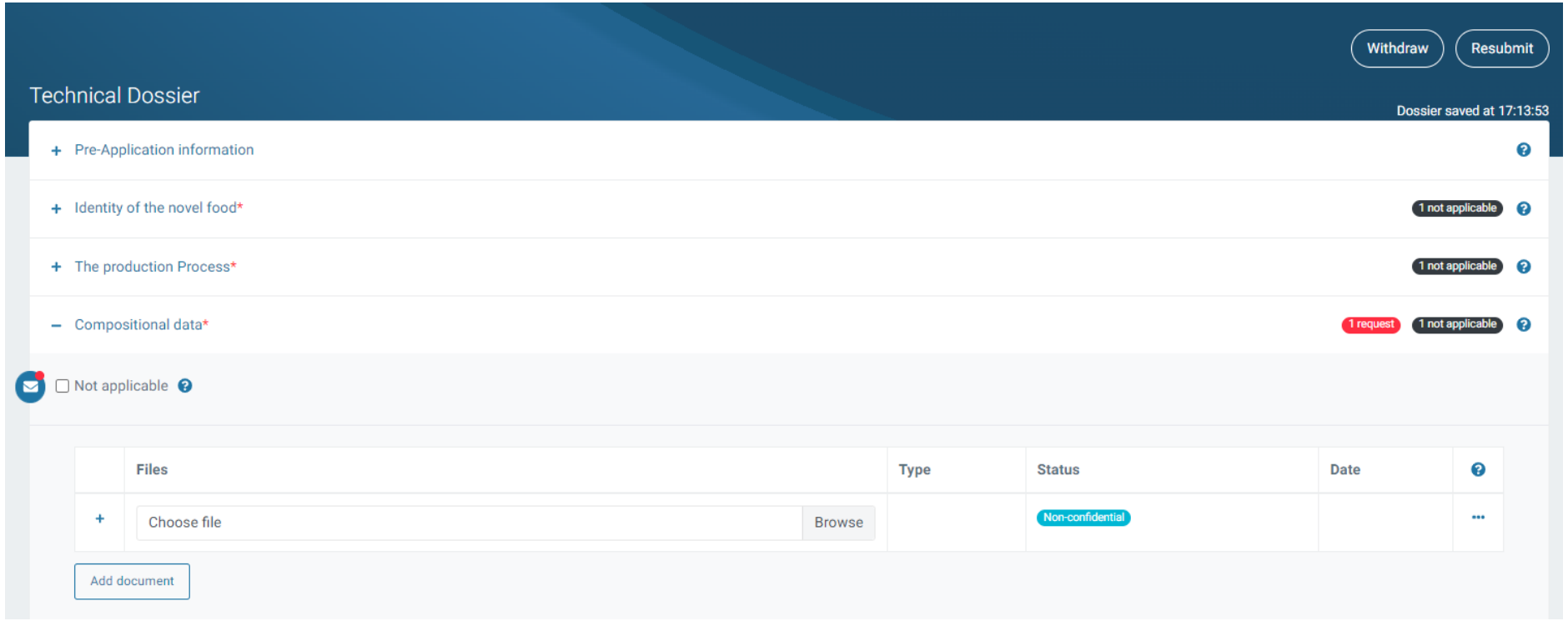
REPLYING TO REQUEST FOR INFORMATION (RFI)

- Where to include the information requested by EFSA
- How to request to have a section unlocked in ESFC
- How to request an extension of deadline

REPLYING TO REQUEST FOR INFORMATION (RFI)

Where to include the information requested by EFSA

- An updated document should be submitted including the requested information
- Do not use the text box to provide replies to the request for information as it will not allow the publication as part of the dossier as required by the Transparency Regulation and will not be considered for the risk assessment



