# THE NOVEL FOOD APPLICATION PROCESS

## PROCEDURES, TOOLS AND SUPPORT INITIATIVES FOR APPLICANTS

## 158TH NDA PANEL PLENARY MEETING

FRONT DESK & WORKFORCE PLANNING UNIT

efsa
EUROPEAN FOOD SAFETY AUTHORITY

# WHAT'S ON THE MENU

1. The novel food application process
2. Support to applicants
3. Lessons learnt in suitability check

# THE EU NOVEL FOOD FRAMEWORK

**Competent Authorities of EU Member States:** can reply to questions on whether a food is novel or not and thus requires a pre-market authorisation under Regulation (EU) 2015/2283, the Novel Food Regulation.

**European Commission:** can clarify aspects related to the novel food regulatory framework and the novel food authorisation. E.g. do I need to apply for a new novel food authorisation or the modification of an existing one? How can I request data protection for my novel food?

**EFSA:** provides sound scientific advice to Commission ad Member States to support the regulatory decision. Deals with the application procedure for products requiring an authorisation (like novel foods) and provides support to applicants.

# THE NOVEL FOOD APPLICATION PROCESS

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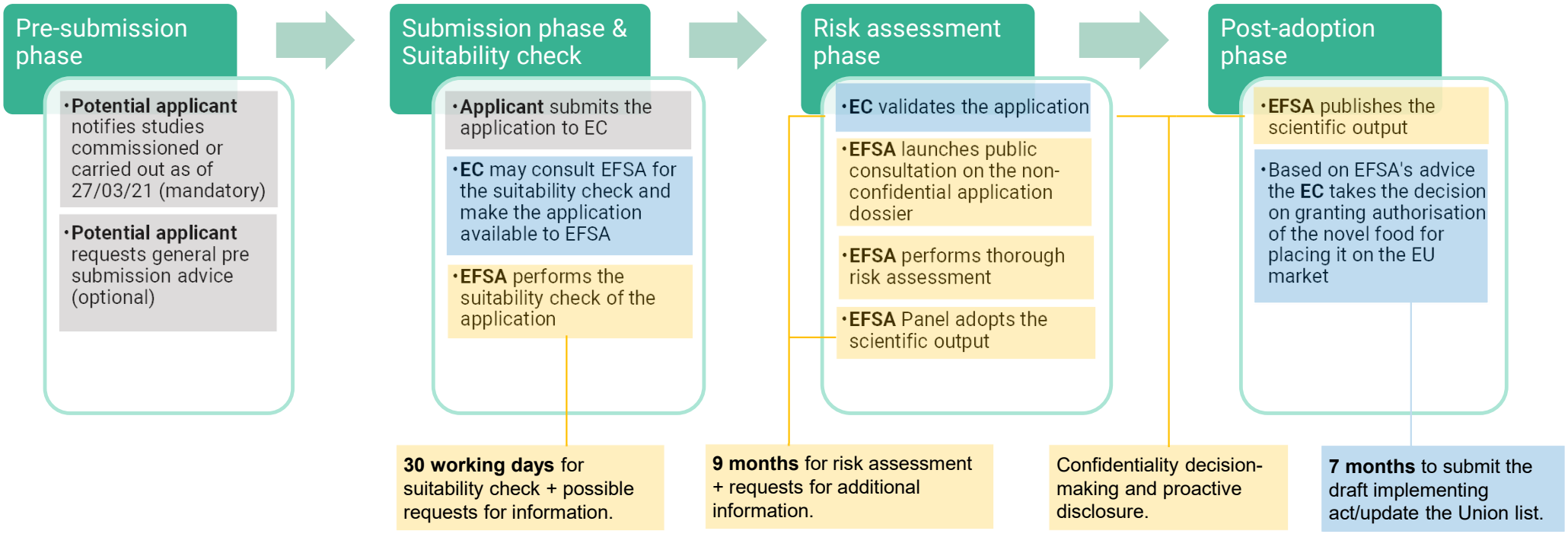



**Reference:** Section 2 of the Administrative Guidance on Novel Foods

# NOTIFICATION OF STUDIES

**Question:** Do we need to **notify in advance all studies** in pre-submission phase **that will be included in the novel food application**? What if some **studies** have been **already done – can we use them**?

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

**Studies** carried out or commissioned **in support of an application under the EU law** shall be notified without delay, i.e. before the starting date.

