



# EFSA'S SUPPORT TO SME APPLICANTS (MICROBIAL FOOD REGULATED PRODUCTS)

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FDP Unit

11/04/2025

MIFFI Conference - Copenhagen

# OUTLINE



1

About EFSA

2

Application procedure

3

Support to applicants

4

Final remarks



# ABOUT EFSA



EFSA was established under EU law in 2002 following a series of food crises

**TO**

**Improve** the EU food safety system

**Help ensure** a high level of consumer protection

**Restore and maintain** confidence in the EU food supply

**Clearly separate** risk assessment and risk management functions



ESTABLISHED  
**2002**

**+570** staff

**650** experts

**1,600** virtual meetings / year

**9,300** scientific outputs since 2003





## What EFSA does



Provides independent scientific advice and support for EU risk managers and policy makers on food and feed safety



Provides independent, timely risk communication



Promotes scientific cooperation





**What EFSA  
does NOT do**



Develop food safety policies & legislation



Adopt regulations, authorise marketing of new products



Enforce food safety legislation

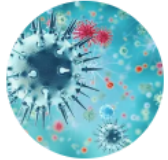


# FOOD REGULATED AREAS: APPLICATION PROCEDURE





# FOOD REGULATED AREAS



## Biological hazard and animal welfare applications

Animal by-product treatments, decontamination substances, stunning methods



## Feed additive applications

Additives and products or substances used in animal feed



## Food contact material applications

Materials, plastic recycling processes, active and intelligent substances



## Food improvement agents applications

Food additives, food enzymes and flavourings, smoke flavourings



## GMO applications

GMOs for use as food or feed and/or for cultivation



## Novel food and traditional food applications

Novel foods and food ingredients, traditional food



## Nutrition applications

Health claims, novel foods, infant formulae, food allergies, nutrient sources

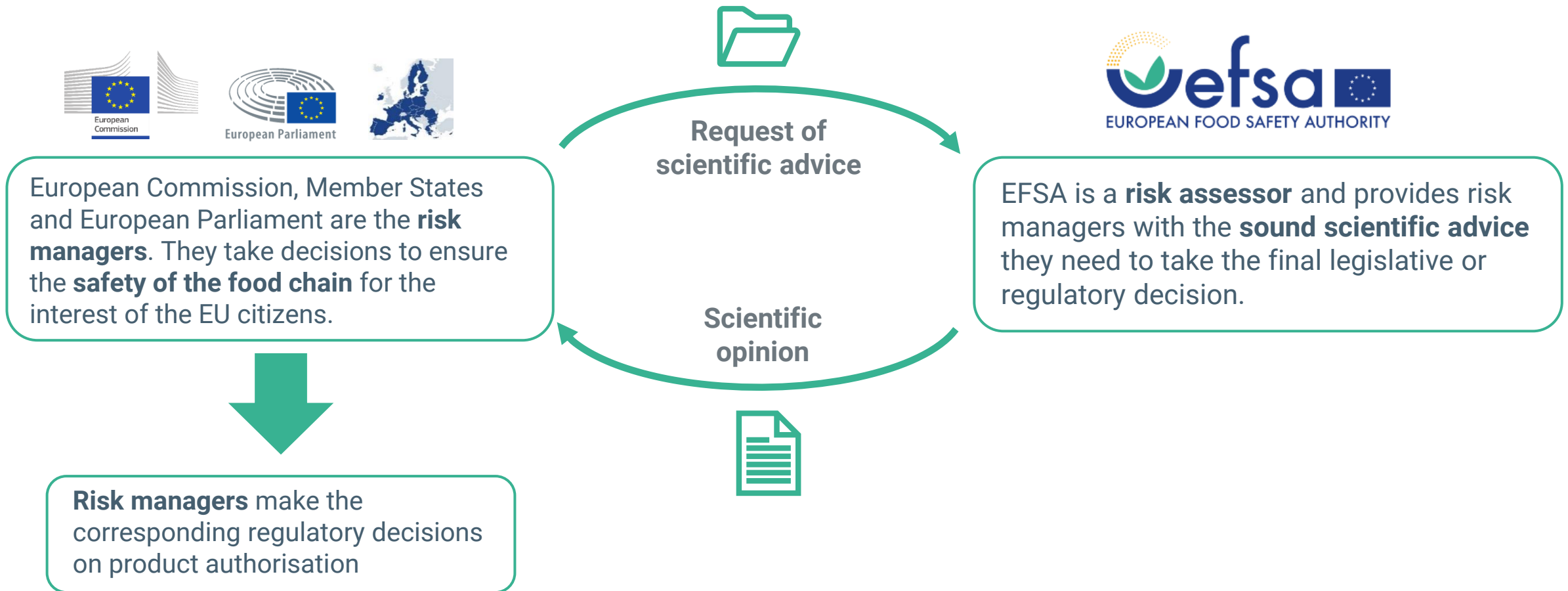


## Pesticide evaluations

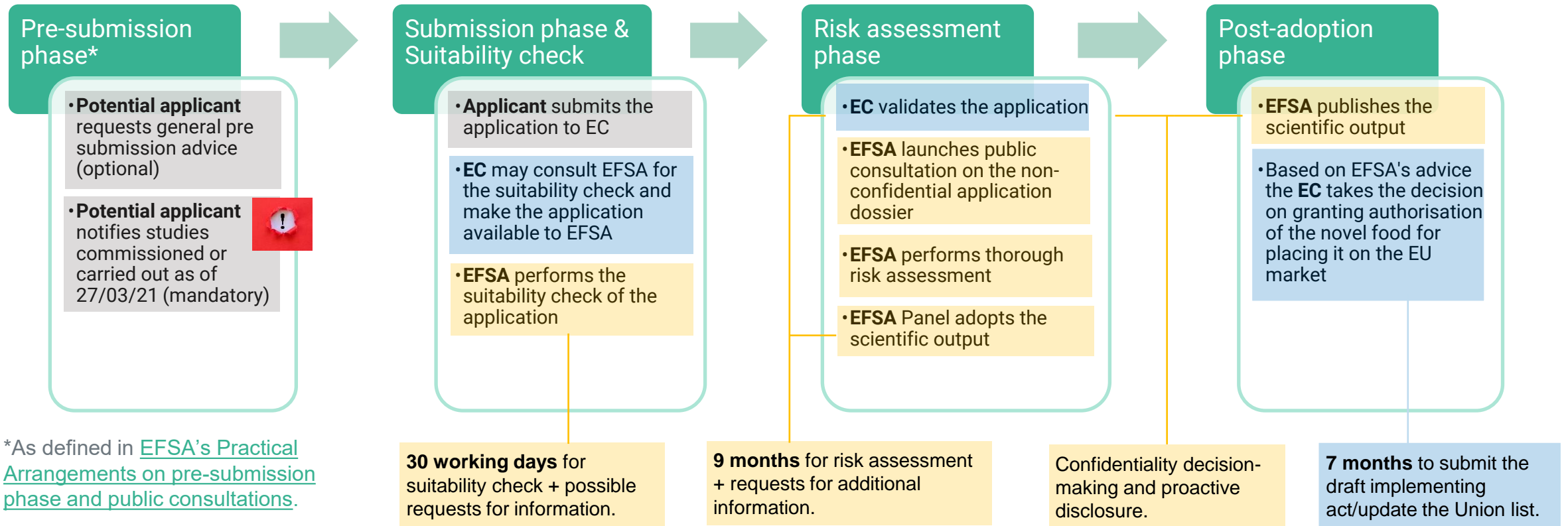
Active substances, maximum residue levels