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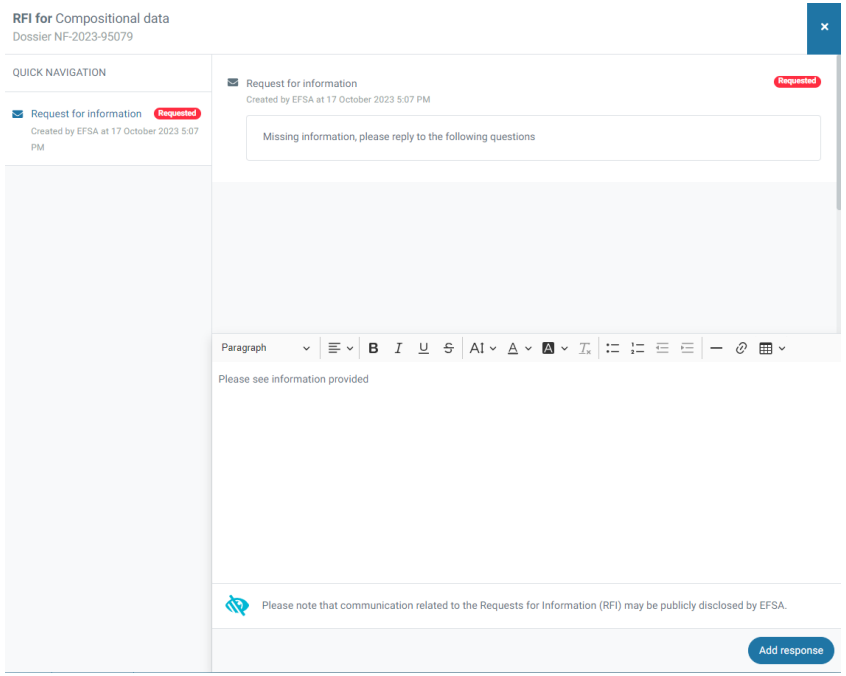