- **Question 4, of Q&A on EFSA's practical arrangements provides indications on analyses exempted from the notification obligations**, i.e. analyses to assess the identity/composition, including impurities, whole genome sequencing, and analyses to determine physico-chemical properties.

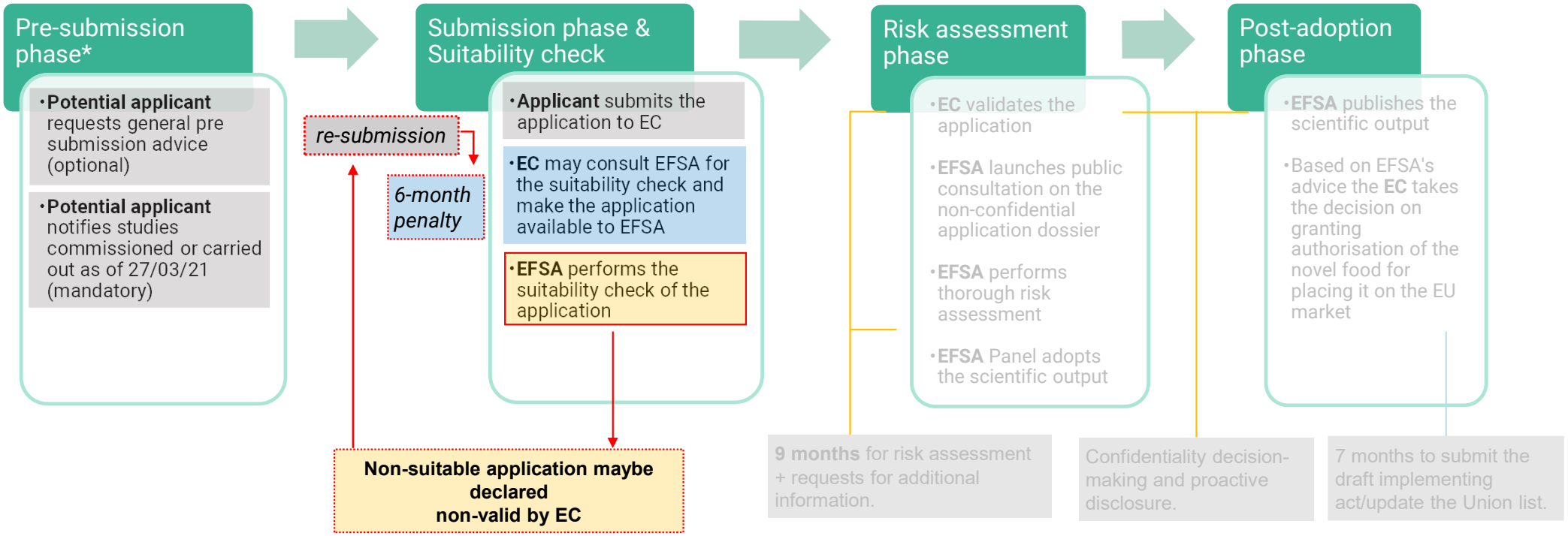
EFSA has set a **Notification of Studies Database** to enable the submission of study notifications.

- It is possible to withdrawn a study form the database, a justification is required.

**Any deviation from Article 32b of the GFL must be justified** by the applicant.

- Studies performed **before 26 March 2021** can be used without notification.
- Studies performed **as of 27 March 2021** and not notified; may be used but a justification for non-notification is needed.
- **Justifications** need to be **submitted with the corresponding application** in ESFC and will be evaluated during the suitability check.

# NON-COMPLIANCE WITH NOTIFICATION OF STUDIES OBLIGATIONS



# NOTIFICATION OF STUDIES (NOS) – AN EXAMPLE

**Question**: Could you provide **a definition for 'stability study'** and indicate the **best way to notify a stability study** […]?

- With compositional data on the novel food in mind the applicant identifies compositional qualifiers, constituents and parameters **susceptible to changes during storage and transport.**
- **The applicant designs a protocol/study plan** to follow their evolution covering the period until the proposed shelf-life of the novel food.
- **The analyses** that will be conducted under this protocol/study plan **can be considered a single stability study.**

## Key points to consider

There is no need to notify separately the single analyses if they are part of the same stability study.

