



WEBINAR ON NOVEL FOOD APPLICATIONS

26 OCTOBER 2023

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



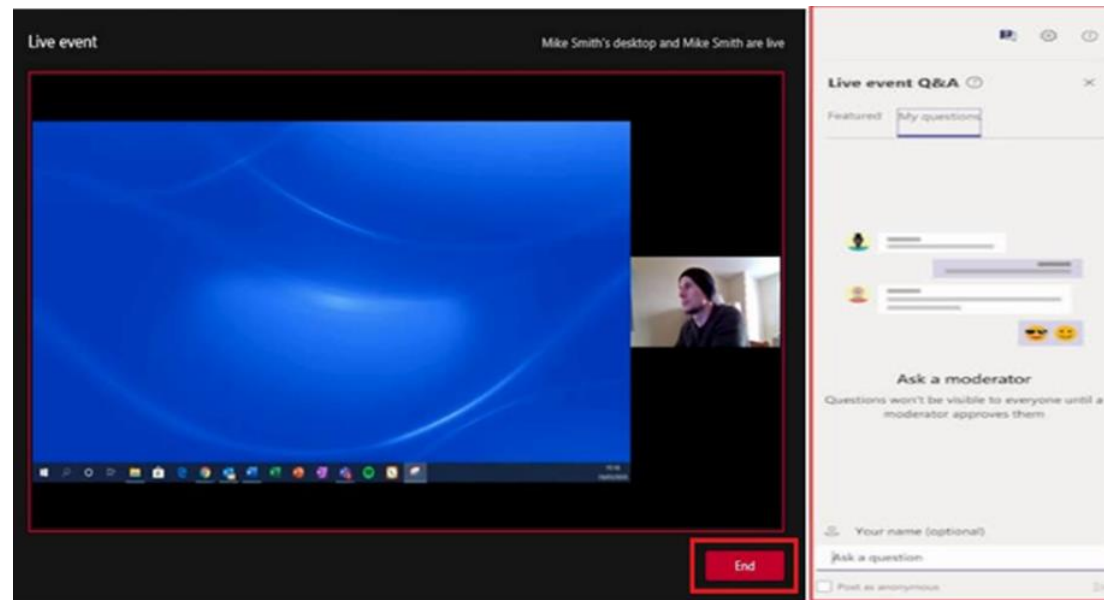
Speaker

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**

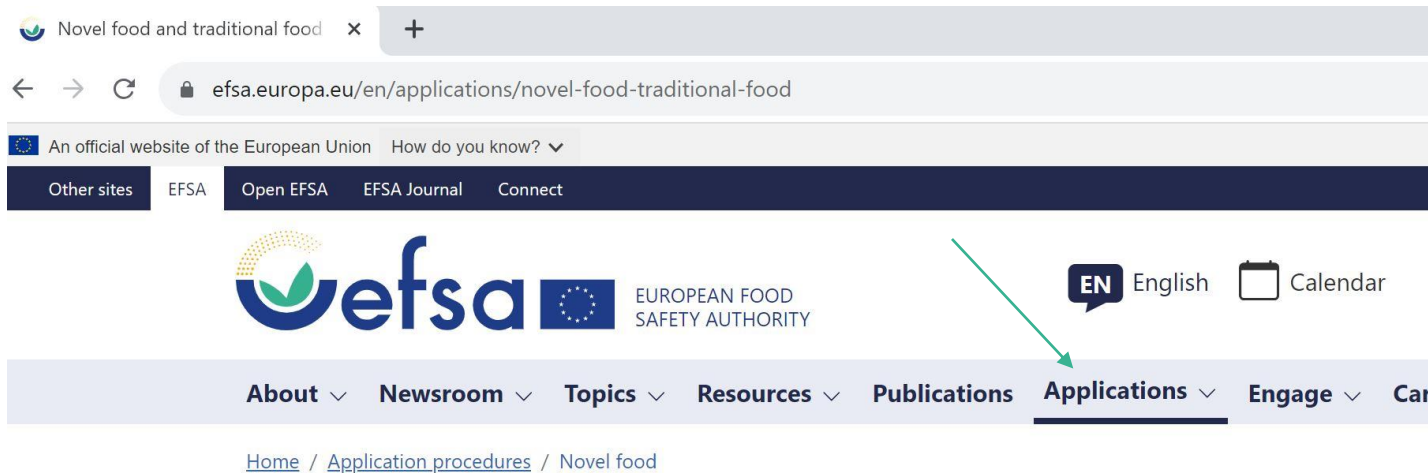


ESFC

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.



