



# SUBMISSION OF FOOD ENZYME APPLICATIONS & SUPPORT TO APPLICANTS

Front-Desk & Workforce  
Planning Unit

24 October 2024



## WHAT'S ON THE MENU

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**Application procedure**

2

**Notification of studies**

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**Support to applicants**

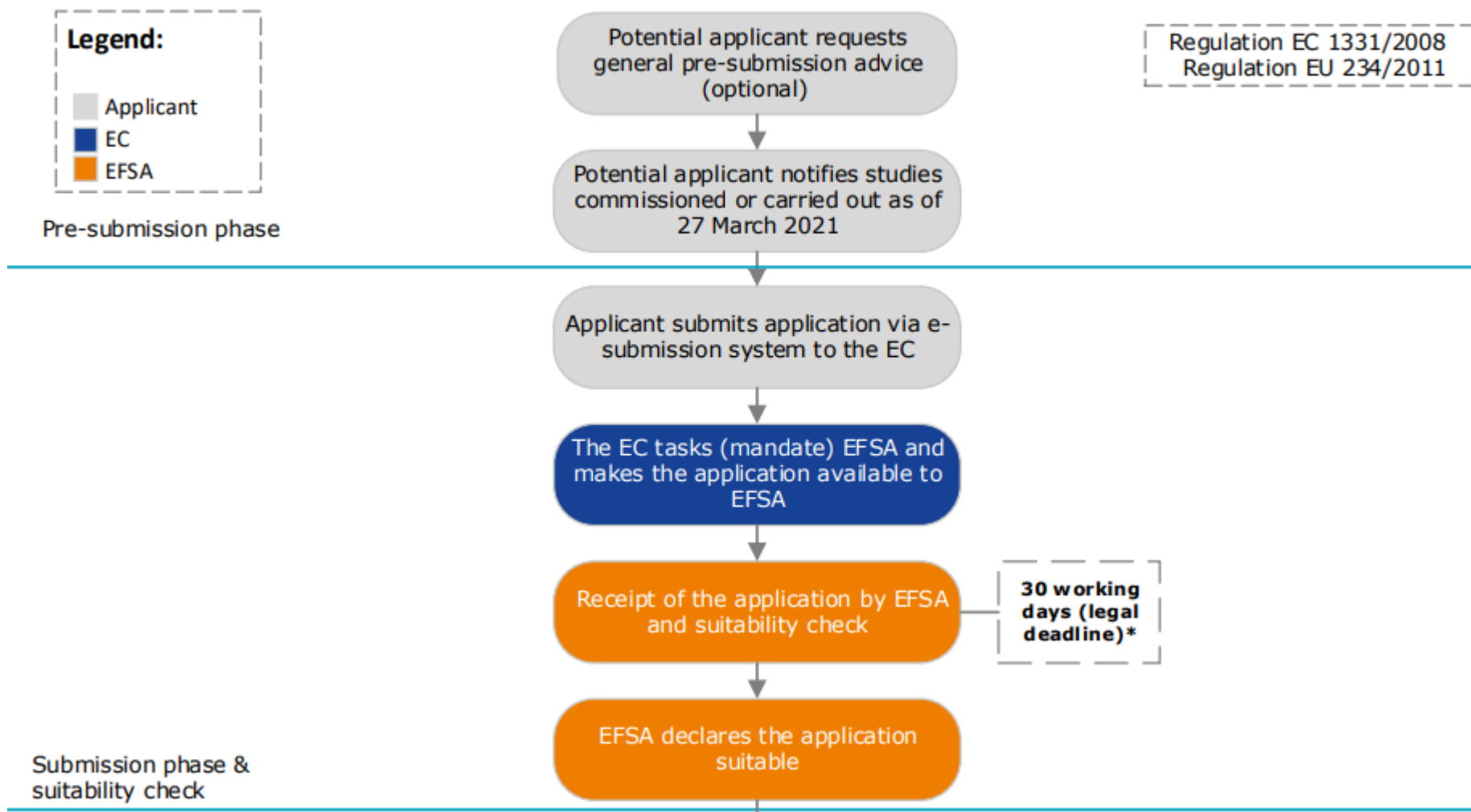
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**Lessons learnt in  
suitability check**