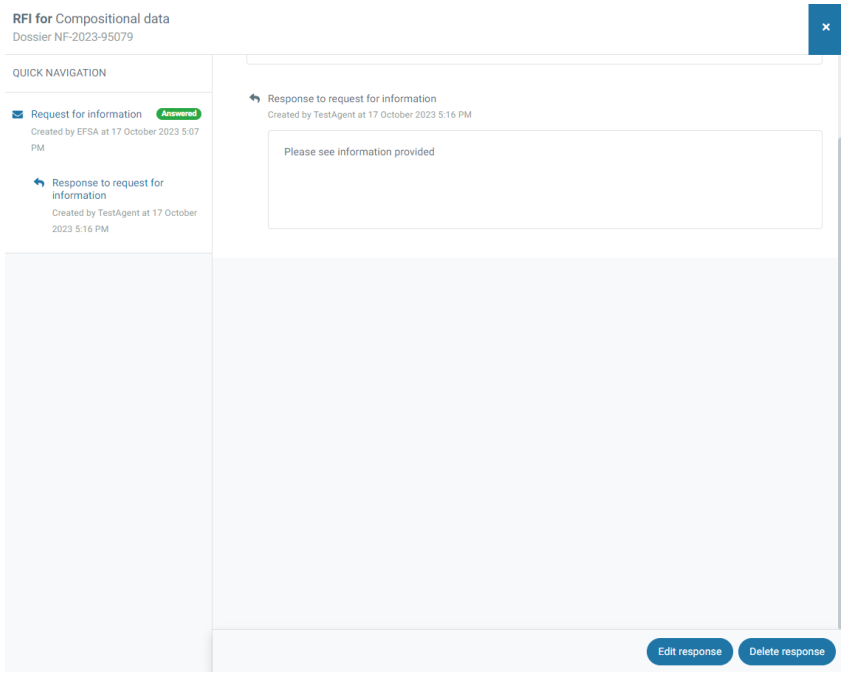

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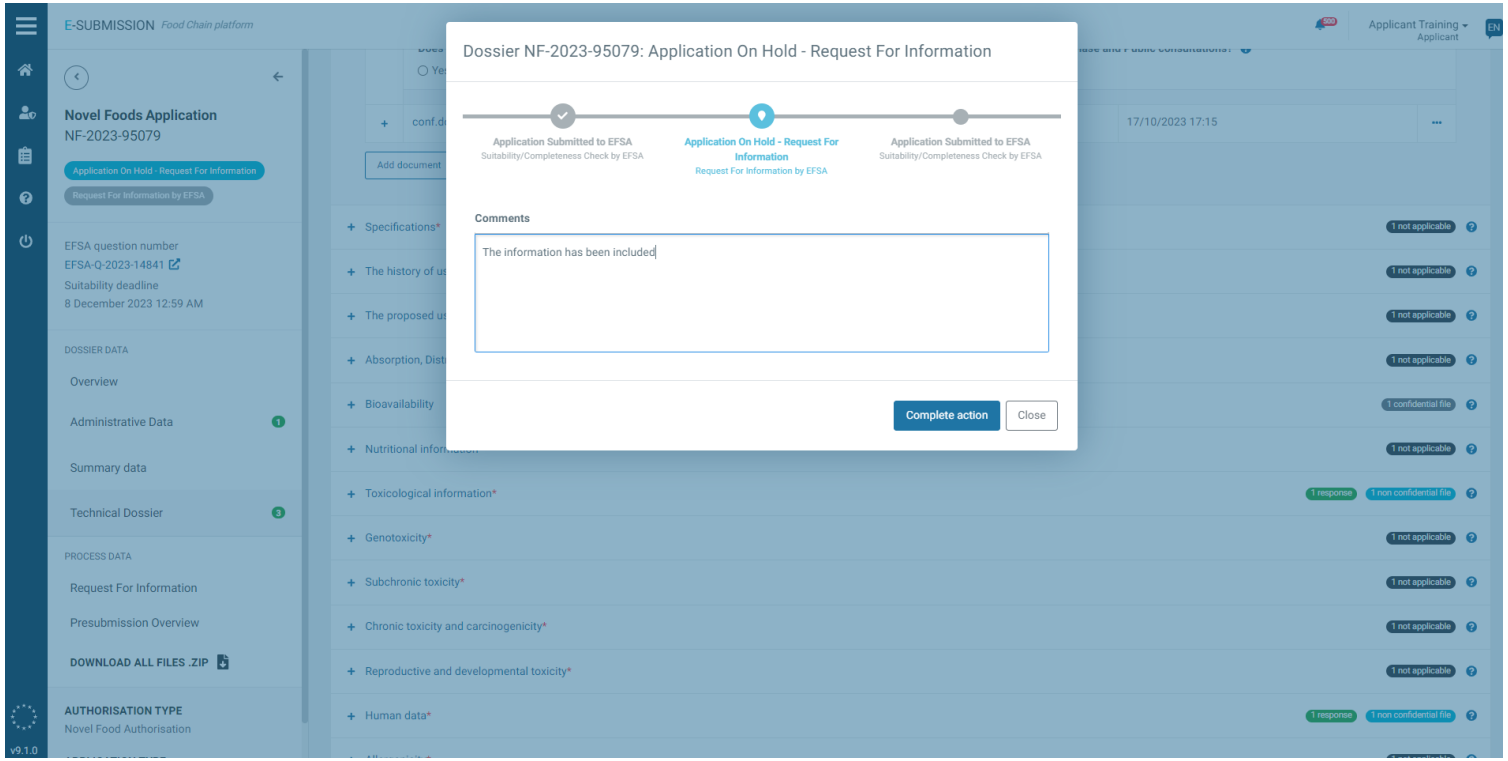