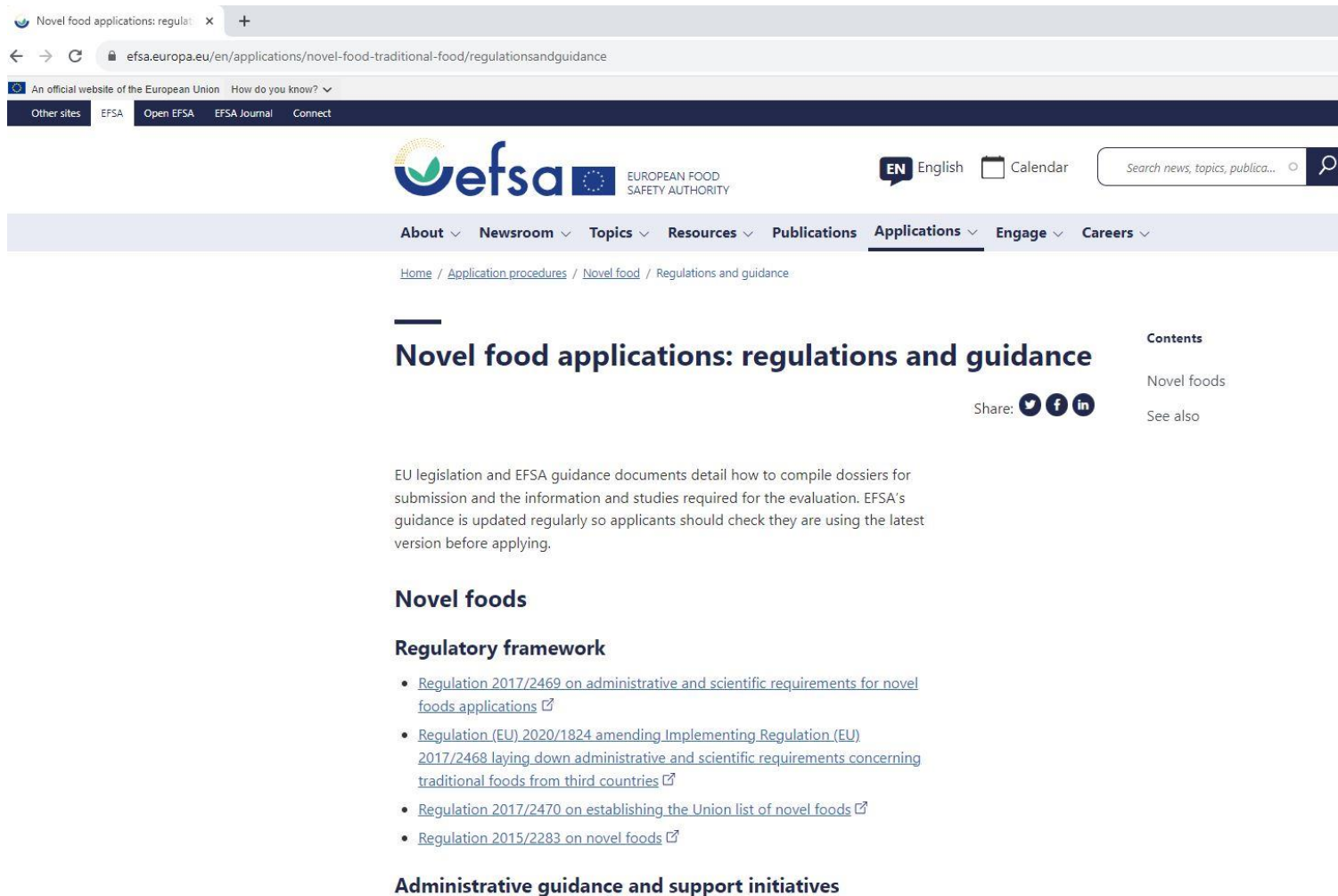
Regulations and guidance

Legal framework, administrative and technical guidance

Information on how to compile dossiers for applications



NOVEL FOOD GUIDANCE DOCUMENTS



The screenshot shows the EFSA website page for 'Novel food applications: regulations and guidance'. The page features the EFSA logo, navigation menus, and a search bar. The main content area includes a title, social sharing options, a brief introduction, and sections for 'Novel foods', 'Regulatory framework', and 'Administrative guidance and support initiatives'.

Novel food applications: regulations and guidance

EU legislation and EFSA guidance documents detail how to compile dossiers for submission and the information and studies required for the evaluation. EFSA's guidance is updated regularly so applicants should check they are using the latest version before applying.

Novel foods

Regulatory framework

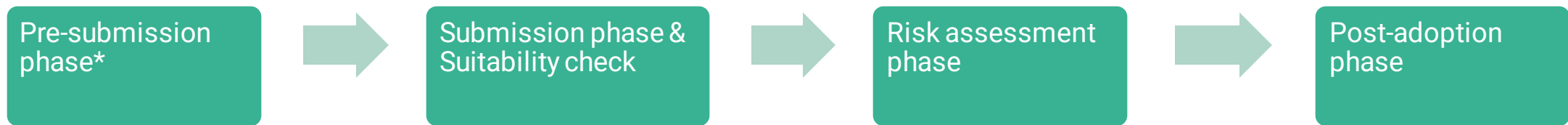
- [Regulation 2017/2469 on administrative and scientific requirements for novel foods applications](#)
- [Regulation \(EU\) 2020/1824 amending Implementing Regulation \(EU\) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries](#)
- [Regulation 2017/2470 on establishing the Union list of novel foods](#)
- [Regulation 2015/2283 on novel foods](#)

Administrative guidance and support initiatives

- **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:

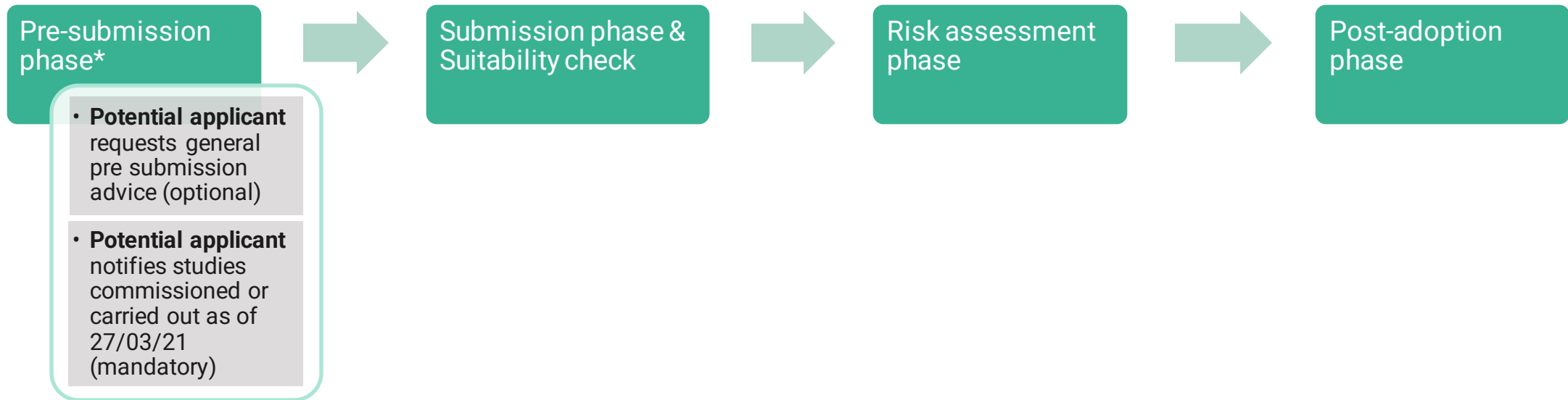
Potential applicant / applicant

EC: European Commission

EFSA: European Food Safety Authority



NOVEL FOOD APPLICATION PROCEDURE IN A NUTSHELL



Legend:

