

MS ROLE IN MANAGING APPLICATIONS FOR REGULATED PRODUCTS (NON-PEST)



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OUTLINE



Regulated products at EFSA

Applications procedure and MS role

IT Platforms

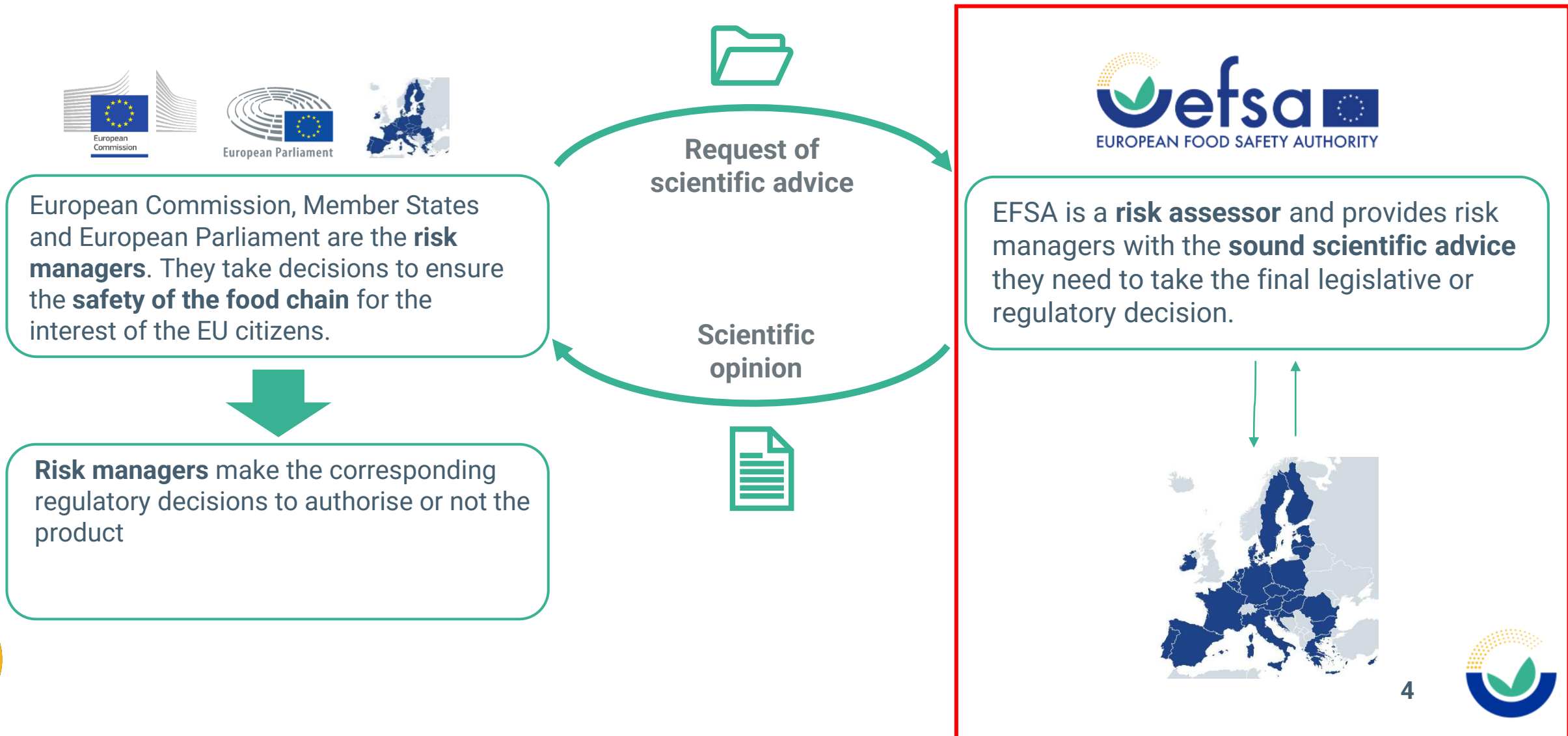
Final remarks

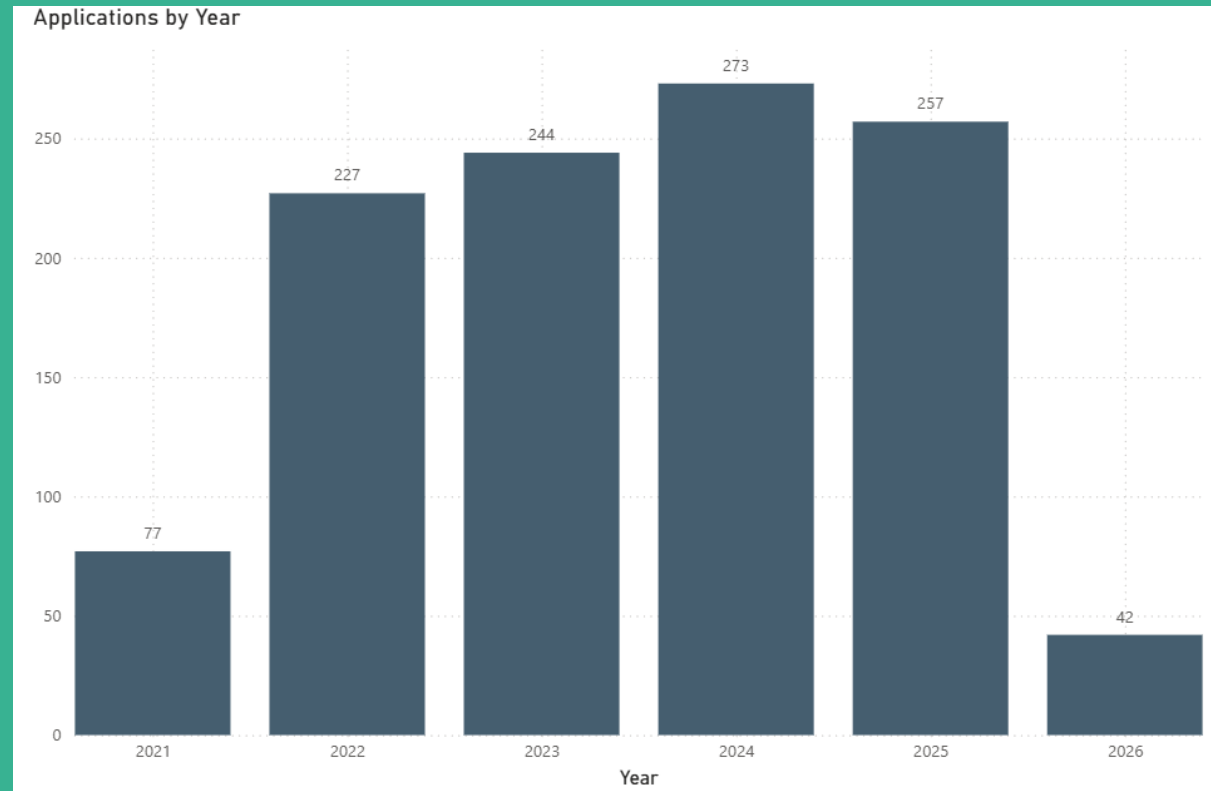


**REGULATED
PRODUCTS AT
EFSA**



EFSA'S ROLE IN THE AUTHORISATION OF FOOD REGULATED PRODUCTS

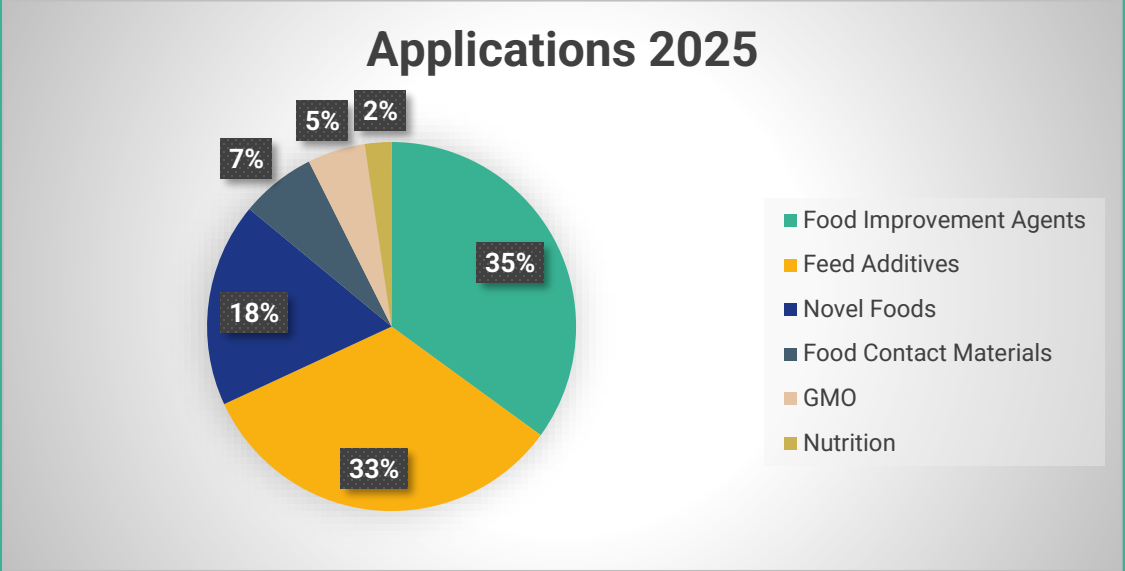




Information current as of 22/02
Data Post -Transparency

Each year, EFSA receives over 200 applications for the authorization of regulated products





Food domain	pcode	Count of App
Feed Additives	Total	85
	02.02.03 Feed additives	85
Food Contact Materials	Total	17
	02.02.08 Food contact materials	17
Food Improvement Agen	Total	90
