EU specialty food ingredients

FACTSHEET

WANTED: HIGH-PERFORMING EFSA FOR THE SAFETY ASSESSMENT OF SPECIALTY FOOD INGREDIENTS!

In short

The European Commission is evaluating the performance of the European Food Safety Authority (EFSA) for the first time and has a unique opportunity to foster a cutting-edge and safe specialty food ingredient sector that enhances the global competitiveness and excellence of the European food and beverage industry. It's time to act and not let go of this incredible asset.

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

The speed and consistency of EFSA's scientific evaluations are essential for maintaining the economic viability and competitiveness of the specialty food ingredients industry in the EU. However, EU business operators are increasingly sceptical about the value of an EU application, as they perceive it as a waste of money and effort. This sentiment is exacerbated by the prevalence of generic authorisations, not easily safeguarded by patents.

What is going on?

The European Commission (EC) is evaluating the performance of 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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Why is EFSA so important?

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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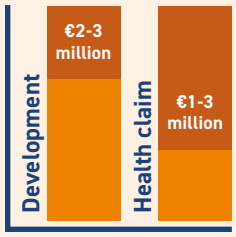
Innovative companies spend between 3 and 8% of their annual turn-over on research and development

The total research and development period for a new molecule or new specialty food ingredient is 4 to 10 years

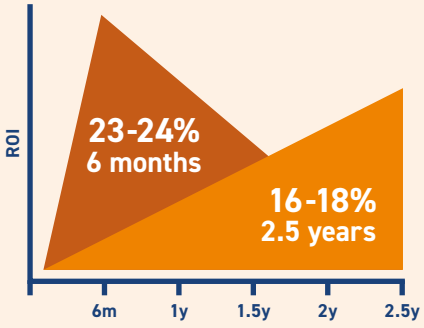


A new specialty food ingredient can typically cost €2-3 million to develop, with a further cost of €1-3 million required if the ingredient is to be marketed with a health claim

The shorter the authorisation procedure lasts, the higher the internal rate of return on investment is:

23-24% for an authorisation procedure lasting 6 months, but it drops to

16-18 % for an authorisation procedure lasting 2.5 years



Why is it so important for EFSA to improve?

In 2019, the Transparency Regulation (EU) 2019/1381 was hastily adopted without conducting any prior economic assessment of its impact on the EU Specialty Food Ingredients sector. Consequently, EFSA had to swiftly adapt all their operational procedures by March 2021. Since then:

- **The adoption of EFSA scientific outputs has significantly increased in terms of timeliness**, especially during the intake phase, now taking on average **around 7 months instead of 30 days**. This is in addition to the 9-month legal deadline for risk assessment of novel food ingredients.
- **Submitting applications and providing data have become overly complex**. Budget and resources for novel food ingredient applications have doubled on average.
- **EFSA's proactive dossier disclosure requires EU applicants to protect and justify their confidential data through complex procedures, in a competitive global context**. Data on EFSA's website is accessible worldwide, including non-EU countries. Furthermore, EFSA has opted to allow non-EU countries to use the Public Access to Documents mechanism.
- **The risk assessment is influenced by ever-changing factors**, such as numerous inquiries about well-built applications caused by experts' limited understanding of food technology and production. Additionally, there are requirements to follow draft guidance documents that have not been finalised, as well as "nice to have" questions for assessing the risk of a specific ingredient.

A few quick fixes to reassure EU applicants

- **Revamped interaction between the applicants and EFSA**
  - **Pre-submission advice** should provide guidance on the most effective scientific approach; they would not be binding and would not indicate acceptance of the dossier.
  - **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.
  - **Offering direct answers** to applicants' questions during the risk assessment would be more helpful than referring them to guidance documents.
- **Simplification of the operational process**
  The operational process, including confidentiality procedures, should be reviewed and simplified to ensure smoothness and reasonable amount of predictability.
- **Proportionality and predictability of EFSA's requests to applicants**
  Data requests must be based strictly on safety assessment needs. This, along with predictable assessment methodologies, should be a fundamental aspect of all EFSA Guidance documents.
- **Prioritisation of EFSA resources**
  EFSA resources should be prioritised for efficient risk assessment and communications, rather than for administrative operations.

What about the European Commission?

The European Commission has a unique opportunity to foster a cutting-edge and safe specialty food ingredient sector that enhances the global competitiveness and excellence of the European food and beverage industry. It's time to act and not let go of this incredible asset.

Urgent measures are necessary, recognising EU applicants of specialty food ingredients as valuable partners in a competitive international environment.

The EC's report will analyse how EFSA adapted to the new requirements set out in the Transparency Regulation and the impact of those requirements on EFSA's performance. However, to maximise its value, it should also assess if its implementation achieved the objective of enhancing the Authority's credibility and trust among consumers.

In simpler terms, was it worth risking EU food innovation?

References

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

European Commission – Processed Agricultural Products in the EU: https://single-market-economy.ec.europa.eu/sectors/agri-food-industrial-ecosystem/trade-processed-agricultural-products/processed-agricultural-products-eu_en

European Commission – Food and drink industry: https://single-market-economy.ec.europa.eu/sectors/agri-food-industrial-ecosystem_en

European Investment Bank report for the European Commission (2019): Feeding future generations: how finance can boost innovation in agri-food: *"[...] development of new food ingredients or functional food is similar to pharmaceutical development (high CAPEX; time to market of up to ten years; investment paybacks after 15 years). Pharmaceutical businesses have high R&D expenses, but typically achieve high prices with their products, which are protected by patents."*

Briefing paper – Economic impact assessment of EU food related regulations on research, innovation and competitiveness in the specialty food ingredients sector (G. Brookes, 2016)

European Commission's report "The competitive position of the European food and drink industry": *"The view of the food and drink processing industry expressed through the interviews is that the novel food legislation has the potential to be a real innovation driver, but that cumbersome approval procedures and uncertainty of return on investment are an impediment to investment in research and innovation, and thereby stifle competitiveness of the industry. Industry associations call for a better dialogue between applicants for authorisation and EFSA and improvement of the EFSA guidance for applicants. EFSA is currently proposing ways to address these issues."*

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.

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