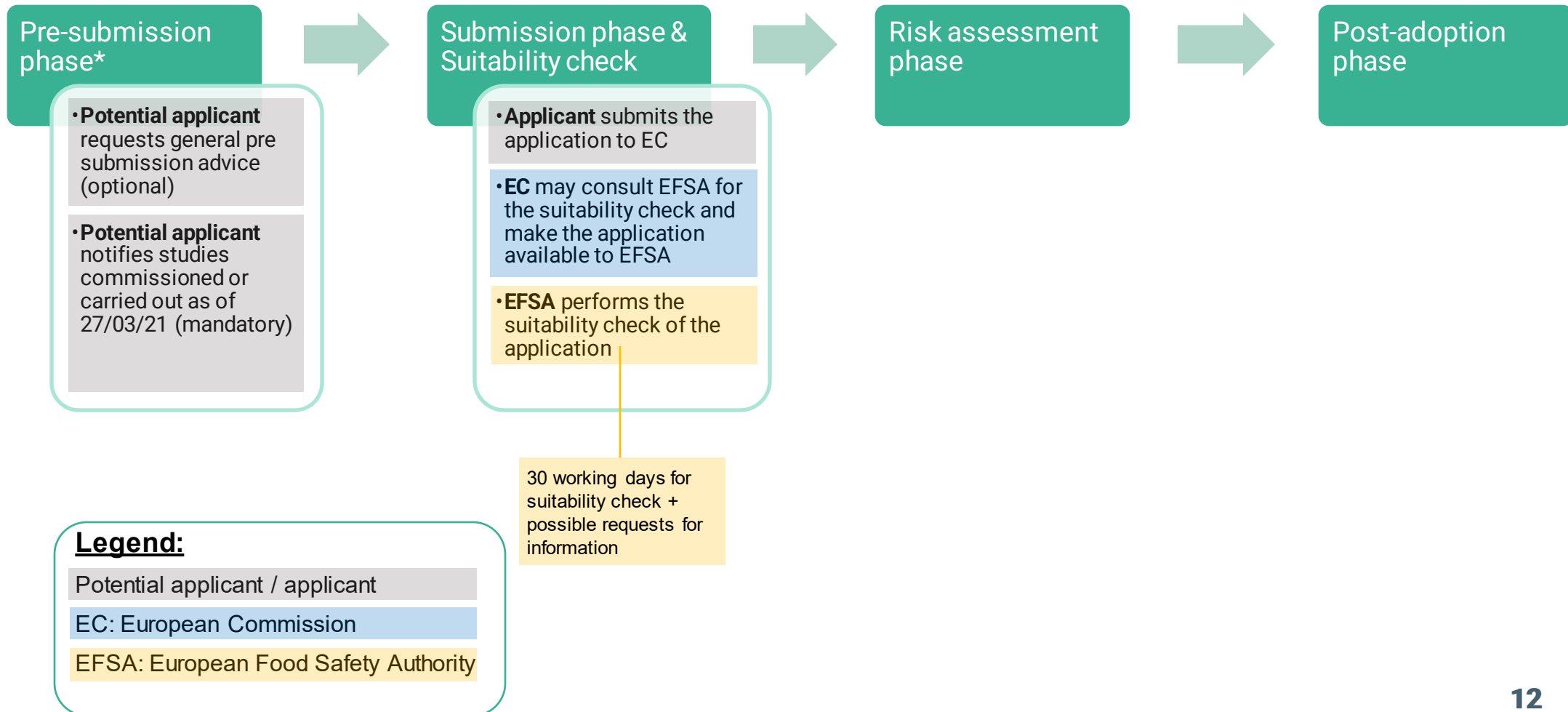
Potential applicant / applicant

EC: European Commission

EFSA: European Food Safety Authority



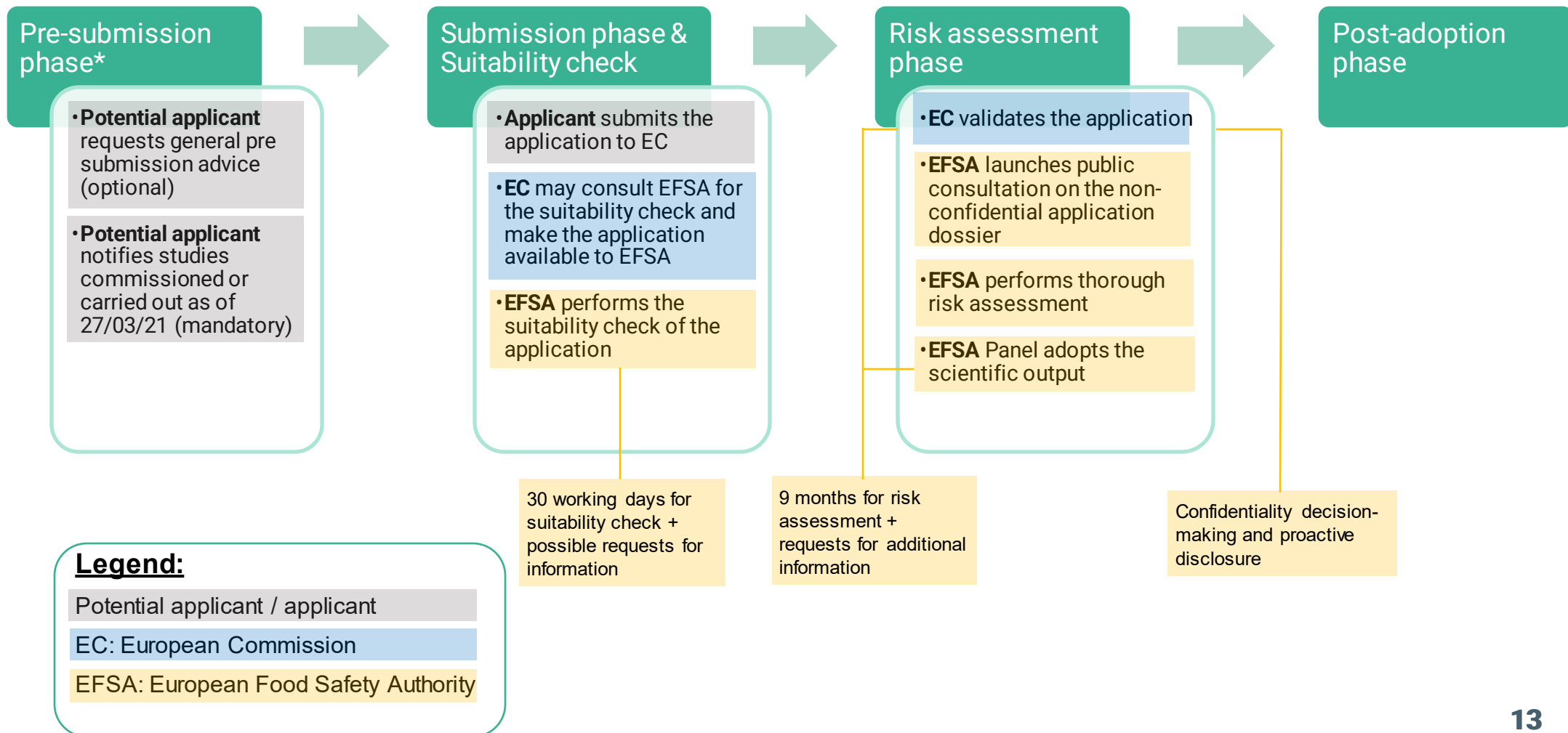
NOVEL FOOD APPLICATION PROCEDURE IN A NUTSHELL



* As defined in [EFSA's Practical Arrangements on pre-submission phase and public consultations](#)



