

# Impact assessment of the regulatory framework on the market access of novel foods based on alternative protein sources (NFAP)

## DELIVERABLE 5.1

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# Executive Summary

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This report provides an integrated analysis of the regulatory landscape, data requirements and practical experiences associated with the authorisation of novel foods based on alternative proteins sources (NFAPs) under the European Union's Novel Food Regulation (EU) 2015/2283. It combines a review of the applicable regulatory framework with insights derived from structured interviews with 15 companies developing or submitting novel food (NF) applications. The findings are intended to support regulators, risk assessors and industry stakeholders by highlighting barriers, opportunities and areas for future improvement in the EU NF system.

The EU NF authorisation procedure is internationally recognised for its scientific rigour and strong consumer protection standards. However, applicants frequently report that the practical timelines for obtaining authorisation extend well beyond the period foreseen in legislation. This is often due to additional data requests (ADRs), which pause the assessment process and may require further studies and method development for additional analytical testing or extensive clarification on submitted information. As a result, the overall duration from dossier submission to authorisation can be lengthy and difficult for companies to predict.

Participants reported that the interpretation of the scientific data requirements including those covering the assessment of the allergenic potential of novel protein sources is of the most challenging aspects, particularly where regulatory precedents are limited. The introduction of the EU Transparency Regulation (Regulation (EU) 2019/1381) in 2021 has strengthened the clarity of the risk assessment process but also introduced new administrative and procedural burdens, including mandatory study notifications, confidentiality justification requirements and the preparation of separate confidential and non-confidential dossiers.

Most of the companies interviewed reported heavy reliance on external regulatory consultants, often in combination with in-house expertise, to navigate the technical, procedural and administrative requirements. Experiences with EFSA's general pre-submission advice (GPSA) service varied. Many participants found that, while helpful for clarifying procedural aspects and confirming applicable guidance, the advice was limited in its ability to address ingredient-specific uncertainties. This reflects the intent of the Transparency Regulation, which requires that GPSA remain general, non-binding and not predictive of assessment outcomes. Within these legal constraints, GPSA provides useful high-level orientation but cannot fully resolve product-specific scientific questions.

The regulatory environment strongly influences financial planning, investment attraction and market strategy. Companies reported increased budgeting needs due to unforeseen data generation requirements, high reliance on investor funding and limited predictability of timelines. As a result, many companies choose to prioritise non-EU markets such as the US and Singapore which offer faster timelines, clearer pre-submission engagement and lower overall costs. Some companies also reported their intention to pursue alternative pathways,

such as entering the animal feed market, to generate revenue while their NF applications progress.



Despite these challenges, applicants highlighted several strengths of the EU framework, including the scientific rigour of EFSA’s assessment, the transparency of the process and the value of clear legislative foundations. The interviews also revealed opportunities for improvement, including increased regulatory engagement, greater clarity on data expectations, enhanced sector-specific guidance and more interactive communication during risk assessment.

Overall, this report underscores that while the EU’s novel food system offers robust consumer protection, the procedural complexity and extended timelines can create barriers for innovation in alternative proteins. Addressing these challenges through improved pre-submission support and a more predictable assessment process would help the EU remain at the forefront of sustainable protein innovation while maintaining high standards of safety and public trust.



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# Abbreviations

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<b>ADME</b>	Absorption, Distribution, Metabolism and Excretion
<b>ADR</b>	Additional Data Request
<b>B2B</b>	Business-to-Business
<b>B2C</b>	Business-to-Consumer
<b>CCP</b>	cell-cultivated product
<b>CIR</b>	Commission Implementing Regulation
<b>DIAAS</b>	Digestible Indispensable Amino Acid Score
<b>DRV</b>	Daily Reference Value
<b>EC</b>	European Commission
<b>EFSA</b>	European Food Safety Authority
<b>ESFCP</b>	E-Submission Food Chain Platform
<b>EU</b>	European Union
<b>FAO</b>	Food and Agriculture Organization of the United Nations
<b>FDA</b>	Food and Drug Administration
<b>GFI</b>	Good Food Institute
<b>GMP</b>	Good Manufacturing Practices
<b>GSPA</b>	General Pre-Submission Advice
<b>HACCP</b>	Hazard Analysis Critical Control Point
<b>IAA</b>	Indispensable Amino Acid
<b>ISO</b>	International Organization for Standardization
<b>LOD</b>	Limit of Detection
<b>LOQ</b>	Limit of Quantification
<b>NAM</b>	New Approach Methodologies
<b>NF</b>	Novel Food
<b>NFAP</b>	Novel Foods based on Alternative Protein Sources
<b>PA</b>	Practical Arrangements