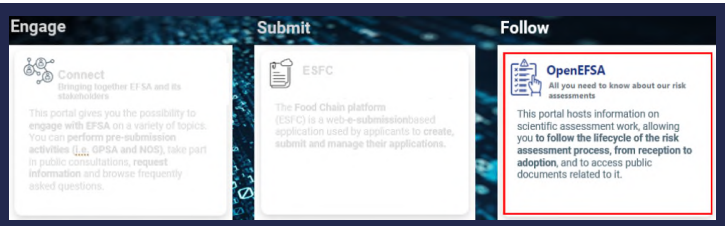
The applicant notifies the study before its starting date (first analysis/timepoint).

Under "Study Design" section the applicant can provide details on the study protocol and time points to monitor the stability of the novel food.

# IT PLATFORMS


**More details** in the EFSA Toolkit page.

# OPENEFSA




efsa OPEN

QUESTIONS | PUBLIC CONSULTATIONS | EXPERTS

Search entire site

## Questions

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

**520 results found** Export (520) questions to CSV

Sorting: Relevance

**Active filters** Remove all filters

Novel Foods ×

**Food domain**

Search food domains

- [x] Novel Foods (520)
- [ ] Administrative and Technical Support
- [ ] Animal Health
- [ ] Animal Welfare
- [ ] Assessment and Methodological Support
- [ ] Biological Hazards
- [ ] Biological Hazards - Animal by-products
- [ ] Biological Hazards - EUSR TSE
- [ ] Biological Hazards - EUSR zoonoses and AMR
- [ ] Biological Hazards - Multinational foodborne outbreaks
- [ ] Contaminants
- [ ] Contaminants - Feed detoxification
- [ ] Data Collection and Analysis
- [ ] Decontamination Substances

Novel Foods EFSA-Q-2025-00283

**Application for authorisation of Isosteviol (ent-16-oxobeyran-19-oic acid) as a novel food**

**Last updated on:** 30/04/2025
**Status:** Intake

Novel Foods EFSA-Q-2023-00301

**Application for authorisation of Dried *C. reinhardtii* algae as a novel food**

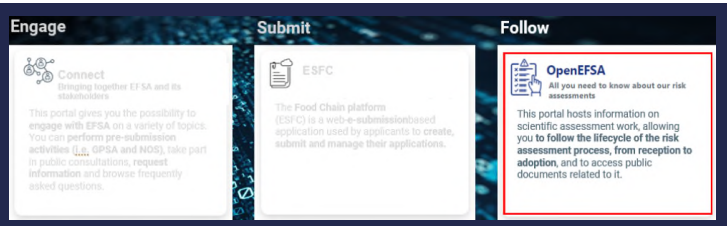
**Last updated on:** 30/04/2025
**Status:** Published

Novel Foods EFSA-Q-2024-00625 PAECILOMYCES VARIOTII KCL-24

**Application for authorization of Dry biomass of *Paecilomyces variotii* KCL-24 as a novel food**

**Last updated on:** 30/04/2025
**Status:** Ongoing Risk Assessment

# OPENEFSA




**Question:** How, a co-notifier can check the dossier? is it possible?

EFSA-Q-2024-00625 | Status: Ongoing Risk Assessment

## Subject

Application for authorization of Dry biomass of *Paecilomyces variotii* KCL-24 as a novel food

## Substances

| Name | CAS |
|---|---|
| Paecilomyces variotii KCL-24 | |

## Output

No Output has been formed yet for this question.

## Supporting documents

All files

## Timeline

24-10-2025
**Risk Assessment Deadline**

24-01-2025
**Dossier Valid**

**2025**

14-10-2024
**Dossier Received**

**2024**

## General Info

**Dossier number**
NF-2024-30790

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

# SUPPORT FOR APPLICANTS

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

## Services for applicants

Share:

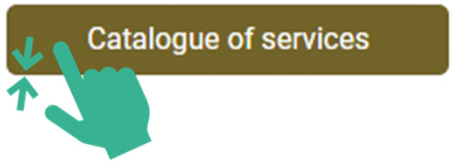
As part of EFSA's ongoing commitment to engage with its stakeholders and to increase understanding of its scientific *risk assessment* work, EFSA has developed a customer-oriented approach to stakeholders in the area of applications for regulated products. Aiming at an interactive and responsive evaluation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

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

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

**Contents**





# SUPPORT AT THE PRE-SUBMISSION PHASE

**Question:** The extent of the support that can be given during the pre-application consultation, particularly the advice on the type of studies that need to be conducted to comply with the requirements.