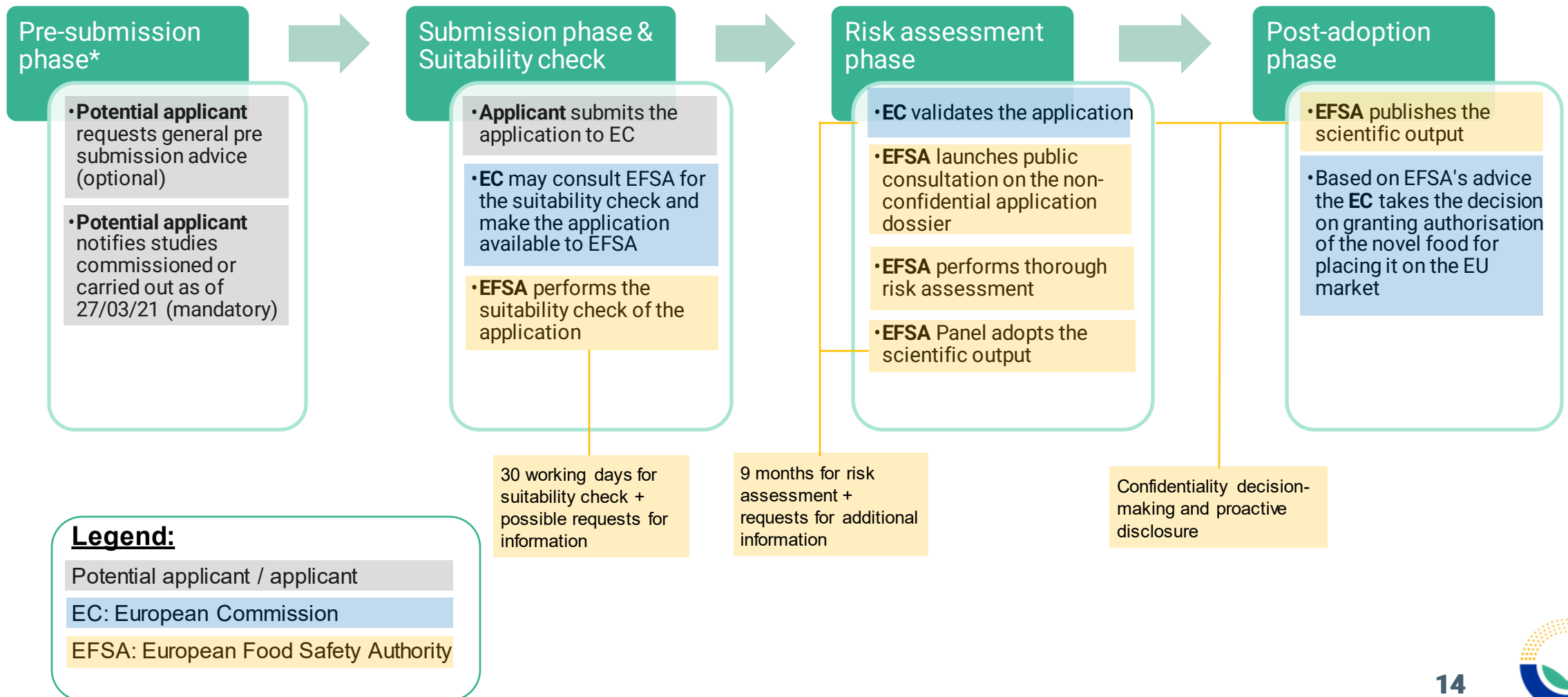
NOVEL FOOD APPLICATION PROCEDURE IN A NUTSHELL



* As defined in [EFSA's Practical Arrangements on pre-submission phase and public consultations](#)



NOVEL FOOD APPLICATION PROCEDURE IN A NUTSHELL



* As defined in [EFSA's Practical Arrangements on pre-submission phase and public consultations](#)





Pre-submission activities



CONNECT.EFSA PLATFORM



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.

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)

Pre-Application ID
New application for JPQ

ID
EFSA-ID-2023-000912

Details History

Request Name New application for JPQ	ID EFSA-ID-2023-000912
Business Operator ABC Company Spa	Contact Name
Subject Of The Application JPQ	Food Domain Novel Foods
Note	Authorisation Type Novel Food Authorisation
	Application Type New Novel Food



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**



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



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 non-inclusion of studies notified or justifications for study withdrawn

E-SUBMISSION Food Chain platform

Applicant Training Applicant EN

Submit

Dossier saved at 16:24:50

Technical Dossier

Pre-Application information

Have you received a pre-application identification from EFSA?

Yes No

Pre-Application Identification*

Enter the Pre-Application Identification e.g.: EFSA-ID-2021-123456

If necessary, please provide the study identifications of studies that have been notified in the database of study notifications (established by EFSA) that have not been included in this application and/or have been withdrawn from the database. In addition, please provide justifications explaining the reasons why these studies were not included or withdrawn, respectively.

The justification for the non-inclusion of pre-notified studies is not subject to confidentiality rules and will be disseminated once the dossier is validated. So please consider this to be a public document in terms of personal and confidential information.

Enter the EFSA study identification e.g.: EFSA-2021-12345678

Justification

Remove

Enter the EFSA study identification e.g.: EFSA-2021-12345678

Justification

Remove

Add

AUTHORISATION TYPE
Novel Food Authorisation

APPLICATION TYPE
New Novel Food

v9.0.0



NOTIFICATION OF STUDIES (NOS)

- **Justifications for non-notification of studies submitted in the dossier**

E-SUBMISSION Food Chain platform

Novel Foods Application
NF-2022-57230

Draft With Applicant

DOSSIER DATA

Administrative Data

Summary data

Technical Dossier

Technical Dossier

Pre-Application information

Identity of the novel food*

Not applicable

If applicable add one document

Files	Type	Status	Date
- RFI During Suitability Check SDD - Software Design Document (7).docx	Study Report	Non-confidential	15/07/2022 17:33

Metadata

Publicly Available

Yes, IPR owned/acquired Yes, IPR NOT owned No

Document type

Study Report

STUDY IDENTIFICATION

Have you received a EFSA study identification ?

Yes No

Justification for not notifying the study or notifying it with delay *

The justification that must be given to explain the reasons why a study was not notified or was notified with delay is not subject to confidentiality rules and will be disseminated once the dossier is validated. Therefore, please consider in terms of providing personal and confidential information that this justification will be disseminated exactly as provided.

Enter a justification for not providing or having delayed an EFSA study identification

