EU specialty food ingredients

FACTSHEET

WANTED: PRACTICAL EFSA TO ASSESS SPECIALTY FOOD INGREDIENTS SAFETY IN REAL-WORLD SETTINGS!

In short

The European Commission is evaluating the performance of the European Food Safety Authority (EFSA) for the first time.

The variety of specialty food ingredients is the result of continuous and substantial investment in innovation by EU manufacturers. They are committed to provide nutritional and technological solutions that meet the evolving societal demands for safe, healthy, tasty, convenient, sustainable and affordable foods and beverages.

Applicants are willing to provide EFSA with the essential information required for assessing ingredient safety. However, the excessive and illogical nature of certain EFSA's inquiries results in time-consuming responses, unnecessary delays, and growing frustration of applicants. This deters EU applications, even more because meeting certain requirements would involve producing at an industrial scale an ingredient that is still uncertain to be approved in the EU.

While maintaining a clear distinction between assessing and managing risks, the European Commission has a responsibility to ensure that EFSA performs risk assessments efficiently and proportionately.

What is going on?

The European Commission is evaluating the performance of the European Food Safety Authority (EFSA) for the first time. A report shall be sent to the European Parliament and to the Council by March 2026.

What are specialty food ingredients?

Specialty food ingredients encompass a wide array of components incorporated into foods for their nutritional and/or technological attributes. These components include vitamins, fibres, functional carbohydrates, additives, special proteins, and fats such as omega-3, along with salt replacers. The absence of specialty food ingredients would render the production of numerous products unfeasible. Among these goods are processed agricultural products, in which the European food industry reigns as the foremost global exporter, boasting a positive EU trade balance.

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How are (novel) specialty food ingredients developed & produced?

After extensive research and trials, a new food ingredient is developed on a small scale in a **laboratory**. It is then gradually scaled up in **pilot units** (from a few kilograms to several tons) to validate production parameters. Scale-up trials can be conducted internally or in external facilities that rent pilot materials for trial periods. Once a stable pilot production process is achieved, the developer can apply for authorisation.

Once it is permitted in the EU, the ingredient can be produced on an industrial scale by the applicant in new or existing facilities. The authorisation of a novel food ingredient or of a food additive being generic, other operators in the EU may produce it in their plants or import it from third countries.

In summary, a specialty food ingredient available on the EU market can be manufactured in multiple manufacturing plants within the EU or imported from third countries.

Why is it so important for EFSA to improve?

Most specialty food ingredients must first undergo a pre-market authorisation process to be used in food and beverage applications within the EU. This process involves EFSA conducting safety assessments.

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EFSA'S REQUIREMENTS COME FROM:

- guidance documents for applicants,
- questions from EFSA experts during the risk assessment.

Guidance documents

EFSA consults on draft guidance documents to improve them. Regrettably, when it comes to the real-world application of ingredient development and production, valuable feedback is consistently disregarded.

A few examples from the recent Novel Food Guidance:

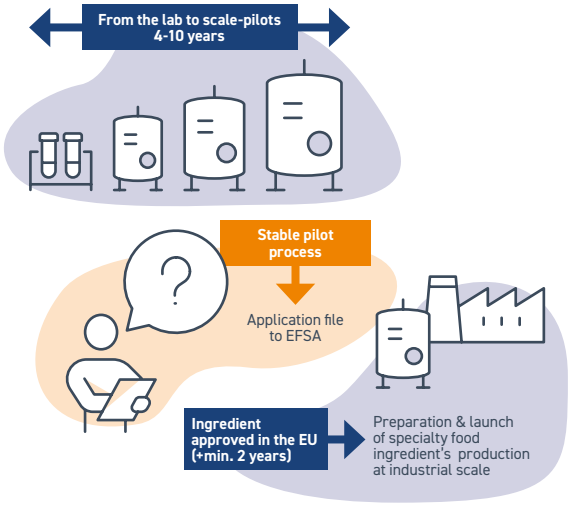
EFSA REQUIREMENTS

Declaration of compliance for every material in contact with the food ingredient.

WHY THIS DOES NOT MAKE SENSE

1. The ingredient is only produced at the pilot scale, so the information on food contact materials (FCMs) at this stage is only representative on what is known so far. FCMs in the future manufacturing plant most likely will differ from those in the pilot phase. Each manufacturing plant has a unique list of FCMs that must comply with EU legislation anyway.
2. Compliance with Regulation (EC) No 1935/2004 for food contact materials used in manufacturing plants is ensured by national control authorities. EFSA's requirement is premature and unnecessary.

From the lab to the manufacturing plant



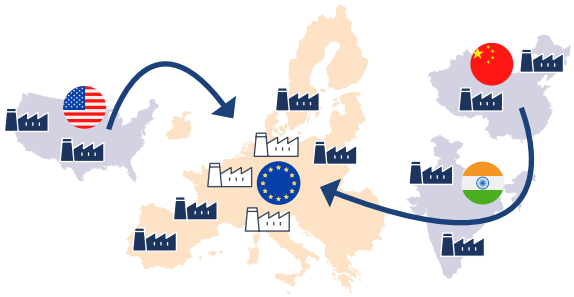
EFSA REQUIREMENTS

Detailed description of measures implemented for production control and quality and safety assurance (e.g., HACCP, GMP etc.). Sampling plan and protocols.

WHY THIS DOES NOT MAKE SENSE

1. The ingredient is only produced at the pilot scale. Information on food safety management systems is not representative as the measures in place at manufacturing plants differ from those in pilot trials. Each manufacturing plant has a unique food safety management system.
2. Compliance with EU legislation of food safety management systems at manufacturing plants producing specific ingredients is ensured by national control authorities and EU legislation. EFSA's requirement is premature and unnecessary.