## General pre-submission advice (GPSA)

- At any time before the submission of a future application potential applicants can submit **questions on the rules and content of a future application.** The reply is provided by EFSA in written or in a telemeeting.
- During the advice, EFSA cannot enter into the study design, endorse or support a hypothesis to be tested. It is not a scientific advice.
- General explanations about the design of studies can be provided only if this is addressed in a EFSA's guidance document.
- SMEs can benefit from a fast-tracking service, i.e. GPSA reply preferably in a telemeeting and in 50% of the standard time.

# 2025 call for support to Novel Food SMEs NOW OPEN!

Supporting **SMEs in Novel Foods** with tailored pre-submission advice at two key stages:

- **Early development** - even before initiating studies
- **Final preparation** - when most dossier information is available

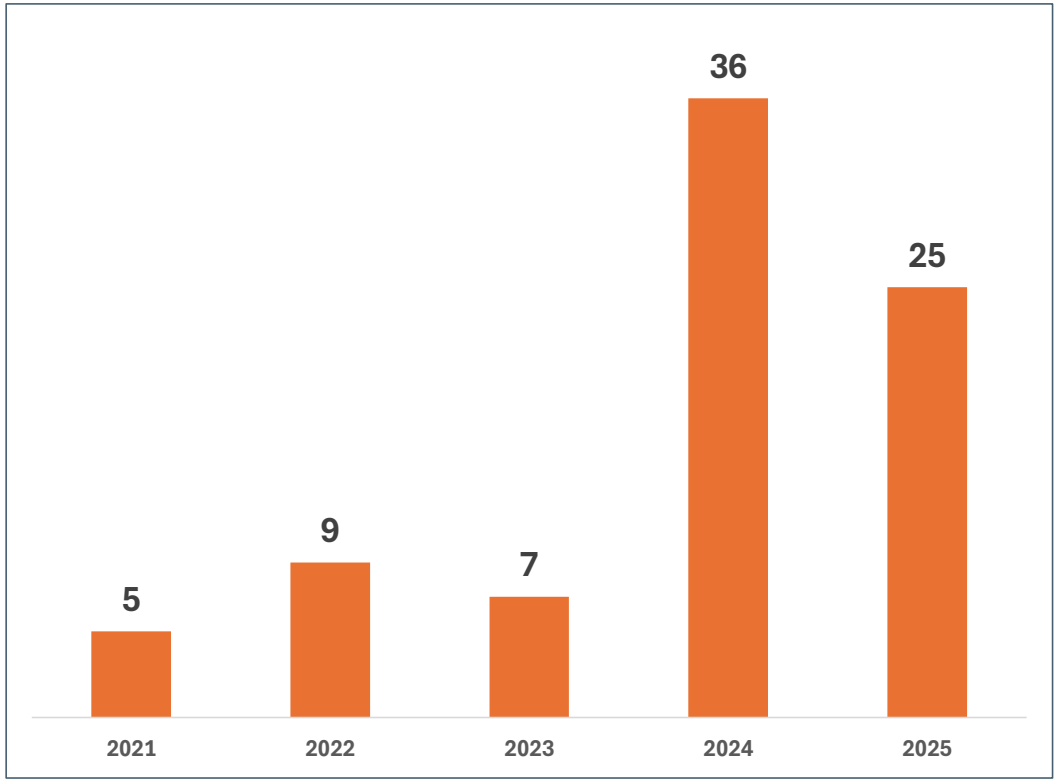
Advice provided through **tele-meetings**

**Confidentiality** ensured

## Learn more and apply by 12 June!

# TREND IN GENERAL PRE-SUBMISSION ADVICE

## GPSA requests on novel food applications received per year




- The numbers includes GPSA requests from SME and non-SME potential applicants.
- Change in the trend 2024 due to the "1st Call for support to Novel Food SMEs" launched in July 2024.
- Since Jan 2025, we have received 25 GPSA requests.

# OTHER SUPPORTING SERVICES

## Clarification teleconference during suitability check or risk assessment

- Organised **during the suitability check or risk assessment phase**, upon request of EFSA or the applicant.
- It can be used to clarify the rationale of questions and ensure understanding of the EFSA's request(s) by the applicant.