Study ID type

Select a study ID type

Enter a value

Submit

Dossier saved at 09:13:00

1 non confidential file

Authorisation Type: Novel Food Authorisation

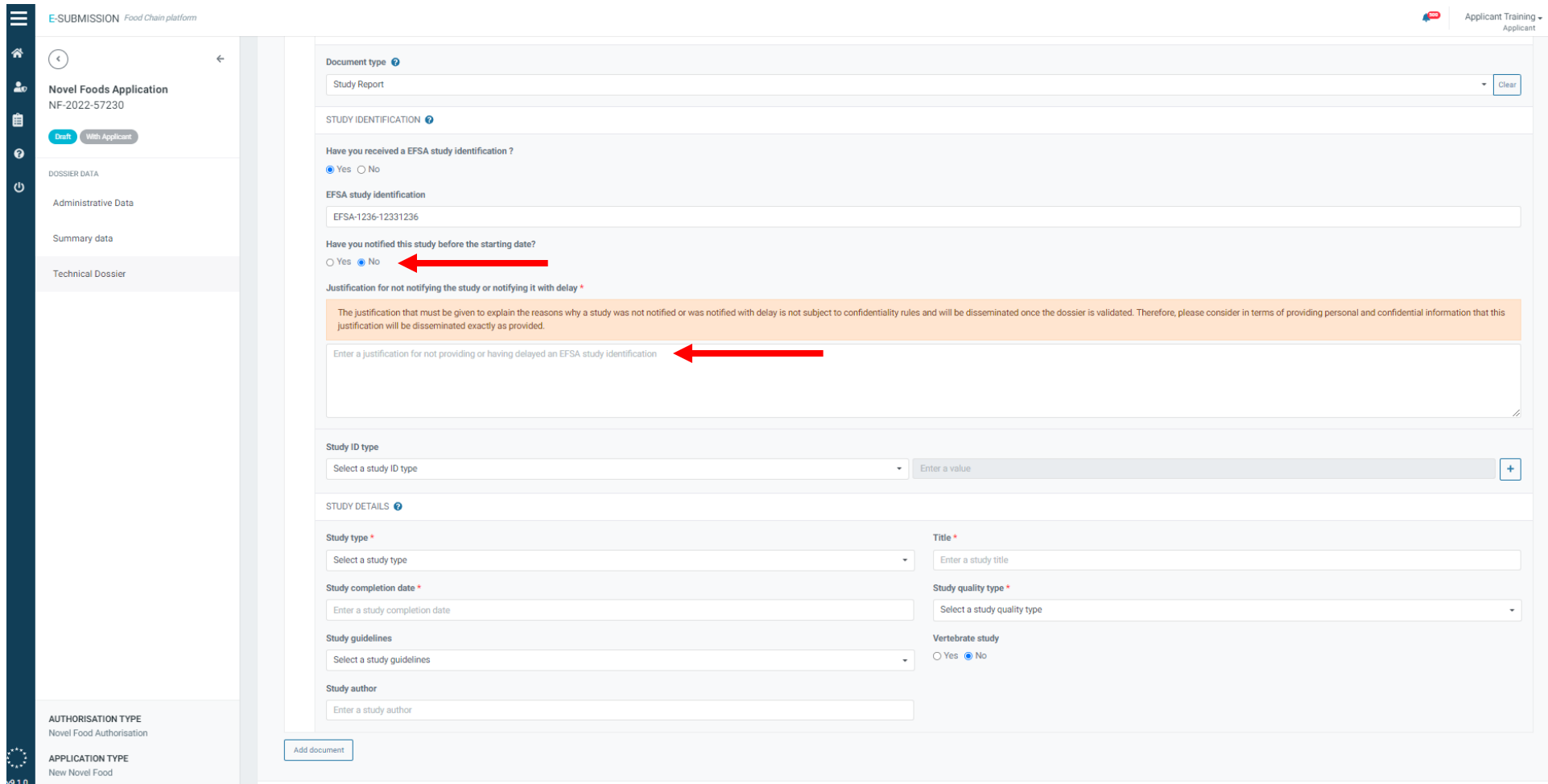
Application Type: New Novel Food

v9.1.0



NOTIFICATION OF STUDIES (NOS)

- Justifications for delay notification of studies submitted in the dossier



E-SUBMISSION Food Chain platform

Novel Foods Application
NF-2022-57230

Draft With Applicant

DOSSIER DATA

Administrative Data

Summary data

Technical Dossier

Document type
Study Report

STUDY IDENTIFICATION

Have you received a EFSA study identification?
 Yes No

EFSA study identification
EFSA-1236-12331236

Have you notified this study before the starting date?
 Yes No

Justification for not notifying the study or notifying it with delay *

The justification that must be given to explain the reasons why a study was not notified or was notified with delay is not subject to confidentiality rules and will be disseminated once the dossier is validated. Therefore, please consider in terms of providing personal and confidential information that this justification will be disseminated exactly as provided.

Enter a justification for not providing or having delayed an EFSA study identification

Study ID type
Select a study ID type Enter a value +

STUDY DETAILS

Study type *
Select a study type

Title *
Enter a study title

Study completion date *
Enter a study completion date

Study quality type *
Select a study quality type

Study guidelines
Select a study guidelines

Vertebrate study
 Yes No

Study author
Enter a study author

Authorisation Type
Novel Food Authorisation

Application Type
New Novel Food

v9.1.0

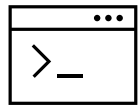
Add document



EXAMPLES OF JUSTIFICATIONS NOT ACCEPTED



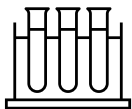
Studies are not notified/notified with delay due to lack of knowledge of applicable NoS obligation requirements (Article 32b(2) of the General Food Law)



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

Technical Dossier Submit

Dossier saved at 09:58:30

+ Pre-Application information ?

- Identity of the novel food* 1 non confidential file ?

Not applicable ?

If applicable add one document

Files	Type	Status	Date	
- RFI During Suitability Check SDD - Software Design Document (7).docx		Non-confidential	15/07/2022 17:33	...

Metadata

Publicly Available ?

Yes, IPR owned/acquired Yes, IPR NOT owned No

Document type * ?

Select a document type



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)



FILES METADATA: DOCUMENT TYPE

Document type

Technical Dossier Dossier saved at 09:59:24

+ Pre-Application information ?

- Identity of the novel food* 1 non confidential file ?

Not applicable ?

If applicable add one document

Files	Type	Status	Date	?
- RFI During Suitability Check SDD - Software Design Document (7).docx		Non-confidential	15/07/2022 17:33	...

- Metadata

Publicly Available ?

Yes, IPR owned/acquired Yes, IPR NOT owned No

Document type * ?

Select a document type ?

Document type is mandatory



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

Document type [?](#)

Study Report Clear

STUDY IDENTIFICATION [?](#)

Have you received a EFSA study identification ?

Yes No

EFSA study identification *

Enter the EFSA study identification e.g.: EFSA-2021-12345678

Study ID type

Select a study ID type Enter a value +

STUDY DETAILS [?](#)

Study type *	Title
Select a study type	abc
Study completion date	Study quality type
2023-10-04	GLP Clear
Study guidelines	Vertebrate study
Select a study guidelines	<input type="radio"/> Yes <input checked="" type="radio"/> No
Study author	
Enter a study author	



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

General information for submission of confidential information

If applicable add one document

Files	Type	Status	Date	
+ RFI During Suitability Check SDD - Software Design Document (7).docx	Study Report	Non-confidential	15/07/2022 17:33	⋮
- conf.docx	Raw Data	Confidential	12/10/2023 14:18	⋮

+ Metadata

- Confidentiality treatment ⓘ

Non confidential file *

non conf.docx

Grounds for confidential file *

- New Ground

Ground * ⓘ

Ground

Justification * ⓘ

Enter a justification for not providing or having delayed an EFSA study identification

Excerpt of the text * ⓘ

Excerpt of the text

Related section * ⓘ

Related section

CONDITIONS CHECK LIST ⓘ

Potential harm Yes

the public disclosure of the document, information or data for which confidentiality status is requested may potentially harm the interests of the applicant to a significant degree and that the harm that may be caused is of a significance corresponding at least to 5% of their total gross turnover for legal persons, or earnings for natural persons, in the year preceding that of the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant should provide a specific reason in the form of a free text in the respective Justification box on why they considered that any public disclosure would potentially harm their interests to a significant degree.