**Q&A**



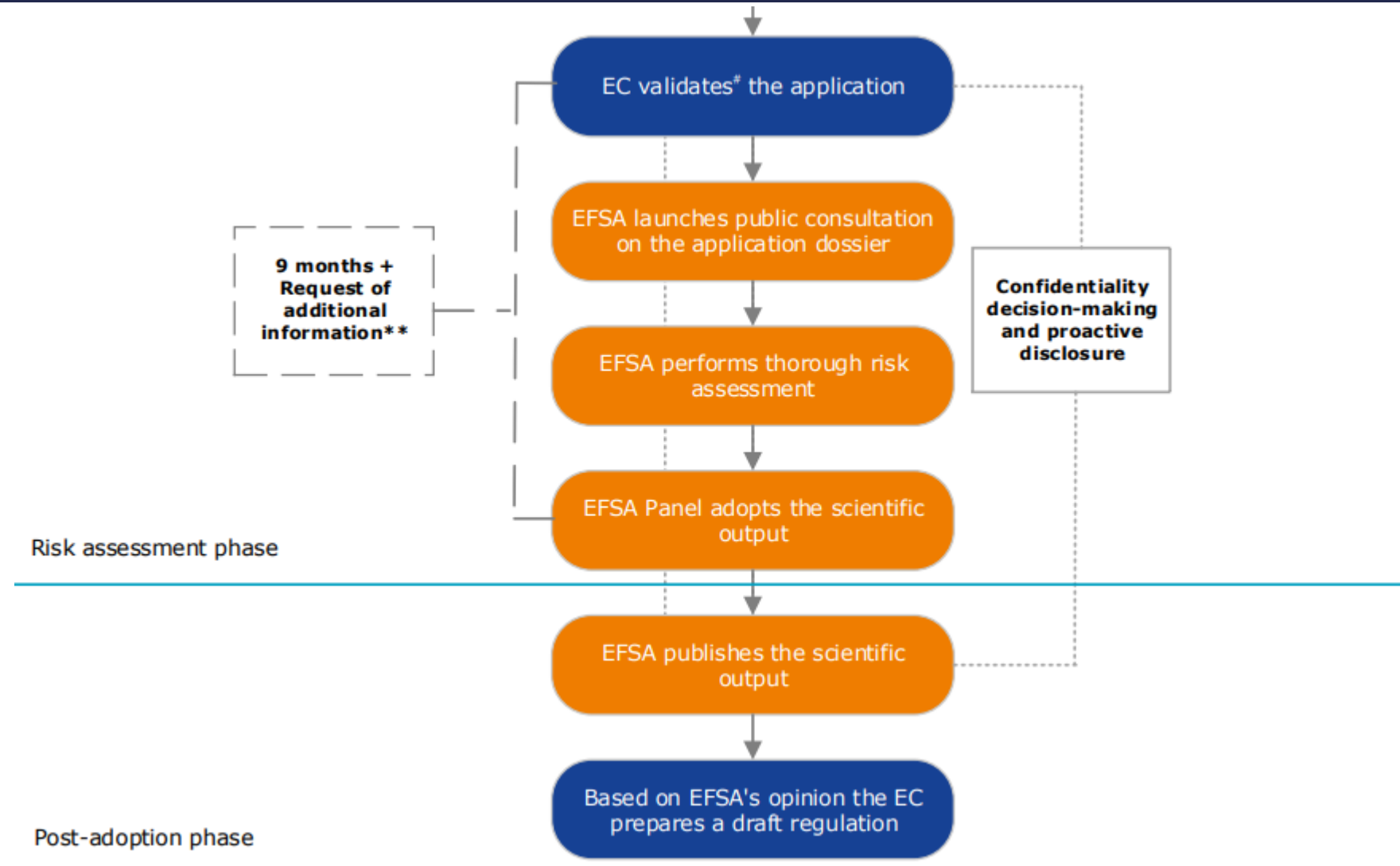
# FOOD ENZYMES APPLICATION PROCEDURE



\*In case certain parts of the application need modification or completion in order to be considered suitable the applicant receives a request to provide missing information.