## Ask a question (at any stage)

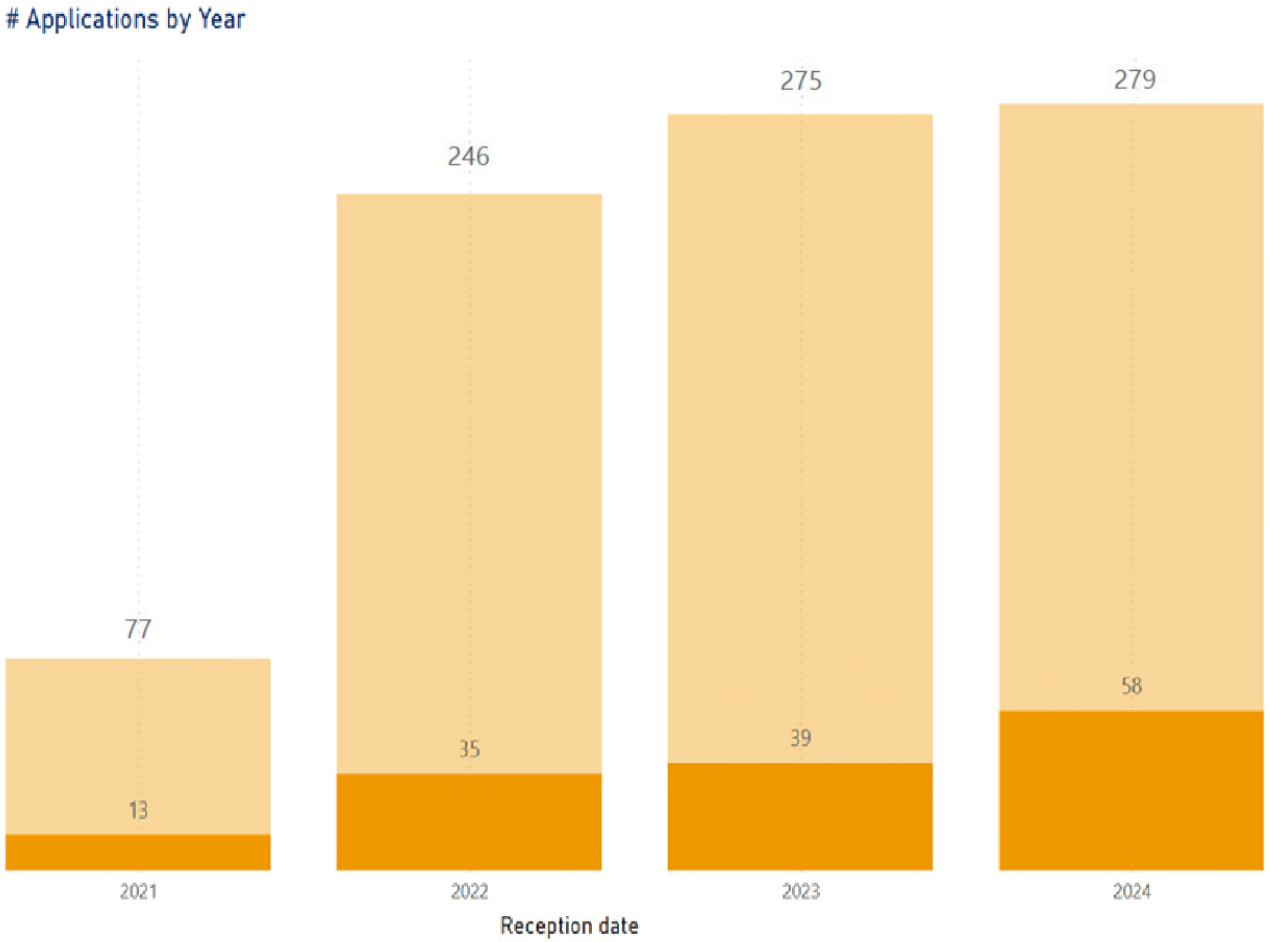
- To increase understanding on general requirements for submitting applications, procedural steps, status of applications, use of tools.
- SMEs can benefit from a fast processing of Ask a Question queries (usually within 7 working days).

## Dedicated support to SMEs on the use of IT tools

- Hands-on session provided by EFSA to guide a SME in the use of the IT tools needed for pre-submission activities and the submission of an application (i.e. Connect.EFSA, ESFC).
- It is recommended to SMEs facing issues when using the tools, it can be requested via the Ask a Question tool.