# EFSA'S ROLE IN THE AUTHORISATION OF FOOD REGULATED PRODUCTS



# NOVEL FOODS APPLICATION PROCEDURE



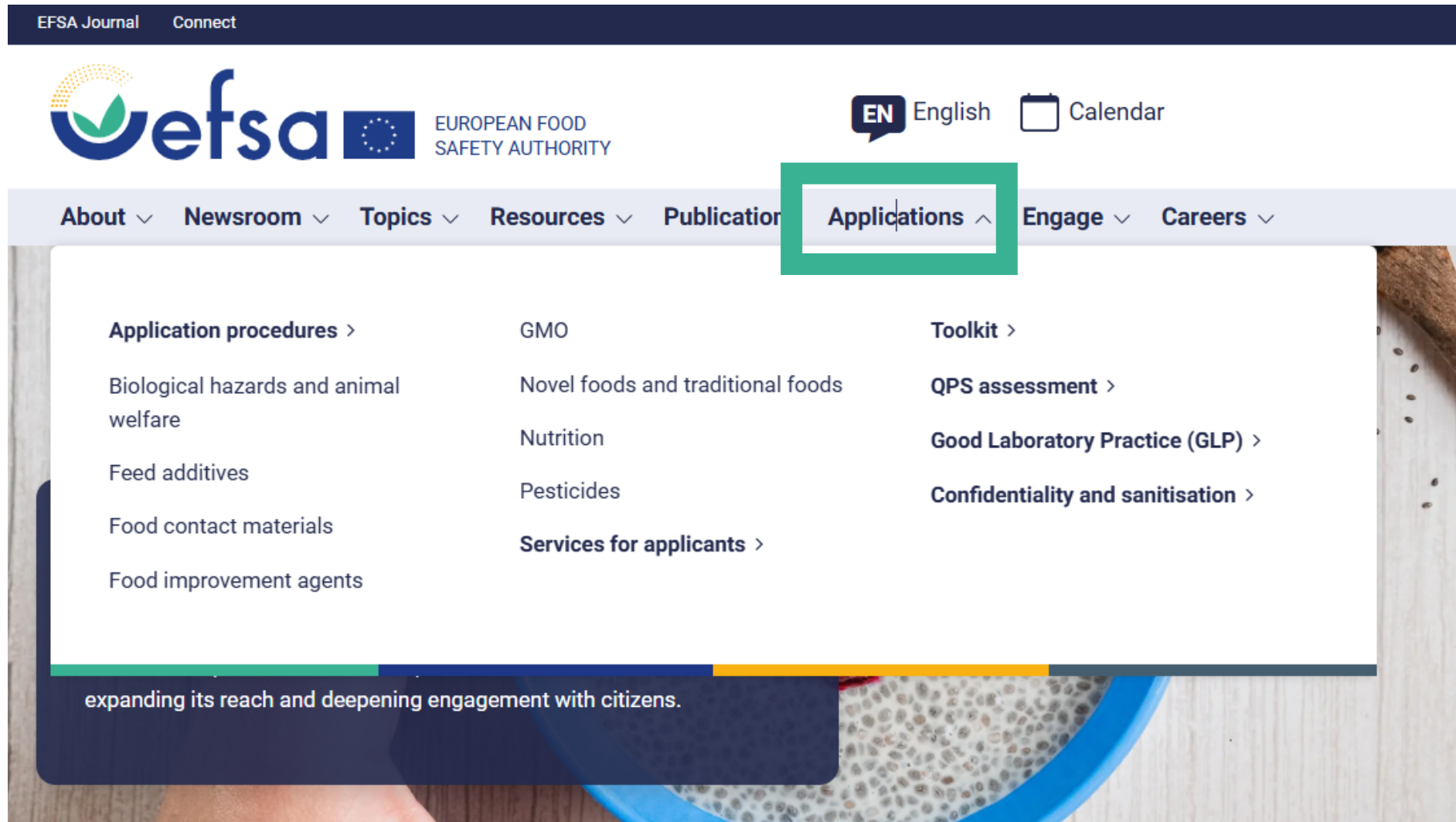
\*As defined in [EFSA's Practical Arrangements on pre-submission phase and public consultations.](#)



# SUPPORT TO APPLICANTS






# KEY INFORMATION IS AVAILABLE ON EFSA WEBSITE



The screenshot displays the EFSA website header and navigation menu. The 'Applications' menu item is highlighted with a green box. Below the navigation bar, a list of application-related topics is shown, including 'Application procedures', 'Biological hazards and animal welfare', 'Feed additives', 'Food contact materials', 'Food improvement agents', 'GMO', 'Novel foods and traditional foods', 'Nutrition', 'Pesticides', 'Services for applicants', 'Toolkit', 'QPS assessment', 'Good Laboratory Practice (GLP)', and 'Confidentiality and sanitisation'. A dark blue banner at the bottom of the page contains the text 'expanding its reach and deepening engagement with citizens.'

EFSA Journal Connect

  EUROPEAN FOOD SAFETY AUTHORITY

EN English  Calendar

About ▾ Newsroom ▾ Topics ▾ Resources ▾ Publications ▾ **Applications** ▾ Engage ▾ Careers ▾

- Application procedures** >
- Biological hazards and animal welfare
- Feed additives
- Food contact materials
- Food improvement agents
- GMO
- Novel foods and traditional foods
- Nutrition
- Pesticides
- Services for applicants** >
- Toolkit >
- QPS assessment** >
- Good Laboratory Practice (GLP)** >
- Confidentiality and sanitisation** >

expanding its reach and deepening engagement with citizens.