# FOOD ENZYMES APPLICATION PROCEDURE



# In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information)

\*\*In case of a request of additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant



# EFSA TOOLKIT: IT PORTALS



## 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.

***Pre-submission activities  
+ Interactions with EFSA***



## ESFC

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

***Submission of applications  
+ Evaluation process (non-pesticides)***



## IUCLID

The International Uniform Chemical Information Database (IUCLID) is a software application for recording, storing, maintaining and exchanging data on intrinsic and hazard properties of chemical substances, and the standard data format agreed for pesticide applications.

***Submission of applications  
+ Evaluation process (pesticides)***



## OpenEFSA

All you need to know about our risk assessments

Dedicated portal hosting comprehensive information on our risk assessments, from receipt of a mandate or dossier to adoption of an output: check the status of assessments, browse data and studies, and details about experts.

***Transparent communication***



## Portalino

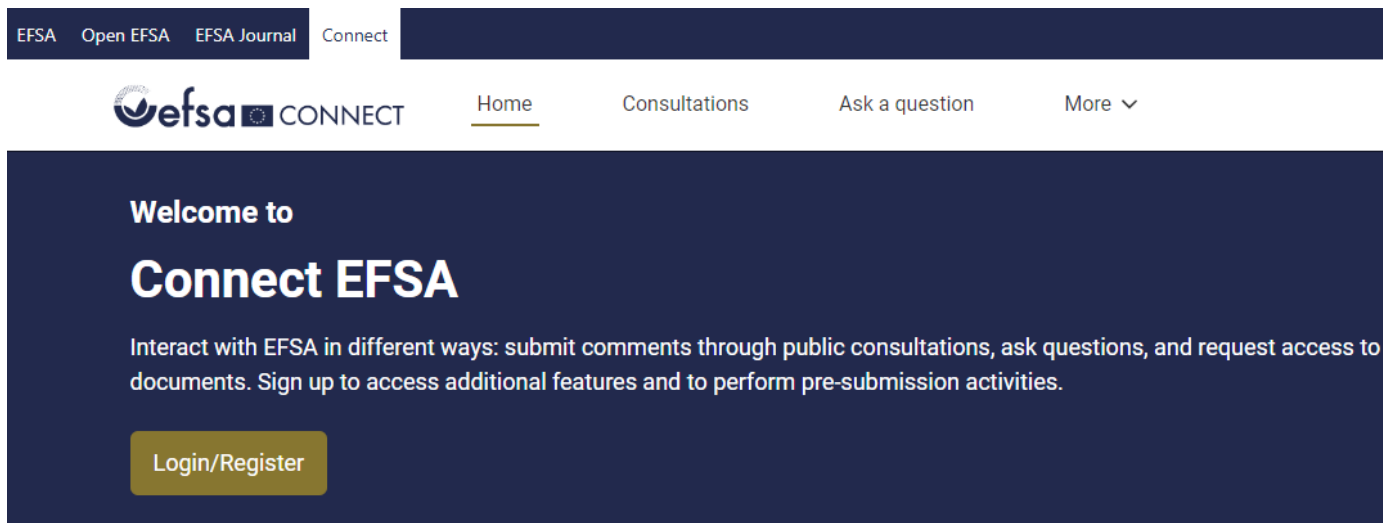
This tool allows applicants to submit confidentiality requests related to applications, datasets and documents supporting the mandates that EFSA receives, or that are submitted in response to EFSA calls for data.