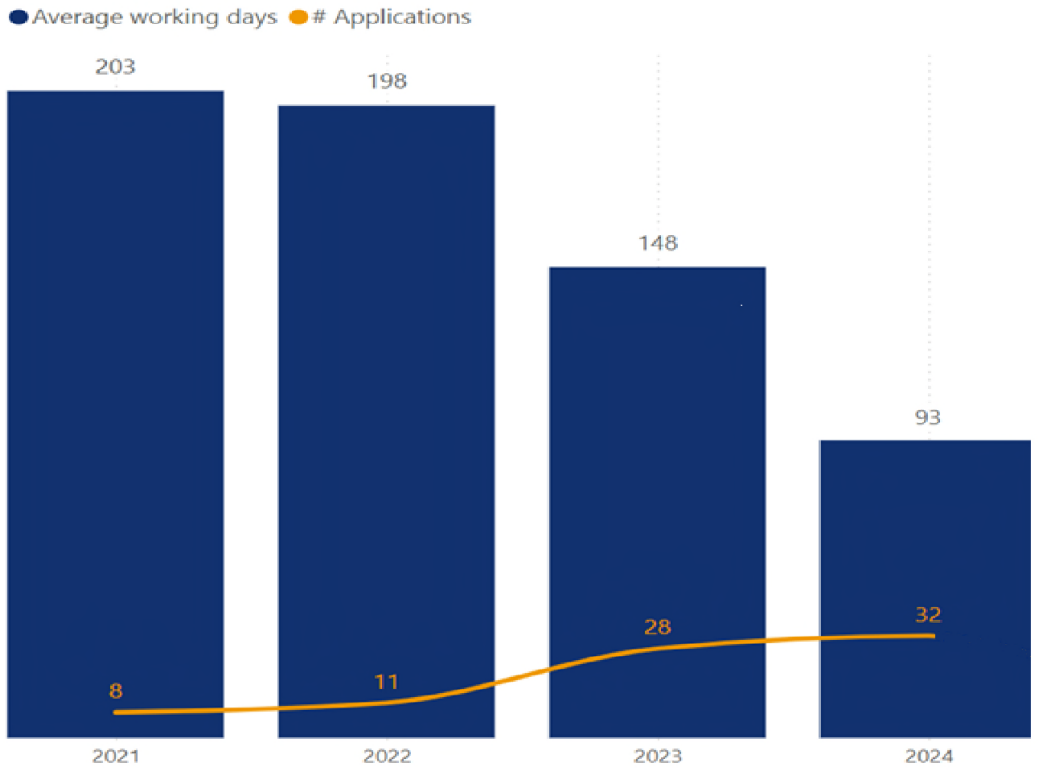
# SUITABILITY CHECK

# TOTAL vs NOVEL FOODS APPLICATIONS 2021 - 2024



# AVERAGE TIME FROM RECEPTION TO VALIDATION

**Question:** The suitability check timeline seems to have lengthen since the Transparency Regulation took effect. How do you explain that? Are you aiming to shorten lead times?



# CONFIDENTIALITY: MISTAKES TO AVOID

- **Personal data** visible in the non-confidential versions
- **Inconsistency**: confidential elements treated as non-confidential in different sections / documents
- Confidential and non-confidential version are not provided in accordance with the instructions:
  - **Confidential**: all information is visible, confidential elements boxed or earmarked
  - **Non-confidential**: identical, confidential elements irreversibly blackened

**Original**

Navigating Novel Food: what EFSA's updated guidance means for safety assessments.

John Doe walks us through the recent updates to the guidance for novel food applications.

**Confidential**

Navigating Novel Food: what EFSA's updated guidance means for safety assessments.

John Doe walks us through the recent updates to the guidance for novel food applications.

**Non-confidential**

Navigating [redacted] what EFSA's updated guidance means for safety assessments.