<b>PCB</b>	
<b>QPS</b>	Qualified Presumption of Safety
<b>QMV</b>	Qualified Majority Vote
<b>SCoPAFF</b>	Standing Committee of Plants, Animals, Food and Feed
<b>SME</b>	Small or Medium-sized Enterprise
<b>UK</b>	United Kingdom
<b>UL</b>	Tolerable Upper Intake Level
<b>US</b>	United States of America



# Introduction

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The European Union (EU) plays a central role in shaping global standards for food safety, innovation and sustainability. As Europe seeks to transition toward a more sustainable food system, the focus on alternative proteins is increasingly supporting the objectives of the European Green Deal and the Farm to Fork Strategy. However, the complexity and duration of the EU Novel Food (NF) authorisation process remain significant barriers to the market entry of these innovative products.

This report, developed under the Horizon-funded EPIC-SHIFT project (Deliverable 5.1), provides an impact assessment of the EU regulatory framework related to the market access of Novel Foods from Alternative Protein (NFAP) sources. The scope of NFAPs under the EPIC-SHIFT project are proteins consisting of and derived from insect, fungi, bacteria, micro- and macroalgae and agriculture and aquaculture by-products. It offers a comprehensive overview of how the existing regulatory process is influencing the market access of new ingredients within the alternative protein sector.

The first part of the report briefly summarises the structure and requirements of a NF application as set out in Regulation (EU) 2015/2283 on NFs and relevant European Food Safety Authority (EFSA) guidance documents.

To understand how these regulatory processes affect market access, structured interviews were conducted with developers of NFAPs who shared detailed insights into their experiences preparing and submitting dossiers, generating data and interacting with EFSA. Their testimonies reveal substantial challenges in interpreting guidance, meeting data expectations and anticipating additional information/data requests during the risk assessment process. These uncertainties have direct implications for investor confidence, financial planning and strategic decisions about which markets to prioritise. This analysis is complemented by an examination of the regulated regulatory timelines and procedural stages, from dossier submission to EFSA's risk assessment, risk management and final authorisation highlighting recurring challenges and delays in comparison to the regulated timelines.

The report also includes recent data published by EFSA taken from their recent [158th Nutrition, Novel Foods and Food Allergens \(NDA\) Panel meeting](#), which highlighted recurring issues with dossier quality and completeness, such as gaps in compositional analyses, toxicological testing and poor contextualisation of evidence. Alongside feedback from applicants, EFSA's own findings reinforce the need for clearer guidance and improved communication regarding expectations for novel food applications to improve the overall quality of novel food dossiers and reduce timelines to market.

Ultimately, this report aims to inform policymakers, regulatory authorities and industry stakeholders about how the EU's NF framework impacts the commercialisation of alternative proteins. It identifies opportunities to streamline the process while maintaining the highest standards of safety and transparency, ensuring that the regulatory system continues to protect consumers and support Europe's leadership in sustainable food innovation.



# Introduction to the EU novel food regulatory framework and application requirements

In the EU, NFs are regulated by [Regulation \(EU\) 2015/2283](#) and are defined as foods that have not been consumed to a significant degree by humans in the EU before 15 May 1997. As per this Regulation, NFs can be divided into several categories which cover the inclusion of foods produced from new production processes and innovative technologies including those which cause a significant change in the structure, composition or level of impurities of the food ingredient compared to its source or conventionally consumed form. Traditional foods, a subset of NFs, are foods derived from primary production with at least 25 years history of safe use in a third (non-EU) country. The categories of NFs covered under the NF Regulation are:

- i. food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997;
- ii. food consisting of, isolated from or produced from micro-organisms, fungi or algae;
- iii. food consisting of, isolated from or produced from material of mineral origin;
- iv. food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
  - traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
  - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;
- v. food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union;
- vi. food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;
- vii. food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
- viii. food consisting of engineered nanomaterials as defined in point (f) of this paragraph;
- ix. vitamins, minerals and other substances
- x. food used exclusively in food supplements within the Union before 15 May 1997



As consumer demand for alternative proteins grows alongside advances in technologies used to produce these proteins, an increasing number of these products are classified as NFs. **Unapproved NFs require pre-market authorisation before they can be marketed in the EU. The approval process involves the preparation and submission of a technical dossier to the European Commission (EC) followed by a risk assessment by the European Food Safety Authority (EFSA).** After EFSA publishes its scientific opinion, the EC begins the risk management phase which involves the EC drafting an Implementing Regulation, which is then presented to the Standing Committee for Plants, Animals, Feed and Food (PAFF Committee) where Member State representatives vote by Qualified Majority (QMV) to formally authorise the NF.