***Other workflows***



# CONNECT.EFSA PLATFORM

Register in the [Connect.EFSA](#) platform



## 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](#)

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



# NOTIFICATION OF STUDIES (NOS)

## Article 32b of the General Food Law

- Potential applicants must notify studies commissioned or carried out as of 27 March 2021

## To keep in mind

- 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 check by EFSA

- **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, applicants are encouraged **to resubmit as soon as possible** as the suitability check will start 6 months after the resubmission



# NOTIFICATION OF STUDIES (NOS)

## NoS obligations

- What falls within a definition of “study”: Question 4, part B of [Q&A to Practical Arrangements](#) (update 28/08/2023)

## Studies to be notified

- Stability, efficacy and safety studies
- Studies to demonstrate absence from the product of viable cells and recombinant DNA of a production microorganism

## Studies exempted from NoS obligations

- 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





# QUESTIONS RECEIVED FROM PARTICIPANTS

## Justifications for delayed (i.e. after the starting date) or non-notifications

- The applicant will need to justify such a delay or non-notification as indicated in the answer to question 42 of the [Q&A to Practical Arrangements](#)
- EFSA verifies the validity of the justification taking into account all relevant factual elements an applicant might provide. The analysis is carried out on a case-by-case basis and there is thus no “standard justification”

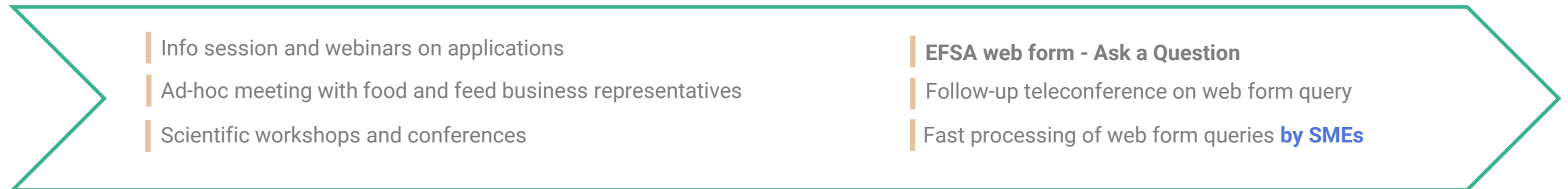
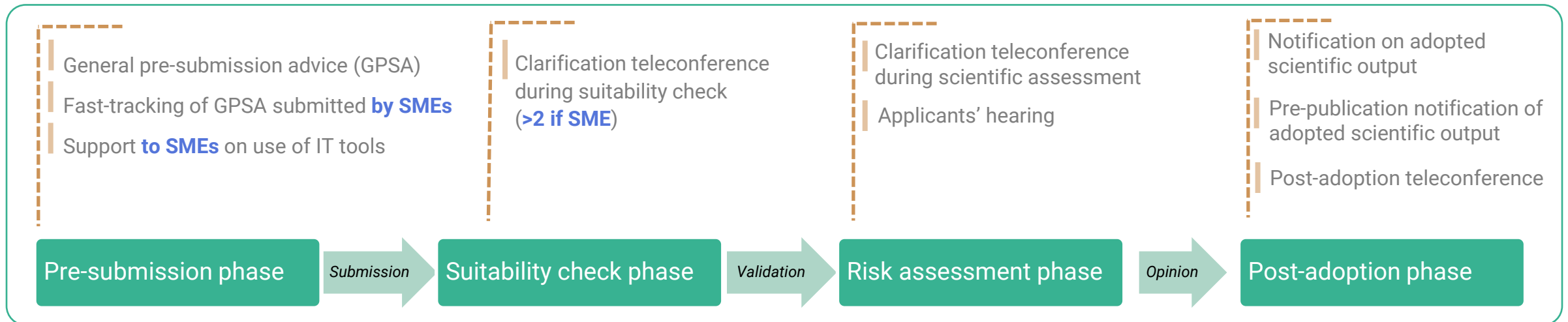
## Search for studies in EFSA database