Worthiness of legal protection: Yes

the document, information or data for which confidentiality treatment is requested is eligible for worthy of legal protection and has not been acquired in an unlawful manner.

Environmental Protection Yes

the document, information or data for which confidentiality status is requested does not fall under the definition of "environmental information" pursuant to Article 2 of the Aarhus Regulation.

Novelty Yes

the document, information or data for which confidentiality status is requested has not been finalised in the form submitted to EFSA more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason in the form of a free text in the respective Justification on why public disclosure of that information would still potentially harm its interests to a significant degree.

Add confidential ground

[EFSA user guide on confidentiality](#)

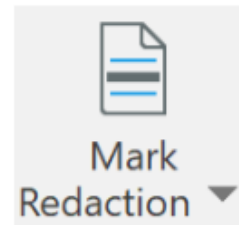


CONFIDENTIALITY AND SANITIZATION

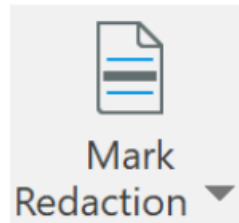
Sanitization of confidential information and personal data

- 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



Dear Sir or Madam



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

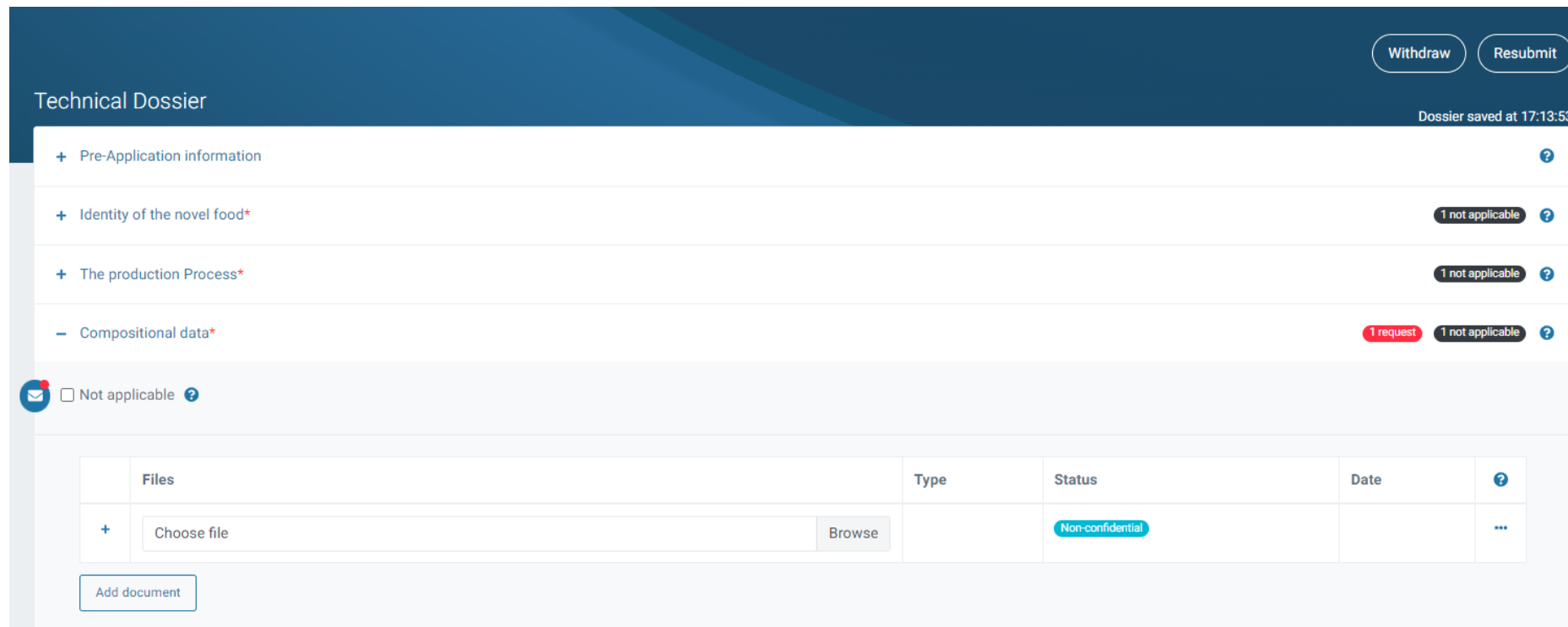
How to request an extension of deadline



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



The screenshot displays the 'Technical Dossier' interface. At the top right, there are 'Withdraw' and 'Resubmit' buttons. Below the title, it indicates 'Dossier saved at 17:13:53'. The main content area lists several sections with expandable/collapsible icons and status indicators:

- Pre-Application information**: Status: 1 not applicable
- Identity of the novel food***: Status: 1 not applicable
- The production Process***: Status: 1 not applicable
- Compositional data***: Status: 1 request, 1 not applicable

Below these sections, there is a checkbox labeled 'Not applicable' with a question mark icon. At the bottom, there is a table for file uploads:

Files	Type	Status	Date	
<input type="text" value="Choose file"/> <input type="button" value="Browse"/>		Non-confidential		⋮

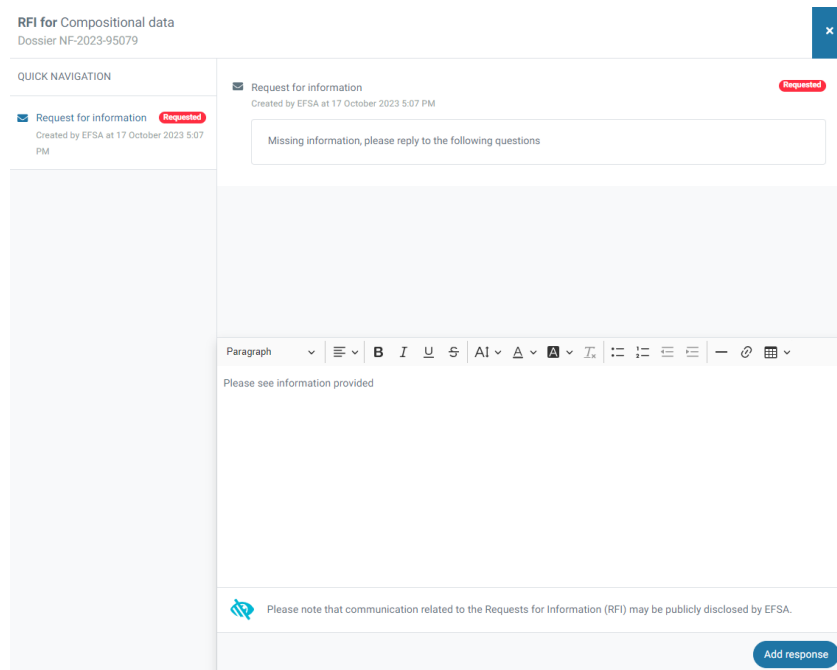
An 'Add document' button is located below the table.