Dossiers must be prepared in line with the structure and requirements outlined in the legislation governing novel and traditional food applications:

- [Regulation \(EU\) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on NFs](#)
- [Regulation \(EU\) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain](#)
- [Commission Implementing Regulation \(EU\) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation \(EU\) 2015/2283 of the European Parliament and of the Council on NFs](#)
- [Commission Implementing Regulation \(EU\) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries](#)

EFSA has developed several guidance documents to support applicants in understanding the data requirements, dossier structure, and application process for preparing a NF dossier. Applicants are expected to follow these documents. The core guidance, applicable to all applications, is divided into two principal documents: administrative and scientific requirements:

Administrative guidance:

- [Administrative guidance for the preparation of NF applications in the context of Article 10 of Regulation \(EU\) 2015/2283](#)
- [Administrative guidance for the preparation of notifications and applications on traditional foods from third countries in the context of Regulation \(EU\) 2015/2283](#)
- [Administrative guidance for processing of applications for regulated products \(update 2021\)](#)

Scientific guidance:

- [Guidance on the scientific requirements for an application for authorisation of a NF in the context of Regulation \(EU\) 2015/2283](#)



- [Guidance on the scientific requirements for a notification and application for authorisation of traditional foods from third countries in the context of Regulation \(EU\) 2015/2283](#)

Depending on the food type, certain cross-cutting guidance may apply e.g. in the case of microorganisms used as ingredients or as production organisms:

- [Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain](#)
- [EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain](#)

The following sections of this report outline the key administrative and scientific requirements for NF applications concerning novel proteins.

## Administrative requirements

As part of the implementation of the Transparency Regulation (Regulation (EU) 2019/1381) (effective 27 March 2021), the platform [EFSA Connect](#) was set up to facilitate pre-submission interactions between applicants and EFSA. Applicants can submit general questions to EFSA using the “Ask a question” tool, request access to documents that are not publicly available and track and participate in public consultations. With regards to the NF application, applicants must use EFSA Connect in order to set up a pre-application ID, notify studies and request optional general pre-submission advice (GSPA). The pre-application ID is a unique identifier which links all pre-submission activities carried out to support a future application related to a specific regulated product in a given regulated product area e.g. NF. Certain studies intended to be submitted as part of the NF application must be notified to EFSA before the study start date. If studies are not notified/notified incorrectly, the application will be considered non-valid and applicants will be required to re-submit the application and notify studies with delay along with a justification. Once the application is resubmitted, the dossier is put on hold for six months. After the six-month penalty period, the application will then proceed to validation.