Once approved in the EU, the specialty food ingredient can be produced and imported from multiple manufacturing plants



Manufacturing plants of original applicant of the specialty food ingredient that is granted an EU authorisation

Manufacturing plants of competitors (applications to EFSA not required)

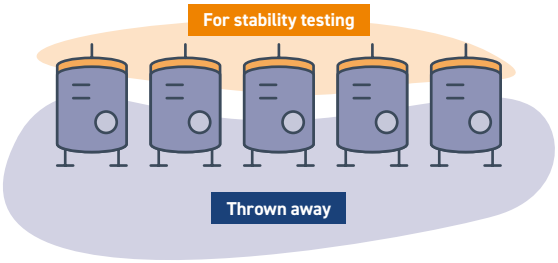
EFSA REQUIREMENTS

Chemical, physicochemical and microbiological stability testing of 5 production batches of the food ingredient over its shelf-life.

WHY THIS DOES NOT MAKE SENSE

Pilot trials are costly and will have a huge impact on the Return On Investment for start-ups and SMEs. Producing 5 different batches for stability testing is not cost-effective. The remaining pilot production goes to waste as the ingredient is not yet approved for sale.

EFSA requirements for stability testing



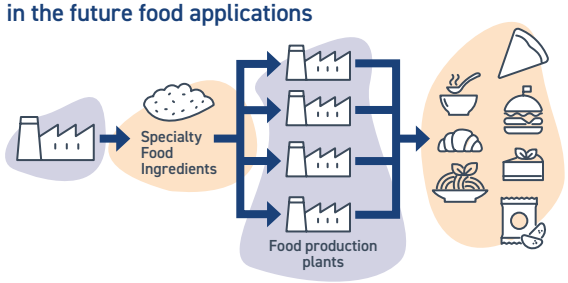
EFSA REQUIREMENTS

The impact of processing on the novel food ingredient in the future food applications shall be investigated and described.

WHY THIS DOES NOT MAKE SENSE

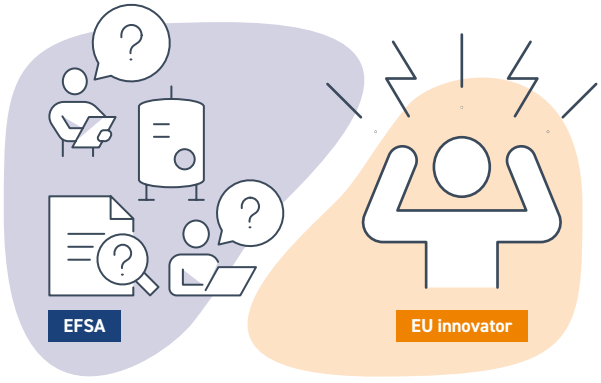
The information is only known by the future purchaser of the food ingredient (once permitted), not the applicant.

EFSA requirements on the impact of processing in the future food applications



Questions by experts during the risk assessment

In the risk assessment process, EFSA may introduce additional requirements that go beyond those listed in the guidance documents. Applicants may find it challenging to differentiate between questions that pertain to safety assessment of specialty food ingredients and questions driven by scientific curiosity. While it is commendable to deepen experts' scientific knowledge, data requests should solely focus on safety assessment needs.



A FEW QUICK FIXES

- **Strengthening EFSA experts' understanding of food technologies**
  - Broaden expertise in EFSA Working Groups and Committees with seasoned food technologists.
  - Train on practical development of novel ingredients and scale-up.
  - Organise visits to specialty food ingredient manufacturing plants.
- **Enhancing experts' knowledge on food legislation**
  - Ensure understanding of EU food laws and quality management system obligations.
- **Revamped interaction between the applicants and EFSA**
  - **Technical hearings** should be used more often to enable applicants to directly address experts' inquiries. An initial technical hearing should be consistently offered to the applicant to provide an overview of the application and its technology. It would save time and resources to both applicants and EFSA experts.
  - **Consider seriously industry's feedback on the draft guidance documents.** Food Business Operators and their associations provide thorough comments for practical and realistic implementation of future guidance documents.

These quick solutions may not solve every issue, but they will help reassure EU applicants that EFSA is committed to promptly addressing the unacceptable deviations observed in recent years.

What about the European Commission?

While maintaining a clear distinction between assessing and managing risks, the European Commission has a responsibility to ensure that EFSA performs risk assessments efficiently and proportionately.

Urgent actions are needed to recognise EU applicants as valuable partners in a competitive global market. It's time to act and not miss out on food ingredient innovation within the EU.

References

EU Specialty Food Ingredients' reply to the Call for Evidence "European Food Safety Authority – evaluation of performance 2017-2024"

EU Specialty Food Ingredients' factsheet: Wanted: high-performing EFSA for the safety assessment of specialty food ingredients

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

EU specialty food ingredients

EU Specialty Food Ingredients represents a united voice for the specialty food ingredients industry on scientific, technical and regulatory issues relating to food products in Europe. It is our aim to ensure that all stakeholders - from manufacturers and retailers to regulatory authorities and consumers - are correctly informed of the use, safety and benefits of specialty food ingredients. In total, more than 200 international and national food ingredients companies are currently involved in the Federation's activities through direct membership or an association. 3-8% of EU specialty food ingredients manufacturers' turnover is dedicated to research and development.

Identification number in the Transparency Register: 6160532422-38

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January 2025