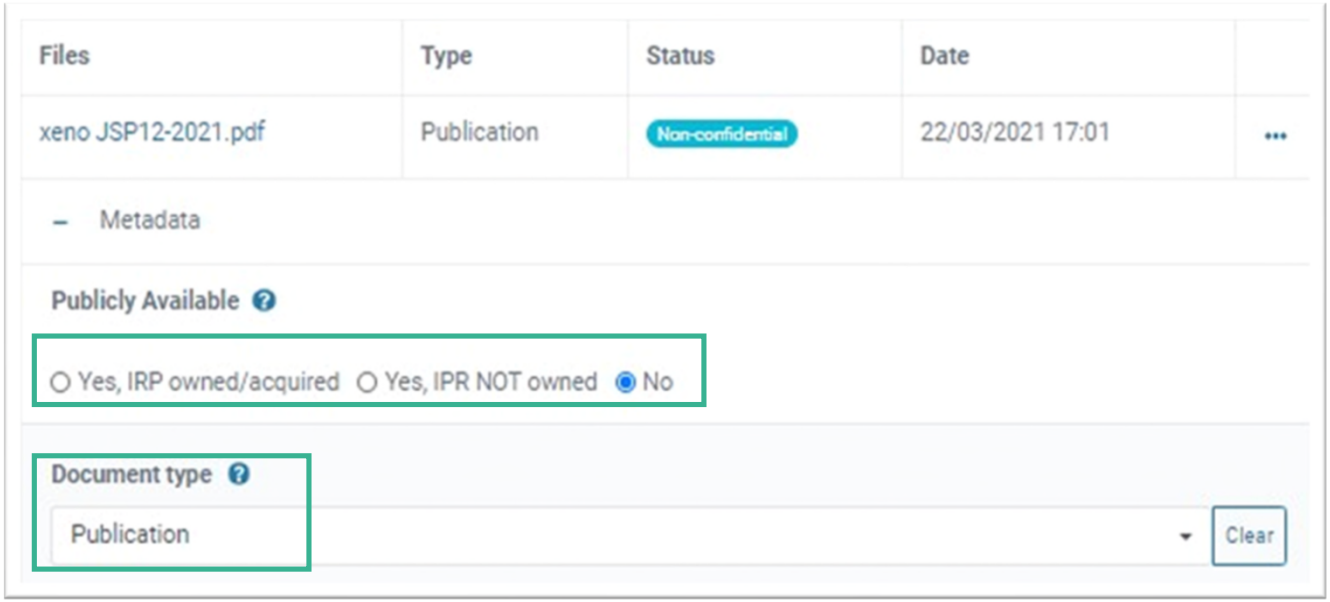
[redacted] walks us through the recent updates to the guidance for [redacted] applications.

**Reference:** EFSA User Guide on Confidentiality available at https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf

# TYPE OF DOCUMENT AND INTELLECTUAL PROPERTY RIGHTS

**Questions:** Clarity on how to handle copyright issues with submitted published articles and Submission of references and formats that are accepted (zip files vs individual uploads)

Study reports and bibliographic scientific literature should be correctly categorised following the indications in the ESFC help menu and EFSA guidance documents.




Zip files are accepted as long as they comply with the previous rules.

**Reference:** Last version of ESFC user guide available at https://food.ec.europa.eu/horizontal-topics/general-food-law/training-and-support_en

Examples of common errors:

- Wrong categorisation of public documents as non-public and consequent missing IPR declaration.
- Cover letters, technical dossier texts, etc. categorised as “publicly available”.
- To claim proprietary “IPR owned” EFSA documents used as supporting literature in the application.
- “IPR reference” is missing or wrong.

# OTHER ADMINISTRATIVE ISSUES IN NF APPLICATIONS

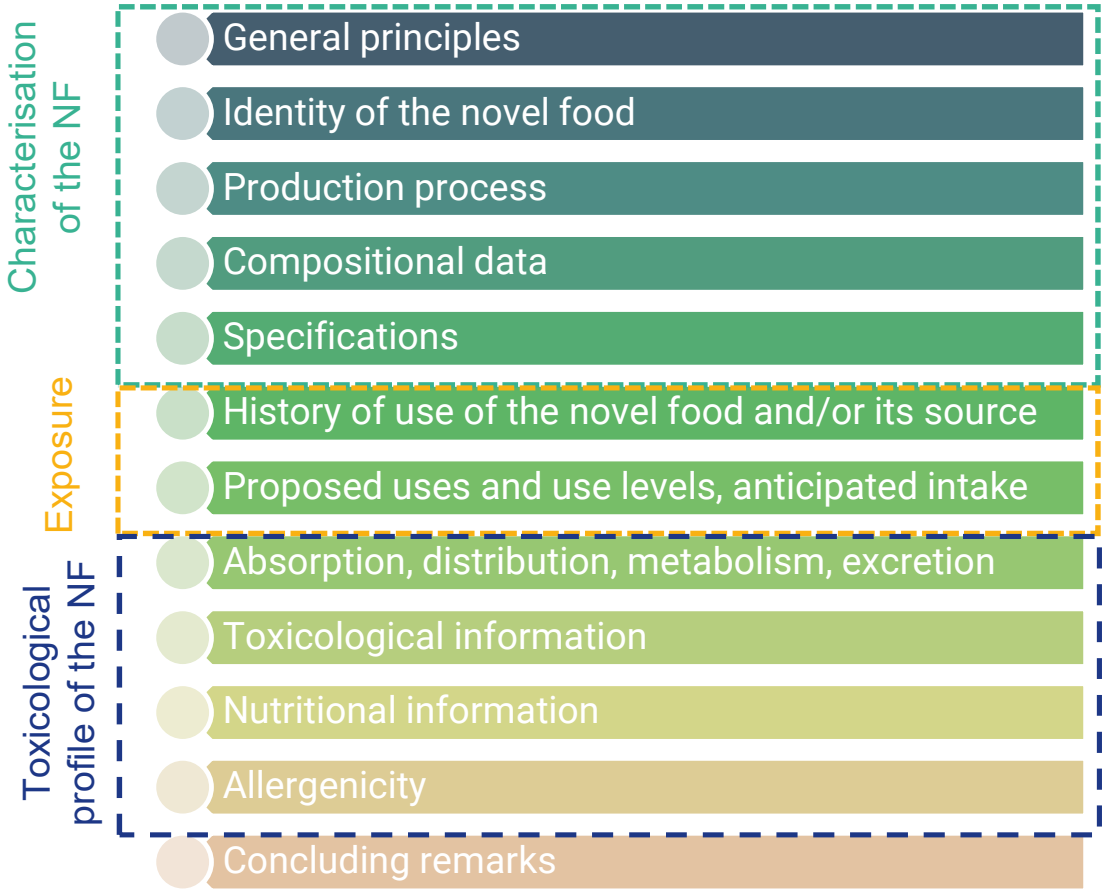
- **Notification of Studies**:
  - Lack of signature and/or starting date in study reports
  - Metadata wrongly completed or not consistent with the NoS Database
  - Justification for delay in the notification not added and/or supporting documents not provided
  - Withdrawn/not submitted studies not indicated
  - Studies not linked to the current pre-application ID