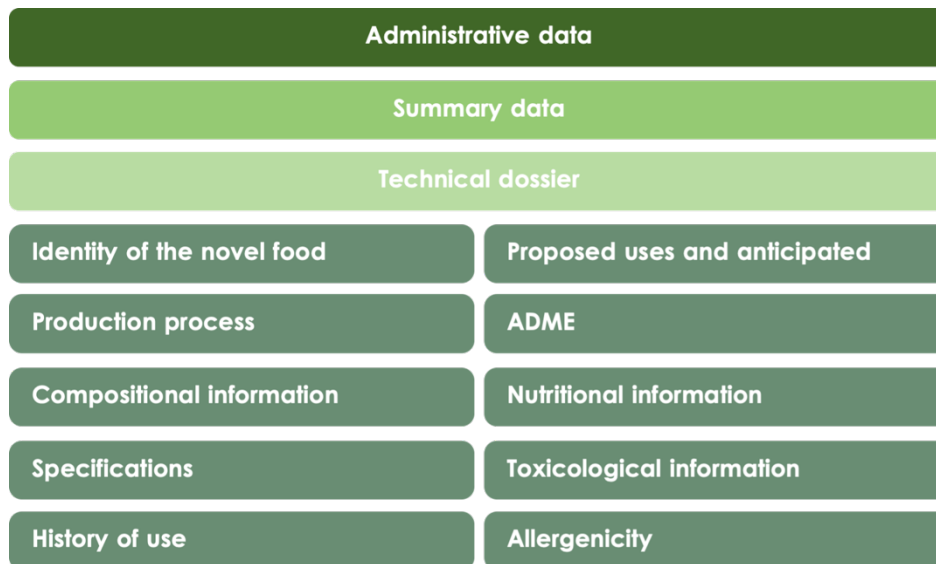
NF applications must be submitted via the e-Submission Food Chain Platform (ESFCP) and include both a confidential and non-confidential copy of the technical dossier with the public disclosure of the non-confidential dossier and other information deemed as non-confidential by EFSA once the dossier has been validated and EFSA has completed their confidentiality review. Applicants can submit requests for confidential treatment of certain information as outlined in the Transparency Regulation. In order to help applicants navigate the requirements of the Transparency Regulation, EFSA published the [Practical Arrangements](#) (PAs) which outline detailed procedures of the Regulation. To further clarify doubts on these requirements, EFSA published the [“Questions and Answers on EFSA Practical Arrangements”](#) (last updated August 2023) which provides answers to questions frequently asked on the PAs formulated by EU Member States and stakeholders.



The dossier must be accompanied by a completed Suitability Checklist (Appendix A of the Administrative Guidance), confirming that all required information has been provided and structured according to the guidance. Administrative components include: a cover letter compliant with Annex I of Commission Implementing Regulation (EU) 2017/2469; details of the applicant, responsible person, and producer; a proposed entry for the NF Union list (including conditions of use of the ingredient and any labelling requirements); data-protection requests; a public summary; and information on the regulatory status of the NF outside the EU. Where relevant, applicants should include Appendix B of the NF administrative guidance, covering information for NFs that are also new nutrient sources, and Appendix C on statistically significant observations in 90-day subchronic toxicity studies. Appendix D should also be completed with data on the characterisation of the novel food. EFSA uses the checklist and supporting documentation to verify the dossier's suitability for risk assessment and may request clarifications or additional information before the dossier is validated, and risk assessment proceeds.

## Summary of scientific data requirements for novel protein applications

The overall structure and key requirements for novel protein food application dossiers is described in the following sections in accordance with current EFSA guidance (EFSA, 2024) and in Figure 1. Below, a high-level overview of the requirements are presented. However, this is non-exhaustive, and the actual studies and data required to support a NF application must be considered on a case-by-case basis and are highly dependent on the source of the NF, the production process and the final composition of the NF.



**Figure 1. Overall structure and administrative and scientific requirements for a novel food application**

## *Identity*

All NF dossiers must begin by establishing the identity of the new protein.

The identity section should include the name of the NF and indicate the NF category(ies) to which it belongs to under Article 3(2)(a) of Regulation (EU) No 2015/2283. A brief description of the NF should be provided including its nature and origin, for example, whether it is a purified protein, a biomass, a fermentation-derived product, or obtained from a non-traditional source.

For purified proteins, key physicochemical properties and structural characteristics should be described using appropriate analytical methods where applicable. If the protein is intended to replicate a naturally occurring counterpart, data must demonstrate structural and functional similarity, including assessment of post-translational modifications (e.g., glycosylation) and any identified differences. Overall, sufficient detail should be provided to establish a clear and consistent identity for the protein.

For proteins produced from or consisting of microorganisms including bacteria, yeasts, fungi, and microalgae, the identity section should include precise taxonomic identification at the genus, species, and strain level, supported by molecular and phenotypic data in accordance with EFSA Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain (EFSA, 2025). If the production organism has been assessed by EFSA and granted QPS (Qualified Presumption of Safety) status ([Zenodo, 2025](#)), this should be clearly indicated, as it reduces the need for certain studies. Any genetic modification must also be described accordingly along with confirmation of the absence of viable cells and host-strain DNA in the final product where applicable.

NFs derived from plants, macroscopic fungi, macroalgae, or animals require clear identification of the source, including scientific name, taxonomy, common names, and part used. Verification via accepted methods and origin details (region, cultivation/harvesting) must be provided.

Thorough characterisation of novel proteins and an assessment of their source is critical.