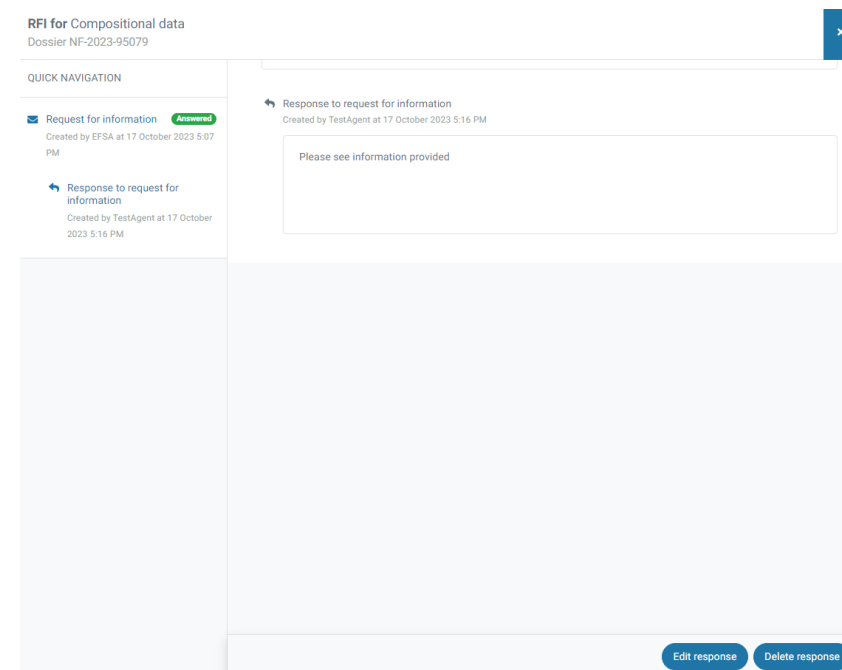
REPLYING TO REQUEST FOR INFORMATION (RFI)

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



The screenshot shows the EFSA RFI interface for 'RFI for Compositional data' (Dossier NF-2023-95079). The 'Request for information' is marked as 'Requested' (red tag). The text box contains the message: 'Missing information, please reply to the following questions'. The interface includes a 'QUICK NAVIGATION' sidebar, a rich text editor with a toolbar, and a footer with a disclaimer: 'Please note that communication related to the Requests for Information (RFI) may be publicly disclosed by EFSA.' and an 'Add response' button.



The screenshot shows the EFSA RFI interface for 'RFI for Compositional data' (Dossier NF-2023-95079). The 'Request for information' is marked as 'Answered' (green tag). The 'Response to request for information' is marked as 'Created by TestAgent at 17 October 2023 5:16 PM' and contains the text: 'Please see information provided'. The interface includes a 'QUICK NAVIGATION' sidebar, a rich text editor with a toolbar, and a footer with 'Edit response' and 'Delete response' buttons.



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 of 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

The screenshot displays the E-SUBMISSION Food Chain platform interface. A modal window titled "Dossier NF-2023-95079: Application On Hold - Request For Information" is open. The modal shows a progress bar with three stages: "Application Submitted to EFSA Suitability/Completeness Check by EFSA", "Application On Hold - Request For Information Request For Information by EFSA" (the current stage), and "Application Submitted to EFSA Suitability/Completeness Check by EFSA". Below the progress bar is a "Comments" section with a text input field containing the text "The information has been included". At the bottom of the modal are "Complete action" and "Close" buttons. The background shows the application details for "Novel Foods Application NF-2023-95079", including the EFSA question number "EFSA-Q-2023-14841" and the suitability deadline "8 December 2023 12:59 AM". The interface also shows various dossier data sections like "Administrative Data", "Summary data", "Technical Dossier", and "PROCESS DATA".



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

The screenshot displays the E-SUBMISSION Food Chain platform interface. On the left, a sidebar menu shows the application details for 'Novel Foods Application NF-2023-95079', which is currently 'Application On Hold - Request For Information'. The sidebar also lists various dossier data sections, with 'Request For Information' highlighted by a red arrow. The main area shows a 'Dossier Overview' with a timeline of events from 17/10/2023. The events include: 'EFSA update' (Mandate code: M-2018-0021), 'Request For Information - Deadline' (RFI deadline: 17/11/2023 23:59) with a 'Request extension' button, 'Application On Hold - Request For Information' (Please reply to RFI from EFSA) with a 'View requests' button, another 'EFSA update' (Mandate code: M-2018-0021), a third 'EFSA update', and finally 'Application Acknowledged by EFSA' (Question Number: EFSA-Q-2023-14841). The interface also features 'Withdraw' and 'Resubmit' buttons at the top right and a 'Dossier saved at 17:21:08' notification.



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

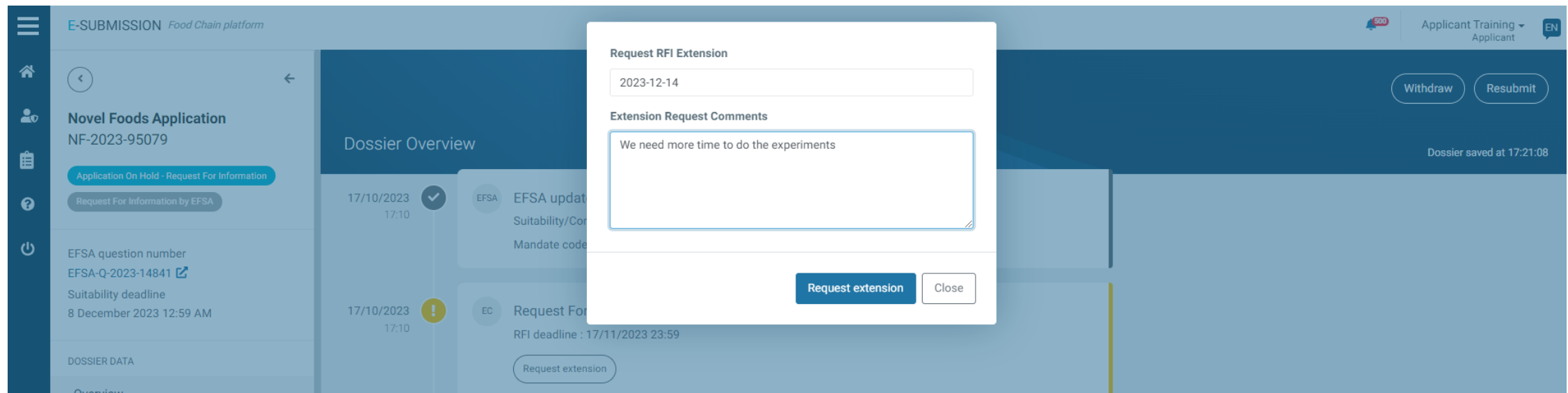
The screenshot displays the E-SUBMISSION Food Chain platform interface. The main content area is titled "Request For Information" and features a red banner with the text "Deadline to resubmit your dossier : 17/11/2023 00:59" and a "Request Extension" button, which is highlighted with a black arrow. Below the banner, there are two sections: "Administrative Data" with "1 Answered RFIs" and "Technical Dossier" with "3 Answered RFIs". The sidebar on the left shows the application details for "Novel Foods Application NF-2023-95079" and includes a "Request For Information by EFSA" button. The top right corner shows "Applicant Training" and "Applicant" options.