- EFSA checks all studies that might be relevant for the subject of the application, which goes beyond studies linked to a pre-application ID (PA-ID)
- The applicant remains responsible to link all studies notified and relevant for its product to a PA-ID before submitting its application



# SUPPORT INITIATIVES DURING THE LIFE-CYCLE OF APPLICATIONS

## EFSA Catalogue of support initiatives



+ '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**



# 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](mailto:sante-e-submission-food-chain@ec.europa.eu)



# SPECIFIC INITIATIVES FOR SMEs

## Fast processing of **Ask a Question** queries

- responses within 7 working days instead of 15



## Fast-tracking of **General pre-submission** advice

- fast processing: 50% standard timeline
- preferably in tele-meeting instead of in writing



## Dedicated support on the **use of IT tools** for preparing an application

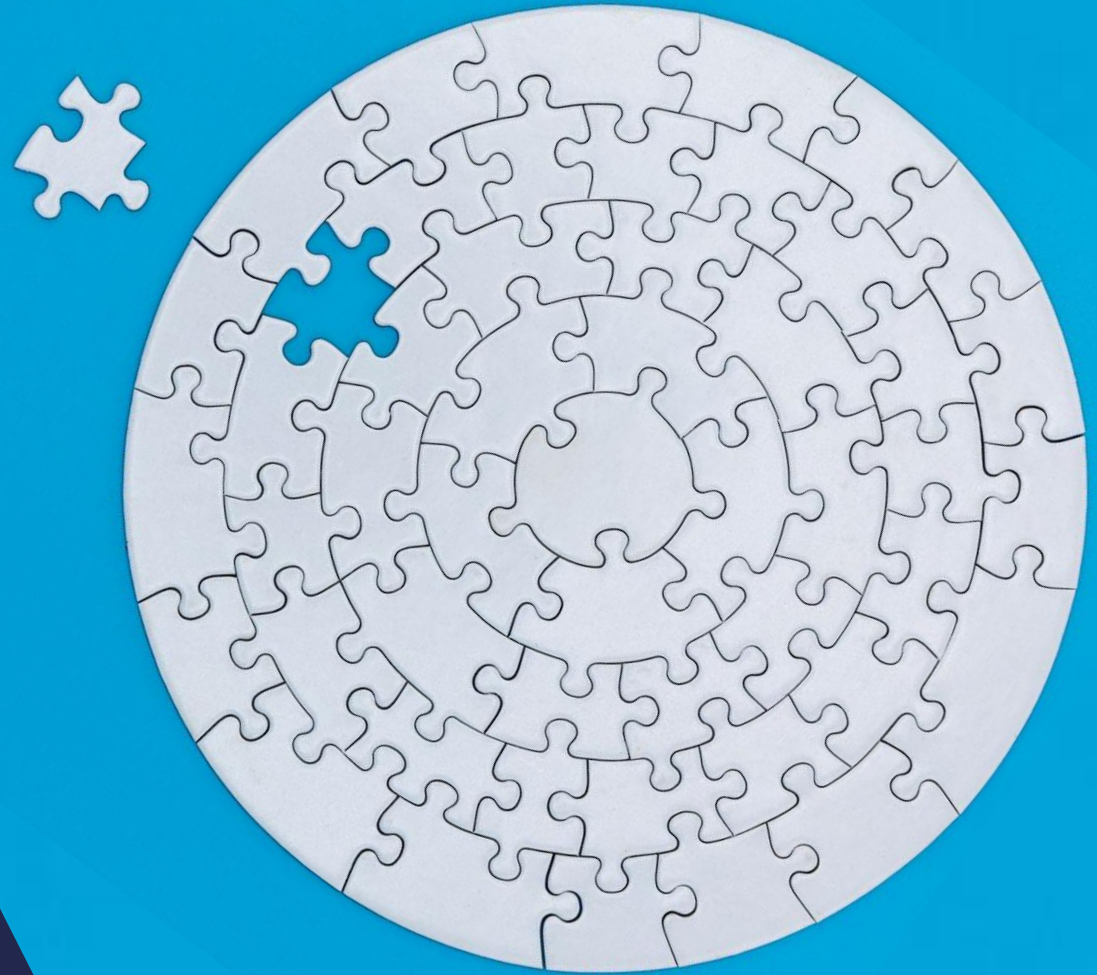
- physical or virtual hands-on session in the use of pre-submission and submission IT tools (Connect.EFSA, ESFC)