## *Production process*

The manufacturing process of a NF must be described in sufficient detail to demonstrate that the process is well-controlled, consistent, and does not raise safety concerns. This includes a clear description of each step, from raw material sourcing and initial processing to final product formulation. Information should be provided on all substances and materials used during production, such as processing aids, solvents, additives and food contact materials. Where applicable, details on fermentation, extraction, purification, or other key processing stages should be included.

Production of the NF should follow a food safety management system based on HACCP principles, in line with [Regulation \(EC\) No 852/2004](#). Key process parameters, control measures (e.g. HACCP,



GMP, ISO) and quality assurance procedures must be described, including critical control points, monitoring, corrective actions, and verification steps. A flow diagram outlining the production process and safety checks should be provided, along with any standardisation criteria used to ensure product consistency.

Typically, specific details related to the production process are accepted as confidential information although a non-confidential overview is required.

### *Compositional data*

Robust compositional data are essential for characterising the novel protein ingredient, providing both qualitative and quantitative information on its chemical, physicochemical, microbiological and nutritional properties. Analytical results must be provided for at least five independent production batches (preferably produced with independent batches of raw material as outlined in the EFSA guidance), covering macronutrient and micronutrient content, purity and stability.

Impurities should comply with regulatory limits or be as low as reasonably achievable and/or below the limit of detection of the analytical method. Common tests include heavy metals, microbial contaminants, PCBs/dioxins, and mycotoxins but vary depending on the production process and raw materials used. Additional impurities introduced during manufacturing or storage agents as well as antinutritional factors from raw materials, should also be assessed if relevant. The analytical battery of tests must be designed on a case-by-case basis taking into consideration the source material and production process to support a detailed understanding of the product's composition and potential food safety risks identified by performing a detailed risk assessment and literature review.

Analytical methods used for compositional testing should be validated and where possible, based on nationally or internationally recognised standards. Each method should be described in detail with appropriate references, including the limits of detection (LOD) and quantification (LOQ). Certificates of analysis should be provided, along with information on laboratory accreditation, including the scope of accreditation in relevant matrices. If in-house methods are used, full analytical protocols and method validation data must be submitted. Standard methods that are modified, or applied to matrices outside their accredited scope, should also be treated as in-house methods. Where analyses are conducted in non-accredited laboratories, a clear justification must be provided.

One of the key challenges faced by many NF producers, particularly start-ups, is the ability to scale up their production process and generate larger batches for commercialisation early in development. These limitations often mean that only pilot-scale batches are available at the time of dossier submission. EFSA guidance expects that batches used for analysis are produced at industrial scale or at a scale representative of it. Therefore, when submitting data from smaller-scale batches, applicants must provide a clear justification demonstrating that the process is representative of the intended industrial-scale production.

Applicants should also address the presence of small particles, including particles in the nanoscale range in line with the EFSA Guidance on technical requirements to establish the presence of small particles, including nanoparticles (EFSA, 2021). For novel foods that are not engineered nanomaterials, applicants must demonstrate either that the fraction of small particles, including those in the nanoscale, is not present, or if present, they are adequately covered by the conventional risk assessment, and do not exhibit properties requiring a nanospecific assessment.

## Stability

The storage conditions of the NF should be specified. Stability should be performed on five independent production batches of the NF to show that the specifications are met throughout the proposed shelf-life. If the NF is intended for use as an ingredient in processed foods, its stability and behaviour in appropriate food matrices considering relevant processing conditions (e.g. heat, pH) must be assessed. This includes evaluating how the NF and its key components are affected by processing and whether/how its presence alters the final food product. Testing should reflect typical processing scenarios based on proposed uses.

## Specifications

Specifications are essential for assuring the identity, quality and safety of a NF and must be clearly established based on the compositional analyses carried out on the product. They should be presented in a table listing each parameter, its acceptable range or limit and the corresponding analytical method used for measurement. These specifications include chemical, physicochemical, nutritional, and microbiological characteristics. The inclusion of each parameter as part of the NF's specification should be duly justified by providing a clear scientific rationale. Applicants must carefully define these specifications in their dossier, as risk managers (the European Commission and EU Member States) rely on them to decide which parameters and limits are incorporated into the final authorisation of the NF.