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



The screenshot displays the ESFC tool interface for a 'Novel Foods Application' (NF-2023-95079). The application status is 'Application On Hold - Request For Information'. A 'Request RFI Extension' dialog box is open, showing a date of '2023-12-14' and a comment: 'We need more time to do the experiments'. The dialog box has 'Request extension' and 'Close' buttons. The background interface shows a 'Dossier Overview' with a timeline of events, including an 'EFSA update' and a 'Request For Information' with a deadline of '17/11/2023 23:59'. The interface also includes a 'Withdraw' and 'Resubmit' button, and a 'Dossier saved at 17:21:08' notification.



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

The screenshot displays the E-SUBMISSION Food Chain platform interface. The top navigation bar includes 'E-SUBMISSION Food Chain platform', 'Applicant Training Applicant', and 'EN'. The main content area is titled 'Dossier Overview' and shows a timeline of events for a 'Novel Foods Application' (NF-2023-95079). The application status is 'Application On Hold - Request For Information'. The timeline includes the following events:

- 17/10/2023 17:23: TestAr - RFI extension deadline requested. Deadline requested: 14/12/2023 23:59. We need more time to do the experiments. (Highlighted with a red arrow)
- 17/10/2023 17:10: EFSA - EFSA update. Suitability/Completeness check deadline: 08/12/2023 00:59. Mandate code: M-2018-0021.
- 17/10/2023 17:10: EC - Request For Information - Deadline. RFI deadline: 17/11/2023 23:59.
- 17/10/2023 17:09: EC - Application On Hold - Request For Information. Please reply to RFI from EFSA. (View requests button)
- 17/10/2023 17:05: EFSA - EFSA update. Mandate code: M-2018-0021.
- 17/10/2023 17:05: EFSA - EFSA update.

The sidebar on the left contains navigation options: Home, Profile, Application, Request For Information by EFSA, EFSA question number (EFSA-Q-2023-14841), Suitability deadline (8 December 2023 12:59 AM), DOSSIER DATA (Overview, Administrative Data, Summary data, Technical Dossier), PROCESS DATA (Request For Information, Presubmission Overview), and DOWNLOAD ALL FILES .ZIP. The bottom of the sidebar shows the AUTHORITY TYPE as Novel Food Authorisation.



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](#)



QUESTIONS

PUBLIC CONSULTATIONS

EXPERTS

Questions

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

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

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

[Show All](#)

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]

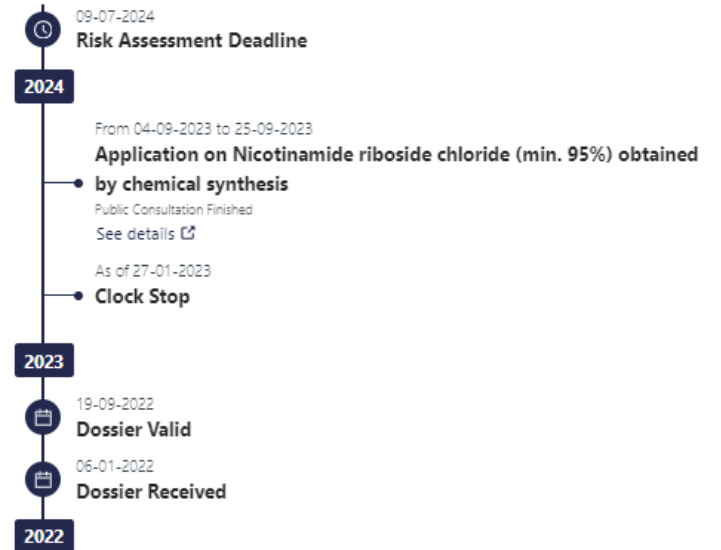
Last updated on: 24/10/2023
Status: Ongoing Risk Assessment

TIMELINE & SUPPORTING DOCUMENTS

NF-2021-1911

[Share](#) [Print](#) [Open in new tab](#)

Timeline: EFSA-Q-2022-00007



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)

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

PUBLIC VERSION OF NOVEL FOOD DOSSIERS

Dossier number: NF-2021-1911

[← Go to question](#)

[GHSTS](#)

[ZIP](#)

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- ▶ 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](#)

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- ▶ Administrative Data
- ▶ Summary data
- ▼ Technical Dossier
 - ▶ Pre-Application information
 - ▶ Identity of the novel food
 - ▼ The production Process
 - ① 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)
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 - ▶ Toxicological information
 - ▶ Genotoxicity
 - ▶ Subchronic toxicity
 - ▶ Chronic toxicity and carcinogenicity
 - ▶ Reproductive and developmental toxicity
 - ▶ Human data
 - ▶ Allergenicity
 - ▶ Concluding remarks
 - ▶ References
- ▼ Annexes to the dossier
 - ① Not applicable
 - ① Study Report - *****
 - ① 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?



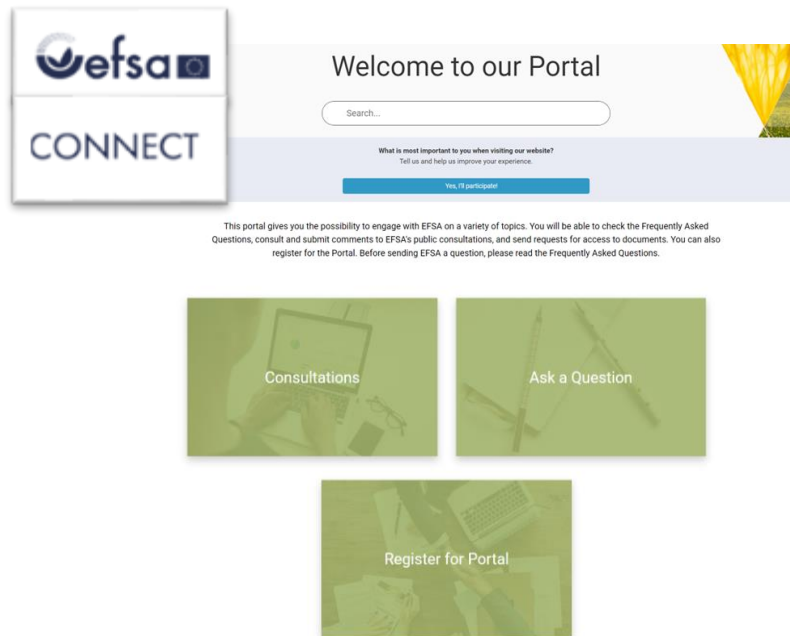
Q&A

- 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
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- 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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