	02.02.06 Food additives	2
	02.02.09 Enzymes	88
GMO	Total	13
Novel Foods	Total	46
	02.02.10 Novel Foods	46
Nutrition	Total	6
	02.02.14 Health Claims	6
Total		257

In 2025, EFSA received a total of 257 applications mainly on Food Enzymes, Feed Additives, and Novel Foods



APPLICATIONS PROCEDURE AND ROLE OF MS



APPLICATION PROCEDURES WEBPAGE

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



[Home](#) / [Application procedures](#)

Application procedures – how to submit a dossier for scientific evaluation

Last reviewed date: 2 December 2025

Many food and feed related products require a scientific assessment of their safety before they can be authorised for the EU market.

EFSA carries out these assessments in support of EU risk managers (European Commission, EU Member States) who decide whether to authorise them.

Organisations or companies that make these products must provide the evidence to prove that they are safe or, in some cases (e.g. health claims), backed by sound science.

I need to apply for a scientific evaluation. What do I do?

Select the product that needs evaluating from the list below.

[Biological hazard and animal welfare](#)

[Infant and follow-on formulae](#)

[Feed additive](#)

[Novel food](#)

[Food additive](#)

[Nutrient source](#)

[Food allergen labelling exemption](#)

[Pesticide active substance and MRLs](#)

[Food enzyme](#)

[Plastic recycling process](#)

[Food flavouring](#)

[Smoke flavouring](#)

[Genetically modified organism \(GMOs\)](#)

[Substances used in plastic food contact material](#)

[Health claim](#)