# SECTORIAL REGULATIONS AND GUIDANCE DOCUMENTS



## Feed additive applications

Additives and products or substances used in animal feed

<https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance>



## Food improvement agents applications

Food additives, food enzymes and flavourings, smoke flavourings

<https://www.efsa.europa.eu/en/applications/food-improvement-agents/regulationsandguidance>



## GMO applications

GMOs for use as food or feed and/or for cultivation

<https://www.efsa.europa.eu/en/applications/gmo/regulationsandguidance>



## Novel food and traditional food applications

Novel foods and food ingredients, traditional food

<https://www.efsa.europa.eu/en/applications/novel-food-traditional-food/regulationsandguidance>



## Nutrition applications

Health claims, novel foods, infant formulae, food allergies, nutrient sources

<https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance>



## Pesticide evaluations

Active substances, maximum residue levels

<https://www.efsa.europa.eu/en/applications/pesticides>



# SECTORAL REGULATION AND GUIDANCE DOCUMENTS (NOVEL FOODS)

## Regulatory framework

- Regulation (EU) 2015/2283 on novel foods
- Regulation (EU) 2017/2469 on administrative and scientific requirements for novel foods applications
- Regulation (EU) 2017/2470 on establishing the Union list of novel foods
- Regulation (EU) 2018/456 on the information requirements that need to be included in the consultation request to establish the novel food status

## Administrative and Scientific guidance

- **Administrative guidance** for the preparation of novel food applications in the context of Article 10 of Regulation (EU) 2015/2283
- Appendix A – **Suitability checklist** for the preparation of NF applications
- **Guidance on the scientific requirements** for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283



### Regulations and guidance

Legal framework, administrative and technical guidance

Information on how to compile dossiers for applications



# SECTORAL ADMINISTRATIVE GUIDANCE (EXAMPLE: NOVEL FOODS)

Technical Report



APPROVED: 23 September 2024  
IMPLEMENTATION DATE: 1 February 2025  
doi: 10.2903/sp.efsa.2024.EN-9041

## Administrative guidance for the preparation of novel food applications in the context of Article 10 of Regulation (EU) 2015/2283

European Food Safety Authority (EFSA)

### End-to-end guide through the application process:

#### Preliminary actions for preparing an application for novel foods

##### Pre-submission phase

- 2.1. General pre-submission advice
- 2.2. Notification of studies

##### From submission of the application to adoption of EFSA's scientific opinion

- 2.4. Submission of an application
- 2.4. Receipt of the application by EFSA
- 2.5. Suitability check of data for RA and validation of the application
- 2.6. Transparency and confidentiality requirements
- 2.7. Public consultation on information contained in the application
- 2.8. Risk assessment, adoption and publication of EFSA's scientific opinion
- 2.9. Spontaneous submission of information
- 2.10. Withdrawal of an application
- 2.11. Preparation of the dossier