REPLYING TO REQUEST FOR INFORMATION (RFI)

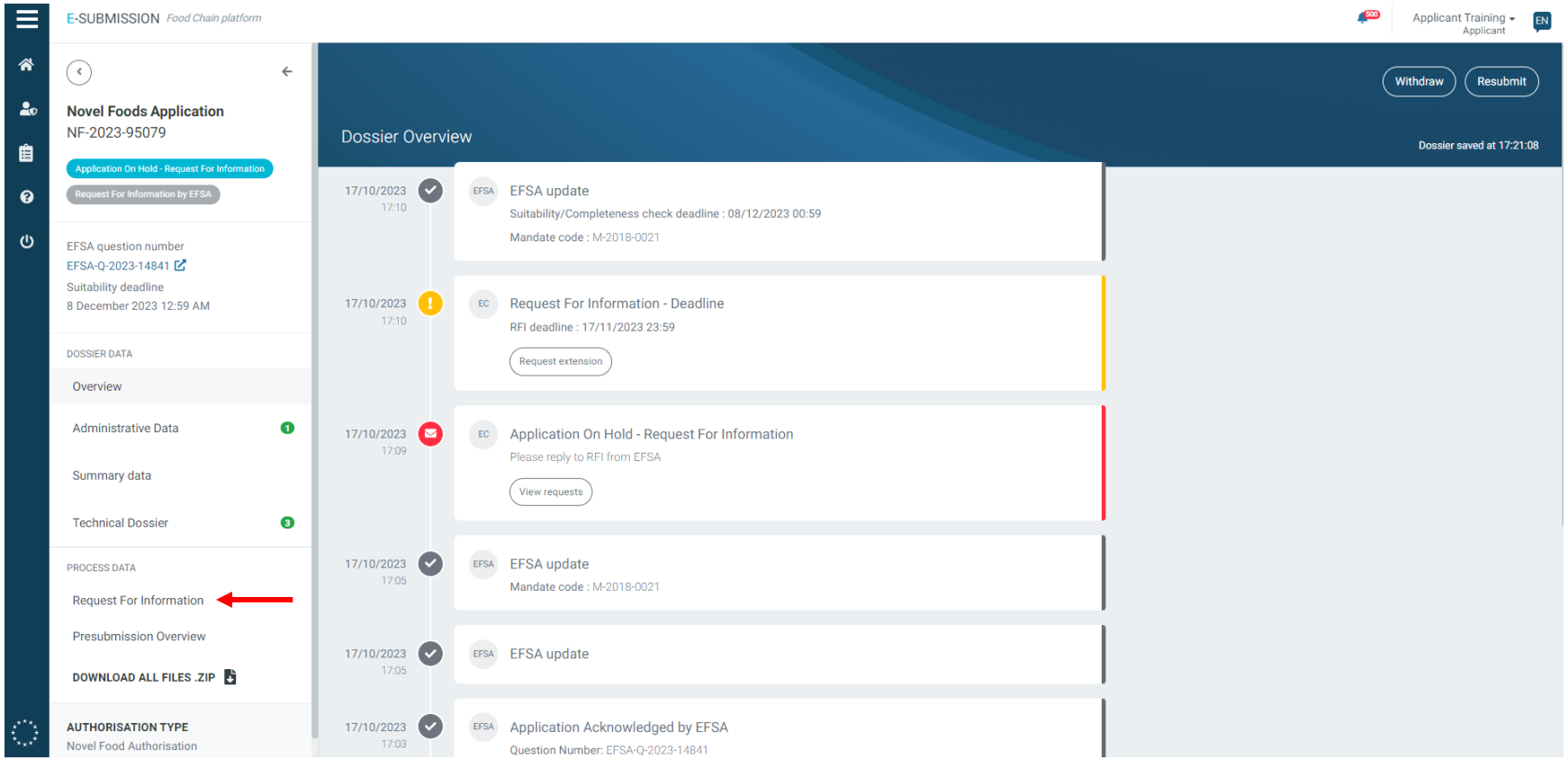
How to request to have a section unlocked in ESFC