## History of use

Information on the food use of the novel protein and the source must be addressed. This should cover the extent of its use, the population groups consuming the product, its role in the diet and any precautions or restrictions associated with its use. A comparison of its compositional similarity to other existing food products should also be provided. Additionally, any other non-food uses of the ingredient, such as its application in medicine, cosmetics, animal feed, etc. should be addressed. A literature review of human studies relevant to the safety of the NF should be conducted and reported in line with systematic review principles, detailing the search strategy, sources, and inclusion criteria (EFSA, 2010).



## *Proposed uses and use levels and anticipated intake*

The target population should be included (general population except if food supplements or foods for special groups), the form (e.g., as whole food, ingredient), the food categories in which the novel is proposed for use, as defined by the EFSA Food classification system ([FoodEx2](#)), whether the NF is intended to replace another food, the proposed maximum amounts in product(s) as consumed and the proposed average and maximum daily intakes for different age/gender groups as appropriate.

Estimations of mean and high (at least 95<sup>th</sup> percentile) anticipated intakes of the NF should be provided for each population group. The safety evaluation will be based on the highest (95<sup>th</sup> percentile) anticipated intake among the population groups from the [EFSA Comprehensive European Food Consumption Database](#).

## *Absorption, Distribution, Metabolism and Excretion (ADME)*

A comprehensive literature review of ADME data on the NF or its components should be conducted, with critical appraisal of the evidence. ADME studies may be necessary for NFs made from new single substances. Potential matrix effects in foods incorporating the NF should be considered, as the food matrix may influence ADME behaviour.

For NFs providing new nutrients, bioavailability must be investigated and addressed by the applicant.

ADME studies should follow a tiered approach, starting with a review of published literature on *in vitro* and *in vivo* studies of the NF or its components. Chemical and physicochemical data can predict dissociation under gastrointestinal conditions, impacting absorption. If studies are needed, *in vitro* models may replace *in vivo* studies if they demonstrate similar predictive value.

## *Toxicological Information*

The requirement for toxicological testing should be determined by considering the composition of the NF, the raw materials and production methods used, and any existing toxicological data from the scientific literature. In some cases, toxicological studies may not be necessary if the NF is thoroughly characterised and shown to be structurally and functionally similar to a naturally occurring equivalent. Such waivers must be supported by robust evidence demonstrating compositional equivalence and a lack of safety concerns, as substantiated by published data. Genotoxicity and chronic toxicity are covered under the scope of toxicological assessment.

The toxicological assessment employs a tiered approach as per Figure 2.

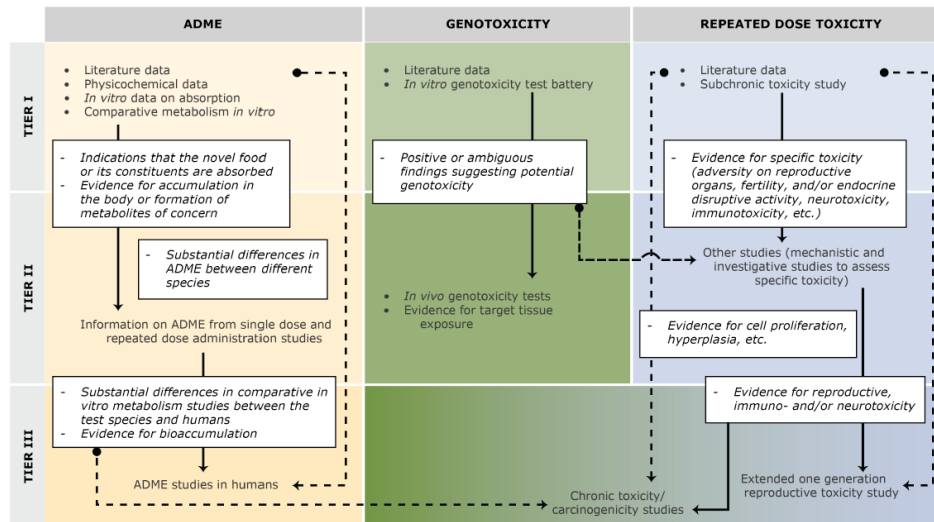


Figure 2. Tiered approach for ADME & toxicological assessment of NFs (EFSA, 2024)

## Human Data

Human intervention studies should be provided if available, especially if safety aspects were investigated. Such studies may be required to confirm safety, particularly for adverse effects observed in toxicological studies or for effects that cannot be studied in animals. Most novel food applications do not require human studies - justification or literature evidence is usually sufficient to address this section.

