Open Letter of Business and Agri-Food Industry stakeholders on the need for a high-performing EFSA to boost the competitiveness of the EU agri-food sector

28 May 2025

The European Commission's Vision for Agriculture and Food recognises the essential role of the agri-food sector for the EU's competitiveness. This critical sector employs over 30 million people and substantially contributes to the EU's economy (EUR 900 billion in 2022).[1] Nevertheless, business and food and feed industry operators face **significant regulatory challenges in the EU** which put them at a competitive disadvantage to other regions.

The undersigned organisations represent thousands of food and feed business operators along the agri-food chain; including food and feed primary, secondary producers, and ingredients suppliers that are directly and indirectly subject to the scientific outputs, guidance documents and opinions of the

[1] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Vision for Agriculture and Food; Shaping together an attractive farming and agri-food sector for future generations (link)

European Food Safety Authority (EFSA). We support the Commission's ambition of regulatory simplification and streamlining. This is essential to accelerate access to innovation and reinforce the EU's global competitiveness. We consider the ongoing EFSA's Performance Evaluation[2] as a unique opportunity to make the Commission ambitions a reality.

Ensuring the safety of the agri-food products is a priority for our industries. It is also a core principle of Regulation (EC) No 178/2002 (General Food Law), which established EFSA as an independent agency to provide scientific advice and support, thereby ensuring a high level of consumer protection. The outputs of EFSA are of great importance to our industries, and we value the work performed by EFSA. In recent years, we have noted several promising developments, particularly in relation to stakeholder engagement and development of EFSA's Catalogue of support initiatives.

While we acknowledge certain improvements, we are concerned about ongoing challenges with EFSA's performance and timeliness which increasingly discourages many businesses from entering the EU market. **Efficient and operational risk assessment processes are crucial to support the uptake of innovation and the acceleration to more resilient and sustainable food and feed production**.

This open letter underlines the main horizontal challenges faced by industry stakeholders at the risk assessment level and proposes solutions for more efficient and science-based processes. Ensuring the continued development of innovative agri-food products necessitating a safety assessment for authorisation within the EU requires urgent action. **We therefore call on the Commission and EFSA to speed up the delivery of EFSA's performance evaluation and to give full consideration to the challenges highlighted in this letter**.

➢ Negative economic repercussions of the complex EU regulatory regime

Companies operating in and entering the EU market face rising costs when submitting applications for authorisation, driven not only by the significantly increased administrative burden under Transparency Regulation (TR) procedures but also by the necessary increase of resources for handling applications. Company staff require increasingly specialized training to efficiently navigate complex administrative procedures, ensuring the submission of high-quality applications.

Meanwhile, companies increasingly view the EU market as less appealing for launching innovative products, as projected timelines and associated uncertainties make regulatory systems in other regions of the world more attractive. As a result, businesses often prioritise investment in innovation elsewhere before considering entry into the EU market. This shift also influences decisions on maintaining R&D facilities in the EU, given that innovative products tend to follow different market pathways. This unfavourable context affects various products, including regulated products, especially if subject to periodical renewals of authorisations.

Solution: Based on the evidence gathered so far, EU policy decision-makers should steer the development of the necessary future revisions of the TR, ensuring it is better suited to its intended purpose and in line with the EU priorities on competitiveness, innovation and strategic autonomy.

[2] Performance Evaluation of European Food Safety Authority: https://food.ec.europa.eu/horizontal-topics/general-food-law/performance-evaluation-european-food-safety-authority_en

➢ Limited value of general pre-submission advice and insufficient interaction with applicants

The current scope of General Pre-Submission Advice (GPSA) and Renewal Pre-Submission Advice (RPSA) tend to restate information already publicly available in legislation and guidance documents, offering limited added value in dossier preparation. The general condition that EFSA officers involved in pre-submission advice shall not be involved during the risk assessment phase of that application further adds to the non-specificity of the advice, because more tailored instructions beyond the guidance documents cannot consistently be followed through in the later process. Pre-submission advice and exchanges during the assessment should provide meaningful and case-specific guidance. Interactions should go beyond restating existing guidance, aiming instead to clarify regulatory expectations relevant to the applicant's specific case.

Effective collaboration between EFSA's technical staff and industry stakeholders could facilitate the development and assessment of innovative products, especially those that may be challenging to navigate strictly within the framework of EFSA guidance documents and the legislative framework in place. As an example, technical hearings should be increased in number during the risk assessment and consistently offered to the applicant when EFSA starts the assessment of new products or the re-evaluation of existing products to allow applicants to directly address experts' inquiries.

Solution: Expanded scope of pre-submission advice such as in the European Medicines Agency and increased interactions between EFSA and applicants during the risk assessment.