# SCIENTIFIC GUIDANCE(S) (EXAMPLE: NOVEL FOODS)

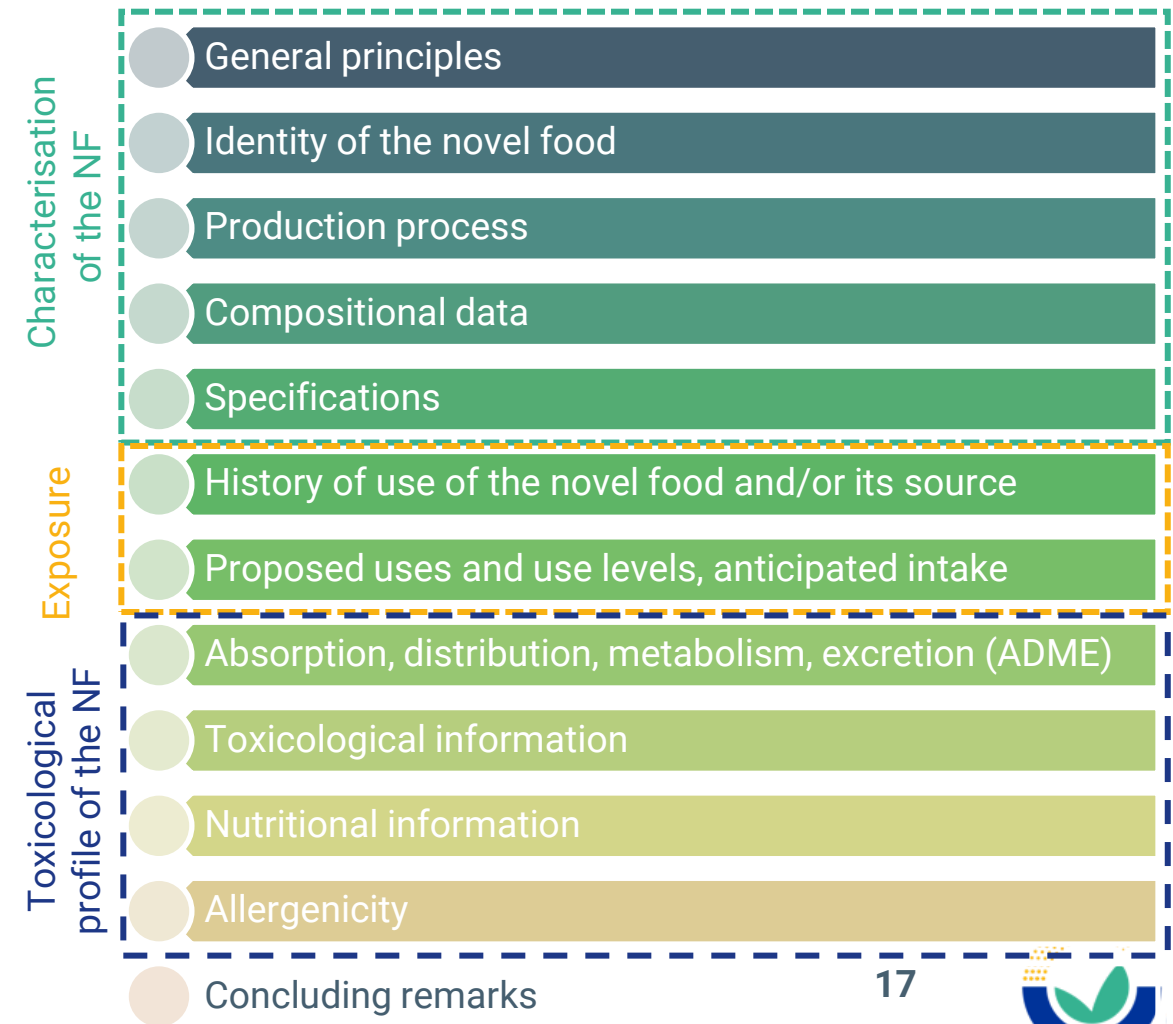
Adopted: 27 June 2024  
DOI: 10.2903/j.efsa.2024.8963

**GUIDANCE**

**efsa JOURNAL**

## Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) | Dominique Turck | Torsten Bohn | Jacqueline Castenmiller | Stefaan de Henauw | Karen Ildico Hirsch-Ernst | Alexandre Maciuk | Inge Mangelsdorf | Harry J. McArdle | Androniki Naska | Kristina Pentieva | Alfonso Siani | Frank Thies | Sophia Tsaouri | Marco Vinceti | Margarita Aguilera Gómez | Francesco Cubadda | Thomas Frenzel | Marina Helnonen | Monika Neuhäuser-Berthold | Carmen Peláez | Morten Poulsen | Miguel Prieto Maradona | Josef Rudolf Schlatter | Alexandros Siskos | Henk van Loveren | Reinhard Ackerl | Océane Albert | Domenico Azzollini | Antonio Fernández Dumont | Wolfgang Gelbmann | Andrea Germini | Maria Glymenaki | Georges E. N. Kass | Eirini Kouloura | Marcello Laganaro | Leonard Matijevic | Vânia Mendes | Estefanía Noriega Fernández | Irene Nuin Garciaarena | Gabriela Precup | Ruth Roldán Torres | Annamaria Rossi | Emanuela Turla | Silvia Valtueña Martínez | Ermolaos Ververis | Helle Katrine Knutsen



# SPECIFIC DOCUMENTS – MICROBIAL FOOD REGULATED PRODUCTS

Adopted: 28 June 2024  
DOI: 10.2903/j.efsa.2024.8912

**STATEMENT**


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

European Food Safety Authority (EFSA)



[EFSA statement on requirements for WGS](#)