## Clarification teleconferences during suitability check

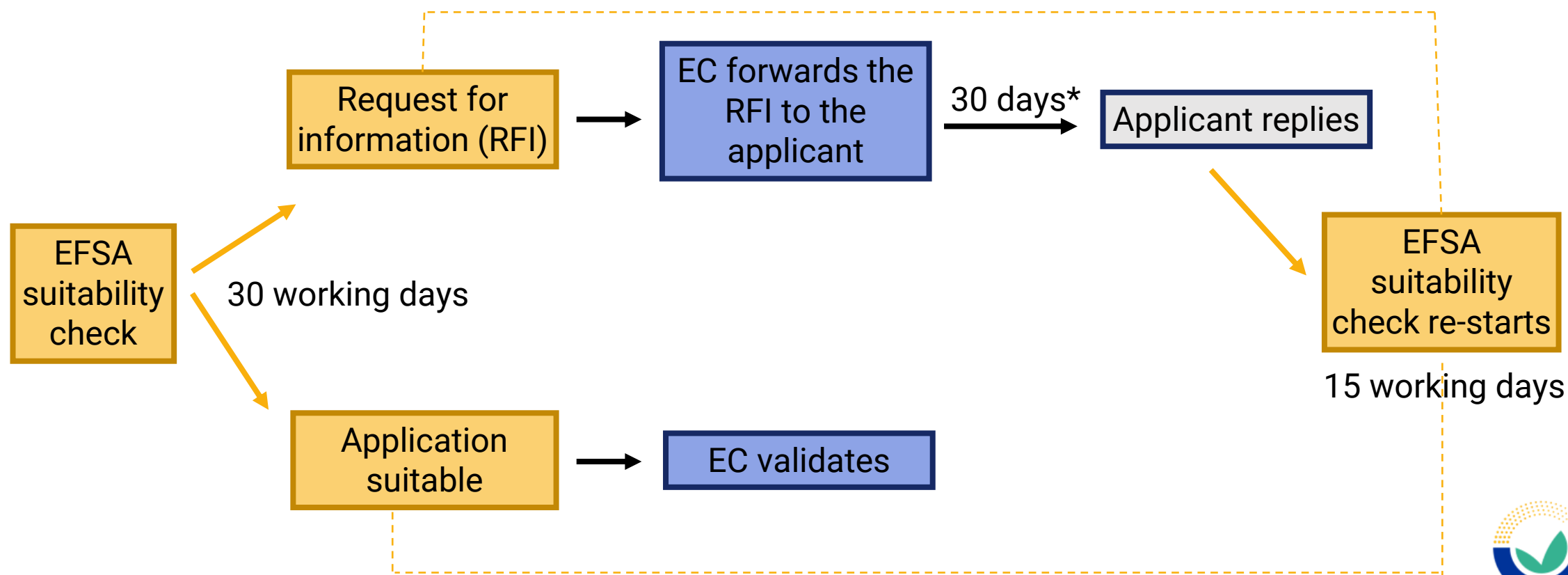
- EFSA can accept more than two requests for the same application

# LESSONS LEARNT PERFORMING SUITABILITY CHECKS



# SUITABILITY CHECK – EFSA TIMELINES

After receipt of the application, EFSA checks the completeness of the application and confirms its suitability to EC when it fulfils the legal requirements, including those on notification of studies, and the requirements set in the EFSA's guidance documents



\* The applicant can request an extension of deadline, if needed



# SUITABILITY CHECK – HOW IT IS DONE

1. The documents provided by the applicant contain all the data required by the EFSA scientific guidance documents
2. Documents provided according to the requirements of the EFSA administrative guidance and notification of studies obligations are fulfilled