➢ Disproportionate administrative burden leading to lengthy risk assessment timelines

Certain procedural aspects introduced by the Transparency Regulation (TR) have increased the administrative burden for applicants and stakeholders, especially SMEs, in particular linked to the notification of studies and confidentiality assessment. Delays from both EFSA and applicants lead to higher application costs, diminishing the EU market's investment attractiveness. As a result, companies face greater challenges in innovating and bringing forward products that align with EU priorities, such as competitiveness, sustainability, resilient agri-food chains, and animal welfare. Operational processes, such as dossier handling and confidentiality management/assessment, should be reviewed to allow EFSA to focus its resources on timely and science-based risk assessments. Greater usability and interoperability of EU submission portals (and data templates) would improve data quality and participation. The improvement of data management requires better alignment of terminology and identification codes between EFSA and the Commission.

Solution: Streamline administrative procedures and prioritise core scientific work. Speed-up the application of the "review clause" (TR article 61) by providing an evidence-based assessment of the performance of the Transparency legislation. Review findings may outline what provisions serve the true purpose of the Transparency goal and what others add undue layers of intricacy of the EU risk assessment system.

➢ Growing complexity and volume of guidance documents with limited value to the safety evaluation process

A growing number of new guidance documents has contributed to increased demands and higher complexity of regulatory submissions, resulting in more clarification questions and longer evaluation timelines. Additionally, there is limited visibility into how stakeholder comments on draft guidance or scientific outputs are considered or incorporated in the final versions. EFSA should clarify how comments from stakeholders, e.g., on draft guidance documents or consultations, are evaluated, addressed, and incorporated into final guidance/opinions. Providing structured feedback loops would foster trust and more meaningful engagement.

The need for a new guidance document should be discussed before the creation of a new mandate with all relevant stakeholders, including industry that is directly impacted. Coherence across guidance documents should also be ensured, including through horizontal guidance where there are overlaps across regulated product types. The content of guidance documents should be drafted with input from real-world industry experts and reflect consistent, science-based and implementable requirements to ensure they are fit-for-purpose, proportionate and predictable. Guidance should also be tested against the feasibility and adoption by the relevant stakeholders of reference (i.e., the applicants undergoing the regulatory dossier process).

Solution: Close involvement of experts, including from industry, at all stages of guidance development and more consideration of stakeholder feedback on draft outputs.

➢ Limited food and feed technology and legislative expertise of Scientific Panels, and relevance of the references used for opinions

The current structure of EFSA's scientific panels and working groups sometimes lacks knowledge of EU agri-food law legislation and input from experts with hands-on experience in areas such as food/feed production and processing, market drivers and farming practices and related dynamics impacting on the quality of the output in areas such as animal health, animal welfare or contaminants. This gap has widened over the years and risks undermining the practical relevance of certain assessments. In some cases, conclusions appear more theoretical than actionable for risk managers, with negative consequences for industry operators. The current independence rules make it challenging for experts with practical knowledge to become panel members, leading to a limited pool of specialists. As a result, in some sectors the same experts are repeatedly selected for panels and working groups over decades. A solution is needed to allow scientists with some industry-funded work to participate in EFSA's work, while ensuring they have no conflicts of interest.

We also observe that some references used in scientific opinions are outdated and do not reflect the latest scientific progress and reality of the situation on the ground. Some of the references used are also inappropriate as they describe the situation in third countries which is completely different from the EU. The lack of expertise and often an overly conservative approach to risk assessment also contribute to the increased adoption of inconclusive opinions.

Solution: EFSA must ensure that its experts have a thorough understanding of EU agri-food legislation, latest scientific evidence, new technologies and of industrial processes. Experts with hands-on experience and knowledge should be able to join EFSA Panels.

➢ Extensive additional data requests and evolving data requirements

We observed an increase of additional requests for data over the years. These requests appear in some cases disproportionate to the likely impact on final safety conclusions, leading to resource-intensive efforts with limited clarity on their necessity. Moreover, the development or modification of guidance documents - or reinterpretation of existing legislation or guidance documents - during an ongoing assessment creates uncertainty unpredictability and delays, particularly when new data are requested that were not foreseeable at the outset.

Solution: Ensure consistent interpretation of data requirements, and limit data requests strictly to what is essential to the safety assessment underpinned by a scientific rationale.

➢ Limited integration of New Approach Methodologies (NAMs)

While EFSA recognises the potential of non-animal testing and alternative methodologies, their practical integration and acceptance remain uneven across sectors. The adoption of validated New Approach Methodologies and fit-for-purpose exposure models should be prioritised and consistently accepted across EFSA panels to reduce the use of animals for testing purposes.

Solution: Prioritisation of NAMs adoption

List of organisations supporting the open letter

Name of the organisation	Logo
European Industrial Hemp Association	
European Federation of Food Safety Consultants	
FEFAC	

Industrial Minerals Association Europe	
Food Supplements Europe	
Euroseeds	
ipiff	
CropLife Europe	
EFFA	
FoodDrinkEurope	
IOFI	

EuropaBio	
EU Specialty Food Ingredients	
FEFANA, Specialty Feed Ingredients Industry	
EMFEMA	
AESGP	
EACL	
FEDIAF, EuropeanPetFood	
Ebic, European Biostimulants Industry Council	

NIA Nanotechnology Industries Association	
Caobisco	
Ipa Europe	
AMFEP	
IBMA