**DRAFT**  
under revision



1  
2  
3 **Guidance on the characterisation and risk assessment**  
4 **of microorganisms used in the food chain**

5 **Endorsed for public consultation by the Scientific Committee on**  
6 **21 November 2024**

7 **Abstract**

8 © 2024 Wiley-VCH Verlag GmbH & Co. KGaA on behalf of the European Food Safety Authority

Public consultation ended last February  
Adoption expected by the end of this year  
[Follow the status in Open.EFSA](#)



# ALSO AVAILABLE ON THE WEBSITE: TOOLKIT - IT PLATFORMS

## Engage



### Connect

Bringing together EFSA and its stakeholders

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

## Submit



### ESFC

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

## Follow



### OpenEFSA

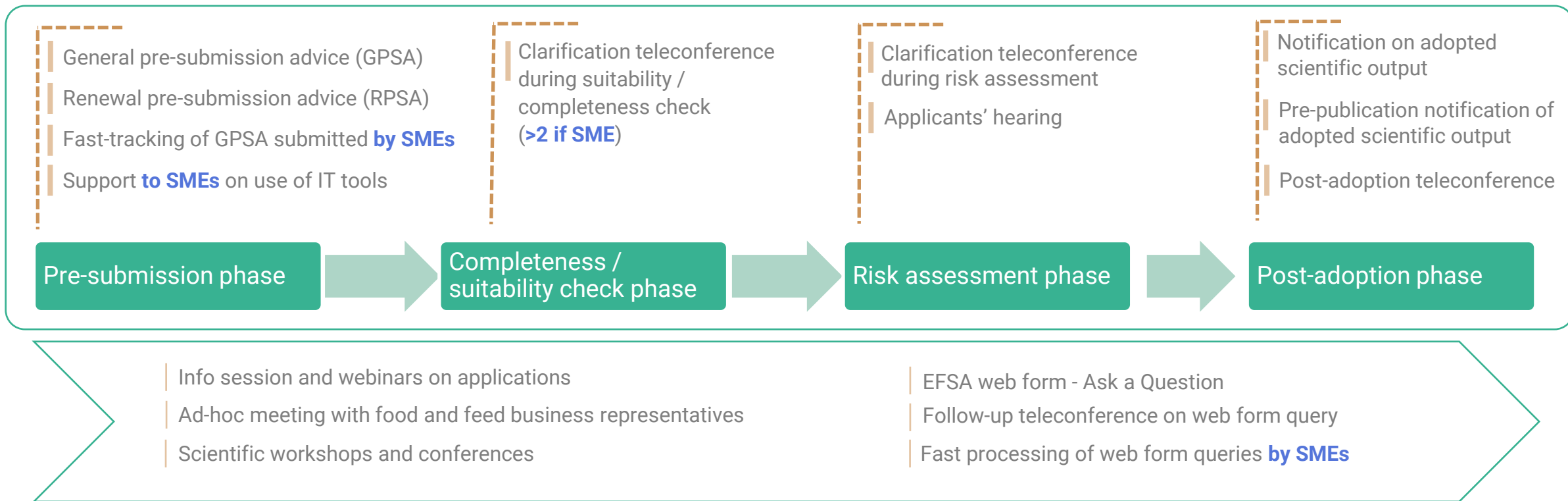
All you need to know about our risk assessments