- If **the application** is **with the applicant** after a request for information
  - Reply to the request for information and include the sections to be opened
  - A new request for information will follow opening the relevant sections
- If **the application** is **with EFSA** after received replies of Request for information
  - **Contact EFSA** staff by email at FDP@efsa.europa.eu indicating the sections to be unlocked
  - A new request for information will follow opening the relevant sections
- **Do not contact**: SANTE-E-SUBMISSION-FOOD-CHAIN@ec.europa.eu

REPLYING TO REQUEST FOR INFORMATION (RFI)

How to request an extension of deadline

- Use ESFC tool to request an extension of use to provide requested information



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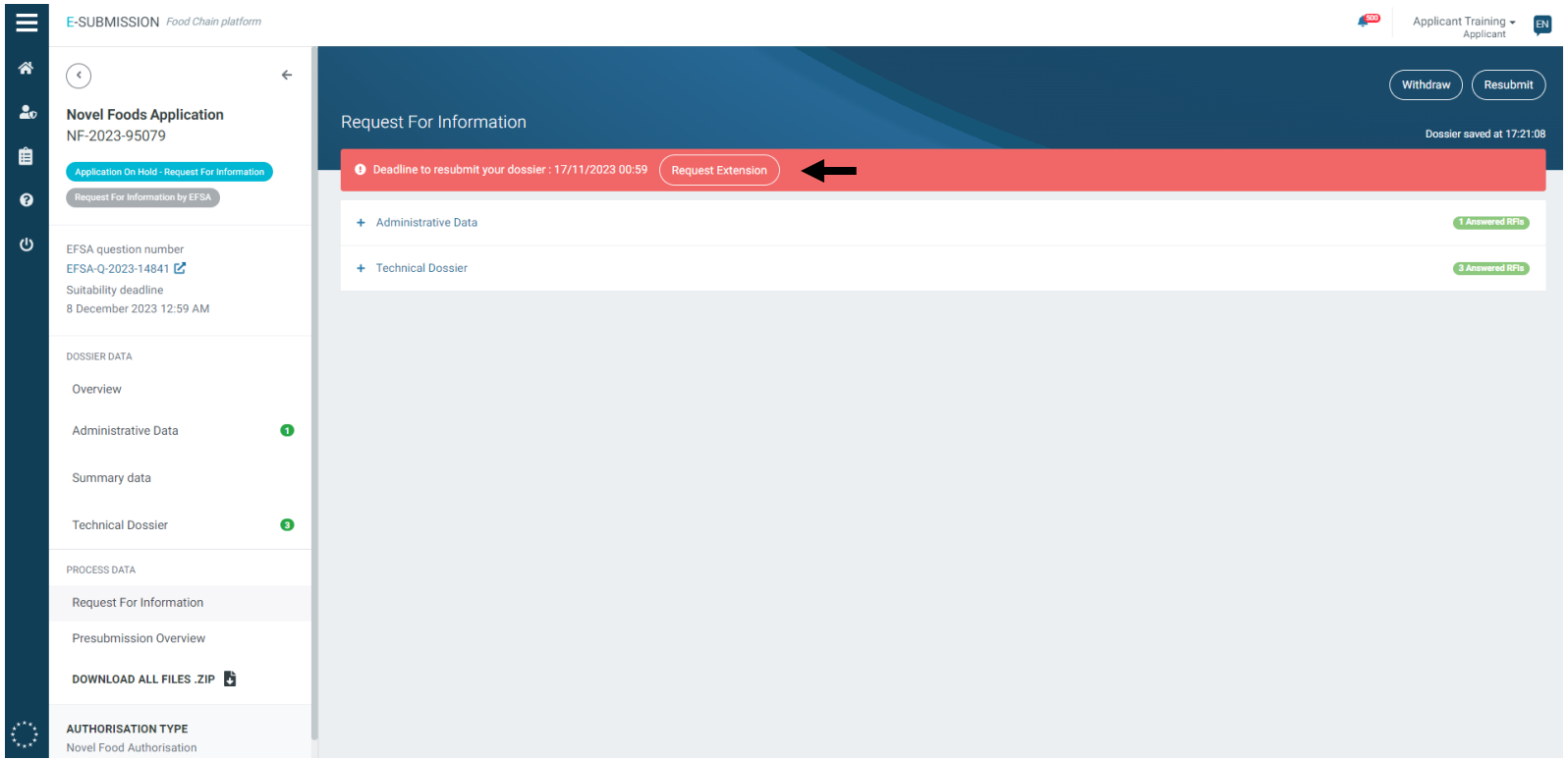

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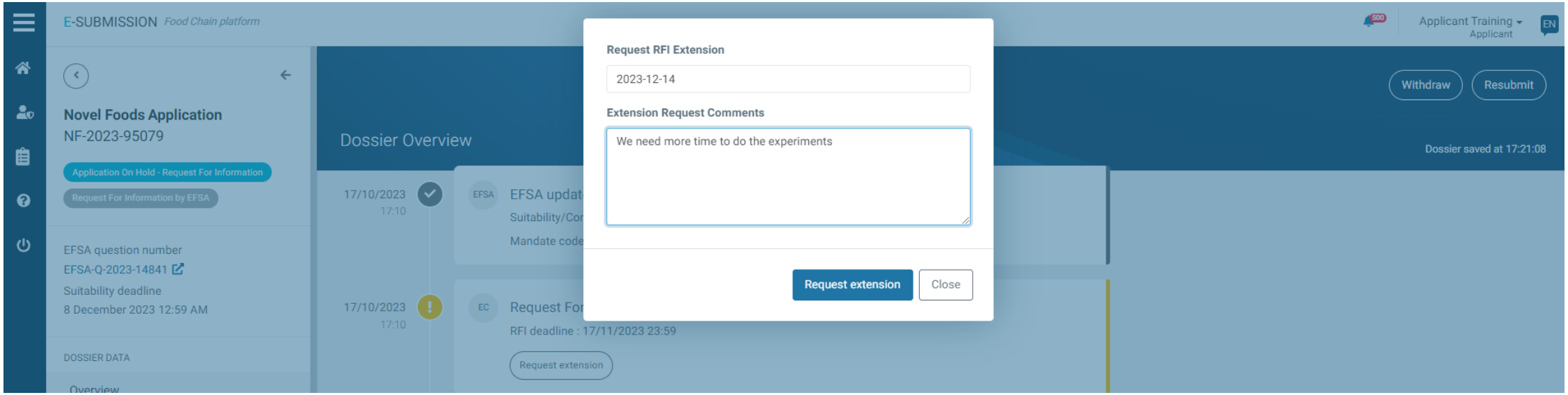