Suitability checklist included in the administrative guidance

3. The content of the dossier is consistent
4. EFSA is monitoring the content of the RFI to ensure consistency



Guidance | [Open Access](#) | [CC](#) [BY](#) [NC](#) [ND](#)

**Scientific Guidance for the submission of dossiers on Food Enzymes**

**Food manufacturing processes and technical data used in the exposure assessment of food enzymes**



Technical report | [Open Access](#)

**Administrative guidance for the preparation of applications on food improvement agents (food enzymes, food additives and food flavourings)**

Supporting Information	
Filename	Description
efs36509e-sup-0001_Appendix_A-Food_enzymes.docx	Word 2007 document, 168.7 KB
efs36509e-sup-0002_Appendix_B-Food_additives.docx	Word 2007 document, 151.9 KB
efs36509e-sup-0003_Appendix_C-Food_flavourings.docx	Word 2007 document, 169.4 KB
efs36509e-sup-0004_Annex_A.pdf	PDF document, 133.9 KB

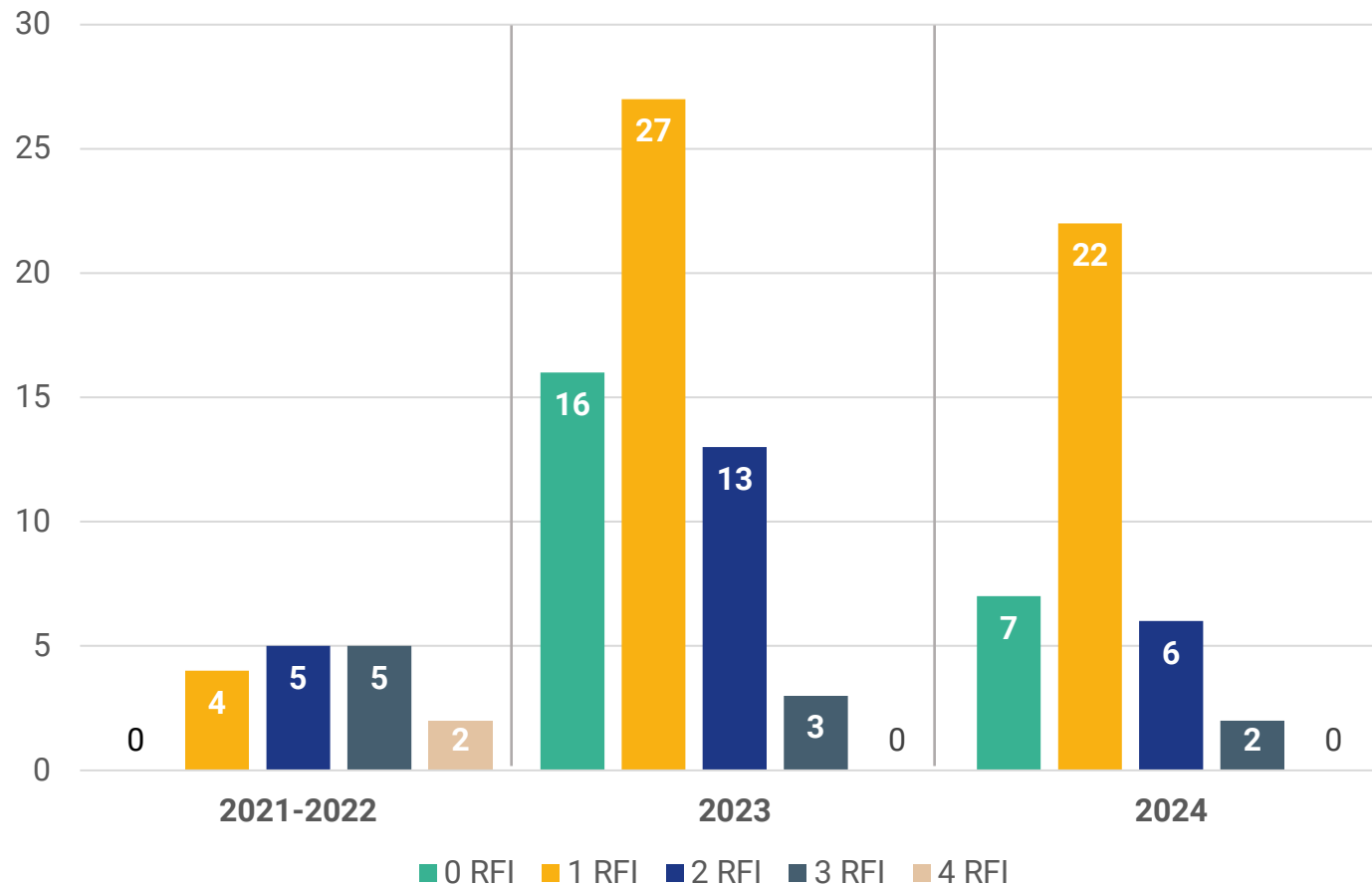
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# IMPROVEMENTS ON THE COMPLETENESS OF THE APPLICATIONS RECEIVED AFTER THE IMPLEMENTATION OF THE TRANSPARENCY REGULATION