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



# SUPPORT INITIATIVES DURING THE LIFE-CYCLE OF APPLICATIONS

## CATALOGUE OF SUPPORT INITIATIVES



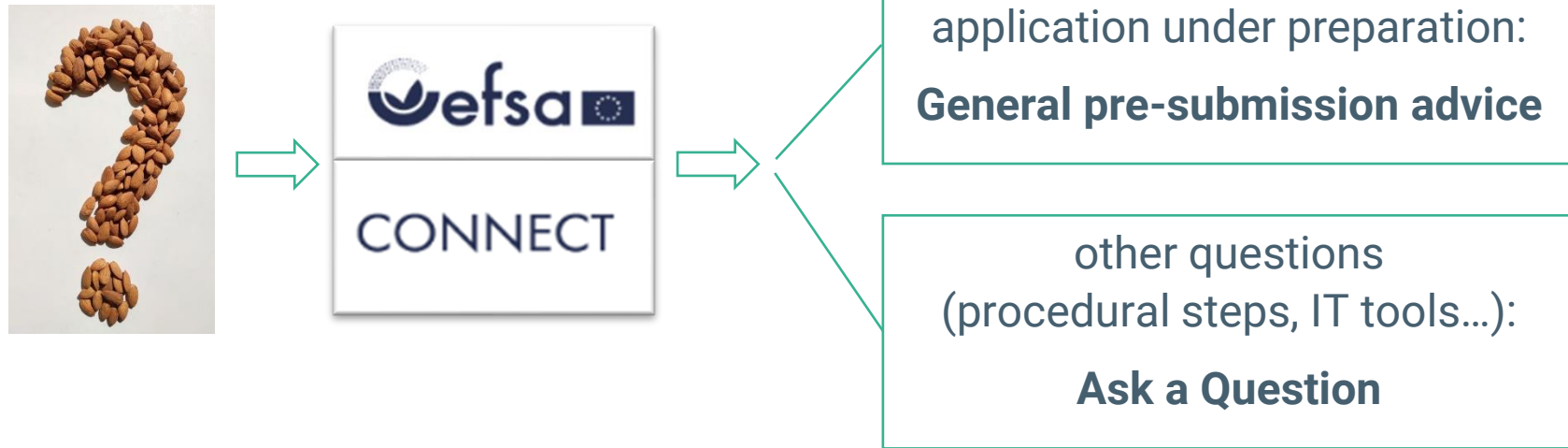
### + 'beyond the Catalogue' initiatives

LinkedIn group 'Support to applicants', mass mailing, informative campaign, call for expression of interest on GPSA, conference attendance with EFSA info point, training sessions organised by Industry Associations



# QUESTIONS DURING THE PREPARATION OF THE APPLICATION?

EFSA is offering two services so the applicant can address doubts to EFSA, *even in very early stages of the preparation of your application*

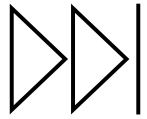


Pre-submission phase\*

• **Potential applicant** requests general pre submission advice (optional)



# SME-TAILORED SERVICES



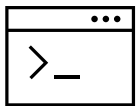
## Fast processing of **Ask a Question** queries

- replies within 7 working days instead of 15



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

- reply preferably in a tele-meeting and in 50% of the standard time lime



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

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



# EXTRA-CATALOGUE ACTIVITIES: CALL 2024 TO SUPPORT NOVEL FOOD SMES



## Aim

raise awareness and facilitate access for Novel Food SMEs to the **General pre-submission advice service**



## Long-term expected benefit

Better quality of NF applications submitted and speed up the Risk Assessment

## Call 2024

### *Early briefing meetings:*

Reply to questions +  
Key information on what is needed to prepare an application.