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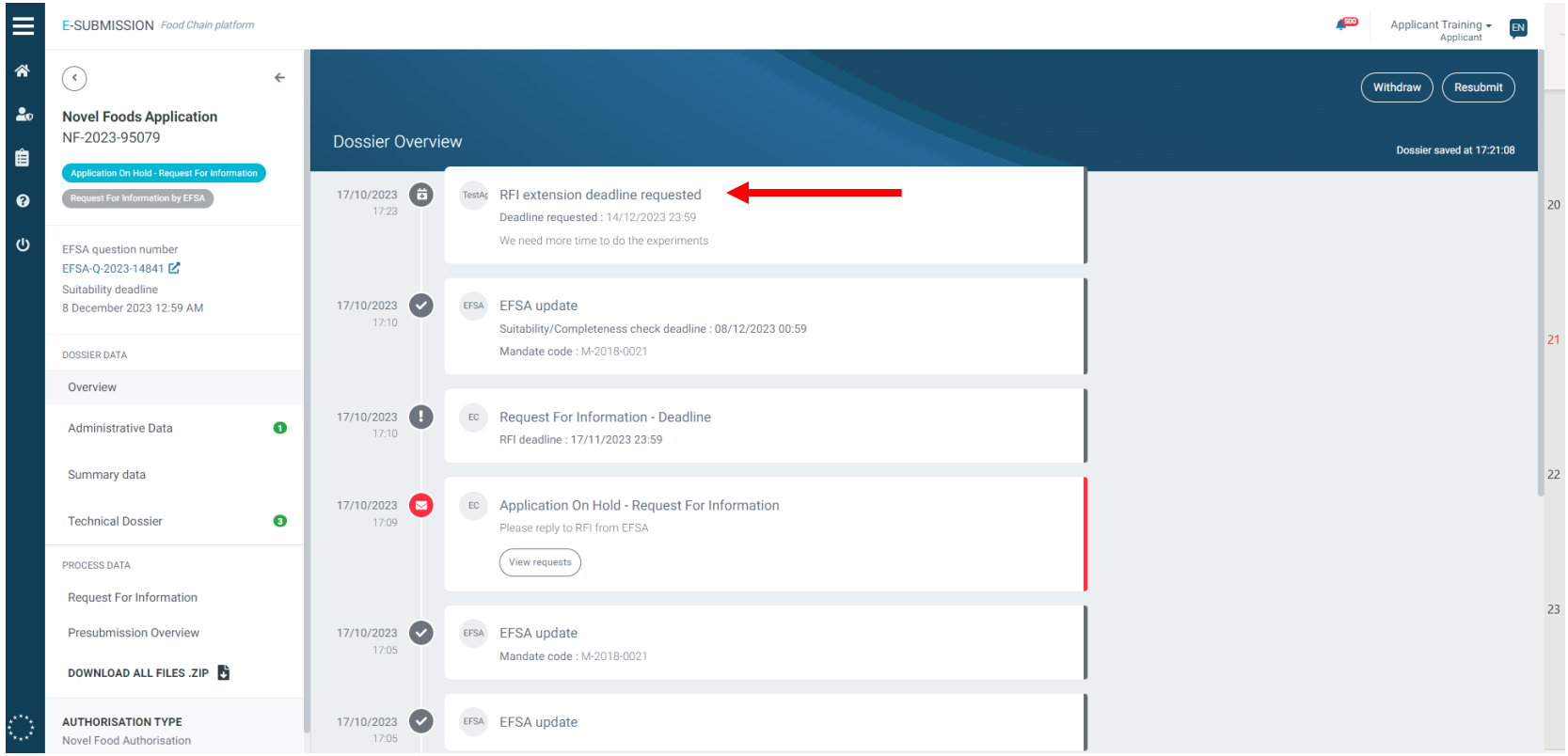
How to request an extension of deadline

- Use ESFC tool to request an extension of use to provide requested information



ADMINISTRATIVE ISSUES

- Lack of signature, starting date in study reports
- Documents submitted in languages different from English
- Annexes with wrong document type
- Documents electronically non-searchable

Q&A Session

Q&A

- How is the review process organized? Can we expect multiple rounds of questions or will all questions be addressed in a single round (unless questions arise of course from the answers provided)?

Q&A

- Notified studies that are now exempt from notification, can/should be withdrawn from Connect.EFSA? under the new interpretation, which studies should be notified?

Q&A

- Will a detailed database be available where all the novel food applications and dossier are collected and freely consultable?