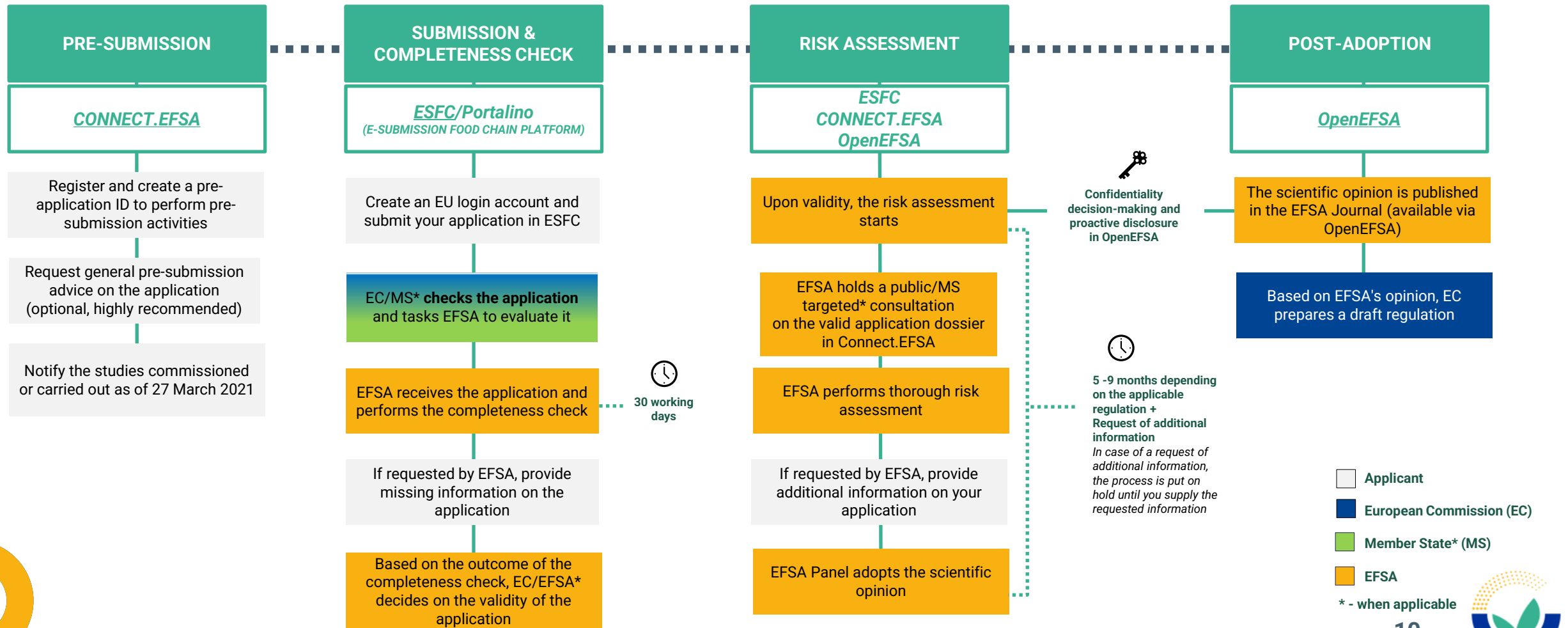
[Traditional food](#)



APPLICATION PROCEDURES PHASES



RISK ASSESSMENT AND POST-ADOPTION PHASES



PRE-SUBMISSION PHASE

MS role

- Promote among applicants the use of EFSA's General Pre-Submission Advice (GPSA) to prepare their dossiers before submission in ESFC

Determination of Novel Food status

- When the novel food status is unclear, the MS where the novel food will be marketed first shall be consulted in line with Regulation (EU) 2018/456



SUBMISSION AND COMPLETENESS CHECK

Food areas involving MS at submission

- Genetically modified organism (GMOs) – excluding renewals
- Plastic recycling process
- Substances used in plastic food contact material
- Smoke flavouring
- Health claim
- Alternative processing methods of animal by-products*

MS responsibilities

- Check the scope of dossiers submitted in ESFC
- Draft the mandate and send it to EFSA
- Forward the dossier to EFSA using ESFC

Contact EFSA in case of doubts before forwarding a dossier

* Submitted via Portalino



SUBMISSION AND COMPLETENESS CHECK

Health Claim applications

MSs are legally obligated to **verify the validity of Health Claim applications**, which involves:

- ensuring the completeness of data as specified in Article 15 of Regulation (EU) 1924/2006
- confirming compliance with Article 32b of Regulation (EU) 2019/1381 on notification of studies obligations

In 2025, EFSA shared with MS a dedicated information package for the correct handling of Health Claim applications



SUBMISSION AND COMPLETENESS CHECK

Traditional Food notifications and applications

Suitability consultation

EC reviews whether the notification meets the criteria outlined in Article 7(2) of Regulation (EU) 2017/2468 and requires MSs to check the dossier in ESFC and submit their comments. Simultaneously, EFSA provides its own feedback to the EC. At this stage, there is no direct interaction between EFSA and the Member States.