Number of valid applications/year of receipt



2024 (37 applications)

2023 (59 applications)

2021-2022  
(16 applications)



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

- Deviations from notification of studies obligations are not justified
  - Confidential and non-confidential version of the documents are not provided according to the EFSA requirements
  - Documents are not provided in the correct format
  - Intellectual property rights are not indicated correctly
  - Data omissions or deviations from the EFSA guidance are not justified
  - Inconsistencies are present between different sections and documents of the dossier
- Read paragraphs 2.2; 2.3 and 2.5 of the [administrative guidance](#)
- Read paragraphs 2.6 and 2.12.4 of the administrative guidance and the [user guide on confidentiality](#)
- Read paragraph 2.12 of the administrative guidance and the [ESFC user guide](#)
- Check the entire dossier carefully and use the checklist included in the administrative guidance



# HOW TO REPLY TO AN EFSA REQUEST FOR INFORMATION DURING SUITABILITY CHECK

- If you have **doubts regarding what EFSA has asked you**: to contact [FDP@efsa.europa.eu](mailto:FDP@efsa.europa.eu) and request a clarification teleconference
- If you have **technical issues in ESFC**: to write to ESFC help desk ([sante-e-submission-food-chain@ec.europa.eu](mailto:sante-e-submission-food-chain@ec.europa.eu)) directly
- If you **need to update other section(s) of the dossier** that have not been opened: follow the instructions included in the request for information. If still in doubt, send an email to [FDP@efsa.europa.eu](mailto:FDP@efsa.europa.eu)
- If you **need additional time to reply**: request an extension of deadline in ESFC directly
- When you are **ready to reply**:
  - your 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)
  - do not reply using only the comment/reply box of ESFC
  - remove obsolete documents
  - check that you have addressed all the points requested by EFSA



# HOW TO SUBMIT DATA THAT ARE FOLLOW-UPS TO AN EFSA INCONCLUSIVE OPINION

- Following an inconclusive opinion, any new data submitted spontaneously by the applicant is considered as a **new application**: in ESFC select 'Application for the authorisation of a new food enzyme'
- **Submit only the new data necessary to address the points leading to the inconclusiveness of the opinion**
- For all the sections for which **no new data have been generated**, choose “**not applicable**” and indicate, as justification, that the data were provided in the context of the initial application (indicating the EFSA-Q number of the initial application)
- Do not resubmit data already evaluated by EFSA
- Provisions on notification of studies, general pre-submission advice, confidentiality, proactive disclosure and public consultation of the information fully apply

See also the information in paragraph 2.10.1 of the [EFSA administrative guidance](#)



# 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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[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



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