OpenEFSA PORTAL

Other sites: EFSA | OpenEFSA | EFSA Journal | Connect

efsa OPEN

QUESTIONS | PUBLIC CONSULTATIONS | EXPERTS

https://open.efsa.europa.eu/

Questions

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

8215 results found Export (8215) questions to CSV

Sorting: Relevance

Food domain

Search food domains

- Administrative and Technical Support (13)
- Animal Health (162)
- Animal Welfare (37)
- Assessment and Methodological Support (22)
- Biological Hazards (48)

Show All

Substances

Search substances

Status

- Application Not Valid (28)
- Application Terminated (20)
- Application Withdrawn (271)
- EFSA Peer Review (74)
- Intake (2224)
- On Hold (1)
- Ongoing Risk Assessment (1259)
- Published (4228)
- Publishing (110)

Transparency Regulation (TR)

- Pre-TR (6810)
- Post-TR (1403)

Feed Additives EFSA-Q-2022-00324 — LACTIPLANTIBACILLUS PLANTARUM NCIMB 30094

Application for Lactiplantibacillus plantarum NCIMB 30094 1k20723 for all animal species [Art.4]

Last updated on: 24/10/2023
Status: Ongoing Risk Assessment

Clockstop expected until 20/10/2023

Pesticides Peer Review (AIR) EFSA-Q-2017-00453

Request for an EFSA peer review (EFSA Conclusion) on the active substance quizalofop-P-tefuryl according to Article 13 of Regulation (EU) No 844/2012 (AIR IV).

Last updated on: 24/10/2023
Status: Intake

Feed Additives EFSA-Q-2019-00301 — KIESELGUR (DIATOMACEOUS EARTH) 1+

Sepiolite and diatomaceous earth for all terrestrial species [Article 4]

Last updated on: 24/10/2023
Status: Ongoing Risk Assessment

Feed Additives EFSA-Q-2023-00440 — LANTHANUM CARBONATE OCTAHYDRATE

Application for Lanthan One (lanthanum carbonate octahydrate) for dogs [Art.4,13]

Last updated on: 24/10/2023
Status: Ongoing Risk Assessment

TIMELINE & SUPPORTING DOCUMENTS

NF-2021-1911 Share Print Open in new tab

NOVEL FOODS

Novel Food Authorisation

EFSA-Q-2022-00007 | Status: Ongoing Risk Assessment

Subject

Application for authorisation of Nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis as a novel food

Substances

Name	CAS
Nicotinamide riboside chloride	23111-00-4

Timeline: EFSA-Q-2022-00007

09-07-2024
Risk Assessment Deadline

2024

From 04-09-2023 to 25-09-2023
Application on Nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis
Public Consultation Finished
See details

As of 27-01-2023
Clock Stop

2023

19-09-2022
Dossier Valid

06-01-2022
Dossier Received

2022

Supporting documents

All files

Document Type	Download file
Mandate	PDF (69.2KB)
Acceptance letter	PDF (24.7KB)
EC Request	PDF (211.6KB)
Notification of Studies	PDF (103.3KB)
Additional Data Request	PDF (149.0KB)

PUBLIC VERSION OF NOVEL FOOD DOSSIERS

Dossier number: NF-2021-1911

← Go to question GHSTS ZIP Share

- Administrative Data
- Summary data
- Technical Dossier
  - Pre-Application information
  - Identity of the novel food
  - The production Process
    - ⓘ Not applicable
    - Technical dossier text - EH_NR Chloride_Production Process_Non-Conf.pdf
  - Compositional data
  - Specifications
  - The history of use of novel food and/or its source
  - The proposed use(s) and use levels and anticipated intake
  - Absorption, Distribution, Metabolism and Excretion (ADME)
  - Nutritional information
  - Toxicological information
  - Genotoxicity
  - Subchronic toxicity
  - Chronic toxicity and carcinogenicity
  - Reproductive and developmental toxicity
  - Human data
  - Allergenicity
  - Concluding remarks
  - References
  - Annexes to the dossier
    - ⓘ Not applicable
    - ⓘ Study Report - ******
    - ⓘ Study Report - ******
    - Study Report - App_05_CoA Batch 25198VSP10020421_Non Conf.pdf
    - Study Report - App_11_Representative NMR Spectra_Non Conf.pdf
    - Study Report - App_04_CoA Batch 25198VSP10201220_Non Conf.pdf

General info

Regulated Domain

Novel Foods

No description available

Receivers

EC-NF

Application type

New Novel Food

Regulatory type

Senders

- Elysium Health Inc. (Applicant)
- ****** (Person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission)
- ****** (Producer)

Subject of the request

Nicotinamide riboside chloride (min. 95%) obtained by chemical synthesis.