Duly reasoned safety objections

During the evaluation period (Art 9 of Reg (EU) 2017/2468) MS may submit duly reasoned safety objections to the placing on the market within the Union of the traditional food concerned. This is done in cooperation with the EC and EFSA and using the ESFC platform.



TARGETED CONSULTATIONS WITH MEMBER STATES

PURPOSE

- Gather feedback from MS on the confidential version of an application dossier
- Ensure transparent, structured, and harmonized involvement of MS who have full access to dossiers through the ESFC tool

WHEN

Upon application validation

SCOPE

Applicable to FEED ADDITIVES and GMO areas

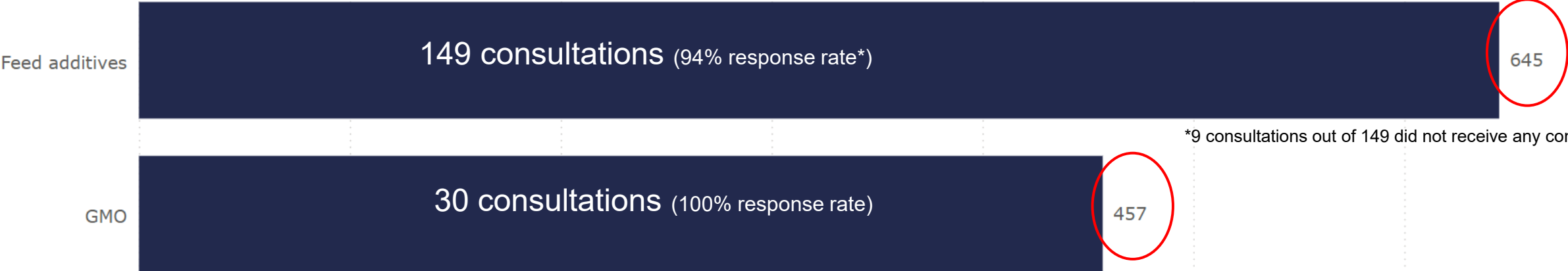
PROCESS & TOOLS

- Comments are gathered (since 2022) via Connect.EFSA
- MS have accounts allowing access to a restricted area to maintain confidentiality



TARGETED CONSULTATIONS AND COMMENTS 2024-2025

No. of closed consultations and comments received



*9 consultations out of 149 did not receive any comments



IT PLATFORMS



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Toolkit

Last reviewed date: 27 January 2025

IT PLATFORMS

Engage



Connect

Bringing together EFSA and its stakeholders

This portal gives the possibility to **engage with EFSA** on a variety of topics:

- **pre-submission activities** (GPSA, NOS)
- take part in public consultations
- **request information**
- browse frequently asked questions

Submit



ESFC/Portalino

ESFC (E-Submission Food Chain platform) is an online tool that allows applicants to **create, submit, and manage their applications**.

Portalino is another submission platform provided by EFSA, designed for submitting dossiers or data related to workflows not available in **ESFC**.

Follow



OpenEFSA

All you need to know about our risk assessments

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



FINAL REMARKS



FINAL REMARKS

Consult EFSA in case of doubts

Novel Food applications

MS shall be consulted by the operator in case of Novel Food status is unclear

Genetically modified organism (GMO)
Plastic recycling process
Substances used in plastic FCM
Smoke flavouring
Health claim
Alternative methods of animal by-products

Promote GPSA to potential applicants

Check scope of dossier submitted in ESFC in line with applicable Regulation

Draft and send mandate in line with dossier

Health Claim applications

MS are responsible for the validation of Health Claim Applications

Traditional Food applications

MSs check dossier in ESFC and submit comments during suitability consultation

MSs may raise duly reasoned safety objections during the evaluation period

FEED Additives and GMO applications

Targeted consultation after validation



FINAL REMARKS



CONTACT US

- Ask EFSA: <https://connect.efsa.europa.eu/RM/s/help>
- FDP unit : FDP@efsa.europa.eu



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