### *Pre-submission meetings:*

Reply to questions +  
flagging frequent shortcomings on applications



# CALL 2024 - TIMELINE AND KEY NUMBERS

## Call open

25/06/24 - 31/10/24

## Appraisal of EOIs

26/06/24 - 16/12/24

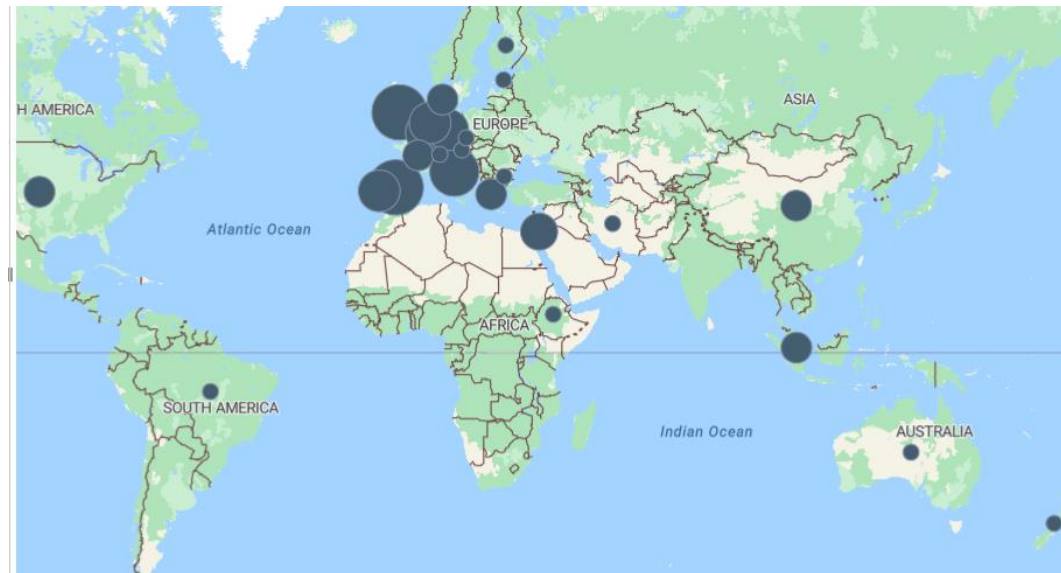
## GPSA tele-meetings

25/07/24 - 30/04/25

66 EOIs received  
(2 duplicates)

47 Eligible

41 *tele-meetings*



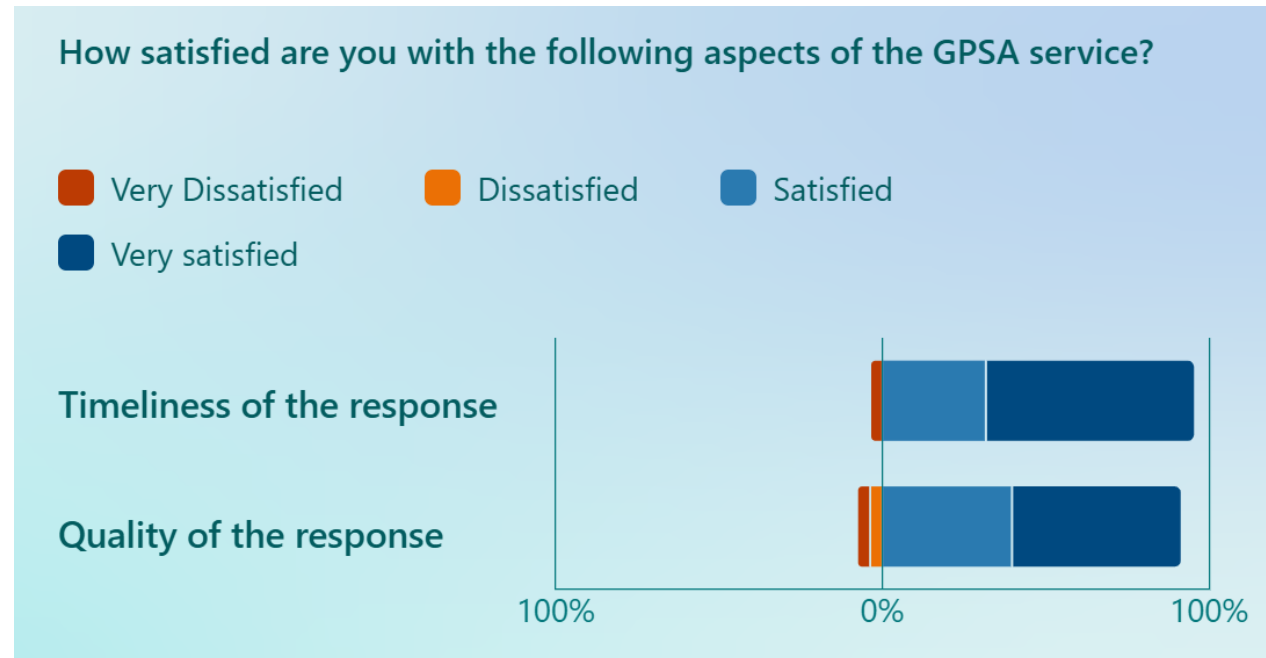
**70%**  
of SMEs submitting EOIs  
never approached  
EFSA before

EOI: expression of interest





# CALL 2024 – SATISFACTION SURVEY



- Respondents found the GPSA service informative and useful and appreciated the direct communication with EFSA staff
- Helpful in clarifying doubts and providing valuable information for Novel Food dossier submission
- However, some respondents noted that the advice was limited in scope and general



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** - most dossier information is available

Advice provided through **tele-meetings**

**Confidentiality** ensured

**Deadline 12 June**



# FINAL REMARKS



# IN CASE OF FURTHER QUESTIONS TO EFSA:

Visit our Info point or contact EFSA:



on rules and content of an application under preparation:  
**General pre-submission advice**

other questions  
(procedural steps, IT tools...):  
**Ask a Question**



# STAY CONNECTED



## 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

[www.linkedin.com/groups/9083910/](https://www.linkedin.com/groups/9083910/)