Components

PUBLIC VERSION OF NOVEL FOOD DOSSIERS

Dossier number: NF-2021-1911

← Go to question | GHSTS | ZIP | Share

- Administrative Data
- Summary data
- Technical Dossier
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    - ⓘ Study Report - ******
    - ⓘ Study Report - ******
    - Study Report - App_05_CoA Batch 25198VSP10020421_Non Conf.pdf
    - Study Report - App_11_Representative NMR Spectra_Non Conf.pdf

Study Report - App_11_Representative NMR Spectra_Non Conf.pdf

Confidential

Type: Study Report | Not publicly available

Files

App_11_Representative NMR Spectra_Non Conf.pdf Public
Sanitized by Applicant — Download

Study identification

Title
Representative NMR Spectrum

Study type
Batch to batch analysis

Author
A. Sambasivarao

ID types
Laboratory study ID: E-SE0619/0049

Study guidelines
-

Completion date
06/25/2019 11:00:00

Quality type

Q&A

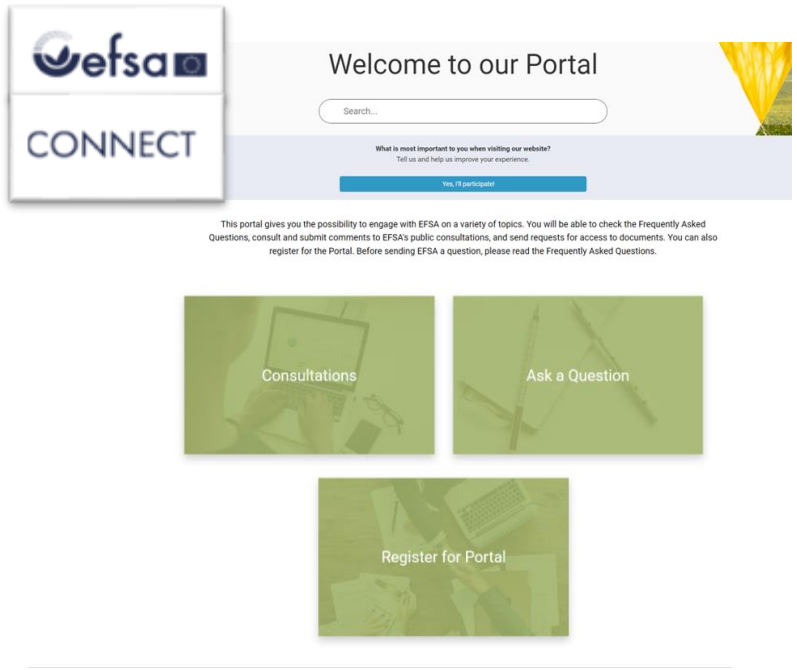
- Does the obligation to notify stability studies imply that such studies need to be performed by an external and certified lab?

Q&A

- What advice would you offer to applicants on how to prepare a thorough and robust submission?

HOW TO ADDRESS QUESTIONS DIRECTLY TO EFSA

Register in the Connect.EFSA platform



and then:

- **Request a General Pre-Submission Advice** by following the instructions in section 3.11 of the User guide on pre-application ID and this video tutorial

OR

- **Send a query to Ask a Question** via the Ask a Question service

THANK YOU FOR ATTENDING OUR EVENT

- In case we did not manage to answer all your questions, please feel free to re-submit them via EFSA Ask a question webform (EFSA.Connect at: https://connect.efsa.europa.eu/RM/s/askefsa)
- The recording of today's webinar will be available on the EFSA website in coming days.
- Please take few minutes to fill out the **satisfaction survey** that you will receive shortly in your inbox. Your feedback is essential to improve our future webinars
- We hope that this webinar will help you to better understand the procedure and requirements for novel food product applications.

JOIN OUR LINKEDIN GROUP

"EFSA support to applicants"

A space where you will find:

- Information and support materials
- Updates on the developments and progress of IT tools and platforms
- Alerts on new training material and upcoming events
- Clarifications to the most frequently asked questions received by applicants
- A space for interaction with your peers with more than 1000 members.

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

USEFUL LINKS

- **Novel food and traditional food applications**
  https://www.efsa.europa.eu/en/applications/novel-food-traditional-food
- **Applicants Toolkit**
  https://www.efsa.europa.eu/en/applications/toolkit
- **Services for applicants**
  https://www.efsa.europa.eu/en/applications/about/services
- **Webinar on novel food applications 2021**
  https://www.efsa.europa.eu/en/events/webinar-novel-food-applications
- **Last webinar on notification of studies**
  https://www.youtube.com/watch?v=NB2Ajn_2R74

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EUROPEAN FOOD SAFETY AUTHORITY