- **Wrong formatting**:
  - Documents submitted in languages different from English
  - Non-word searchable documents (in particular, scanned documents)
  - Documents wrongly categorised in ESFC
  - Complex naming of documents and consistency around the technical dossier text

- **Table of contents is not respected/upload of documents in wrong sections**:
  - e.g. documents on Identity of the NF are uploaded under Production Process


- **Same annex is uploaded in different sections of the dossier**:
  - Upload it only once, in the section that is more relevant. In the remaining sections, a reference will suffice

# SCIENTIFIC GUIDANCE ON NF – GENERAL SHORTCOMINGS




**Supporting documentation is missing in different sections of the application:**

- Certificates of analysis / raw data
- Study reports
- Comprehensive literature reviews
- Bibliographical references
- When used in the production process:

❑ Food enzymes: information on the regulatory status or previous EFSA's assessments

❑ Microorganisms: WGS sequence and FASTA files in the correct format*



*EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain

# CHARACTERISATION OF THE NF - SHORTCOMINGS

- General principles
- Identity of the novel food
- Production process
- Compositional data
- Specifications

- Lack of characterisation of the NF which is essential for the risk assessment of NF applications
- The NF or the novel part is not well identified. What is the NF subject of the application?
- Missing a clear distinction with regards to the non-novel ingredients/excipients used to formulate the final product intended to be marketed
- Missing information about the production process materials used, description of steps, description of measures implemented for production control and quality and safety assurance
- Missing information and description of the analytical methods used, validation reports in case of in-house methods and accreditation certificates for the laboratories
- Number of analysed batches / Inconsistencies in batch numbers
- Missing / incomplete data on stability
- Specifications not supported by compositional data

# EXPOSURE - SHORTCOMINGS

**History of use of the novel food and/or its source**

**Proposed uses and use levels, anticipated intake**

- Information on authorisations in non-EU countries not consistent with the administrative sections
- Comprehensive literature review of human studies missing
- Information on the proposed uses (food categories and maximum levels of use) not clear and/or inconsistent along the dossier
- Proposed uses should be listed and mentioned also in the “cover letter” and in the “administrative data”
- Food categories for the proposed uses not listed
- Maximum amounts of the NF in the food categories not indicated
- Target population not clear

# TOXICOLOGICAL PROFILE - SHORTCOMINGS

**Absorption, distribution, metabolism, excretion (ADME)**

**Toxicological information**

**Nutritional information**

**Allergenicity**

- Toxicological data missing, (e.g. deviating from the proposed Tiered approach) and no scientifically sound rationale is provided
- Missing supporting documentation, e.g. quality certifications of laboratory and accreditations, GLP statements for tox studies
- Information on the nutritional profile of the NF and comparison with similar foods already authorised

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