## Nutritional Information

A NF is considered nutritionally disadvantageous if its consumption leads to the excessive intake of nutrients (e.g. exceeding established upper levels (ULs)) or adversely affects consumers' nutritional status by increasing the risk of inadequate nutrient intakes. To demonstrate that a NF is not nutritionally disadvantageous, references to compositional data must show it will neither cause nutrient excesses nor impair the bioavailability of other nutrients. Where available, information on protein-quality metrics should be provided.

Protein quality must be assessed if the highest mean consumption contributes  $\geq 15\%$  of the average protein requirement for any population group, or if the NF is intended as a protein source in single-meal replacements for weight control or foods for special medical purposes. Assessment shall follow FAO's Digestible Indispensable Amino Acid Score (DIAAS) method (FAO, 2013), based on determining the true ileal digestibility of each indispensable amino acid (IAA), combining digestibility coefficients with IAA composition to calculate digestible IAA content, and comparing against age-specific IAA reference scoring patterns to derive the DIAAS value.

Certificates of analysis for all batches used in digestibility studies must be provided. Given that protein quality depends on total protein, IAA content, antinutrients and processing, digestibility measurements on multiple batches may be necessary to ensure accurate characterisation.

## Allergenicity

The assessment of allergenicity is intended to establish the potential of a NF to cause allergic reactions and to inform appropriate risk management and labelling measures. The extent of data required depends primarily on the presence and nature of proteins within the NF, as well as the characteristics of its source.

NFs that contain no proteins, such as those produced via chemical synthesis or of mineral origin, are exempt from specific allergenicity data requirements. Conversely, NFs derived from allergenic sources listed in Annex II of [Regulation \(EU\) No 1169/2011](#) are presumed to retain the allergenic potential of the source material and are therefore subject to mandatory allergen labelling. For NFs derived from other allergenic sources not covered by Annex II, applicants are required to provide evidence on the prevalence and severity of allergic reactions associated with the source, its allergenic potency and the detection of known allergenic proteins in the NF. In cases where the allergenic potential of a NF is unknown, EFSA recommends a tiered, risk-based approach focusing on potential cross-reactivity. This involves a progression from literature reviews and bioinformatic analyses (Tiers I–II) to *in vitro* testing for IgE binding (Tier III), and, where indicated confirmatory clinical investigations such as skin-prick testing or double-blind, placebo-controlled food challenges (Tier IV). For complex foods containing multiple or mixed proteins, a similar stepwise approach is applied, adapted to the specific composition and protein profile of the product.

## Novel food approval process

The procedure for obtaining novel food approval is outlined below and in Figure 3.

Applicant companies must submit their dossiers electronically via the ESFCP to the risk manager, the European Commission (EC). Following submission, the EC performs a validity check to ensure that the application is submitted within the appropriate scope (e.g. novel food application) and to check the completeness of the dossier.

Once the dossier is considered valid, the EC will send a mandate to EFSA no later than one month following dossier submission who will then perform a suitability check of the dossier. Once the dossier has passed EFSA validation, EFSA will carry out their scientific review in the stage of the process referred to as the “risk assessment”. As outlined in the legislation (Article 11 of Regulation (EU) 2015/228) EFSA has nine months to perform this assessment. This timeline may be extended due to an Additional Data Request (ADR) (clock-stop). An ADR may be issued by the EC during their validity check and/or by EFSA during their suitability check and subsequent risk assessment. Applicants are required to respond to ADRs directly via the ESFCP by the deadline outlined in the request.

At the end of the risk assessment, EFSA will publish its scientific opinion stating whether they conclude the novel food as safe under the proposed conditions of use (positive opinion) or its safety cannot be established (inconclusive/negative opinion).



The application then enters the risk management phase whereby the EC drafts a Commission Implementing Regulation and within seven months submits it to the EC Standing Committee of Plants, Animals, Food and Feed (SCoPAFF) which reviews the opinion and votes on whether to approve the product or not. Each EU Member State is represented in SCoPAFF. The EC will grant the novel food authorisation if the EU Member States vote to approve the product (by Qualified Majority Vote – QMV = 55% of member states representing 65% of the EU population vote in favour). Once approved, the EC will publish the Commission Implementing Regulation (CIR) authorising the novel food, and the novel food will be included in the [Union list of novel foods](#).

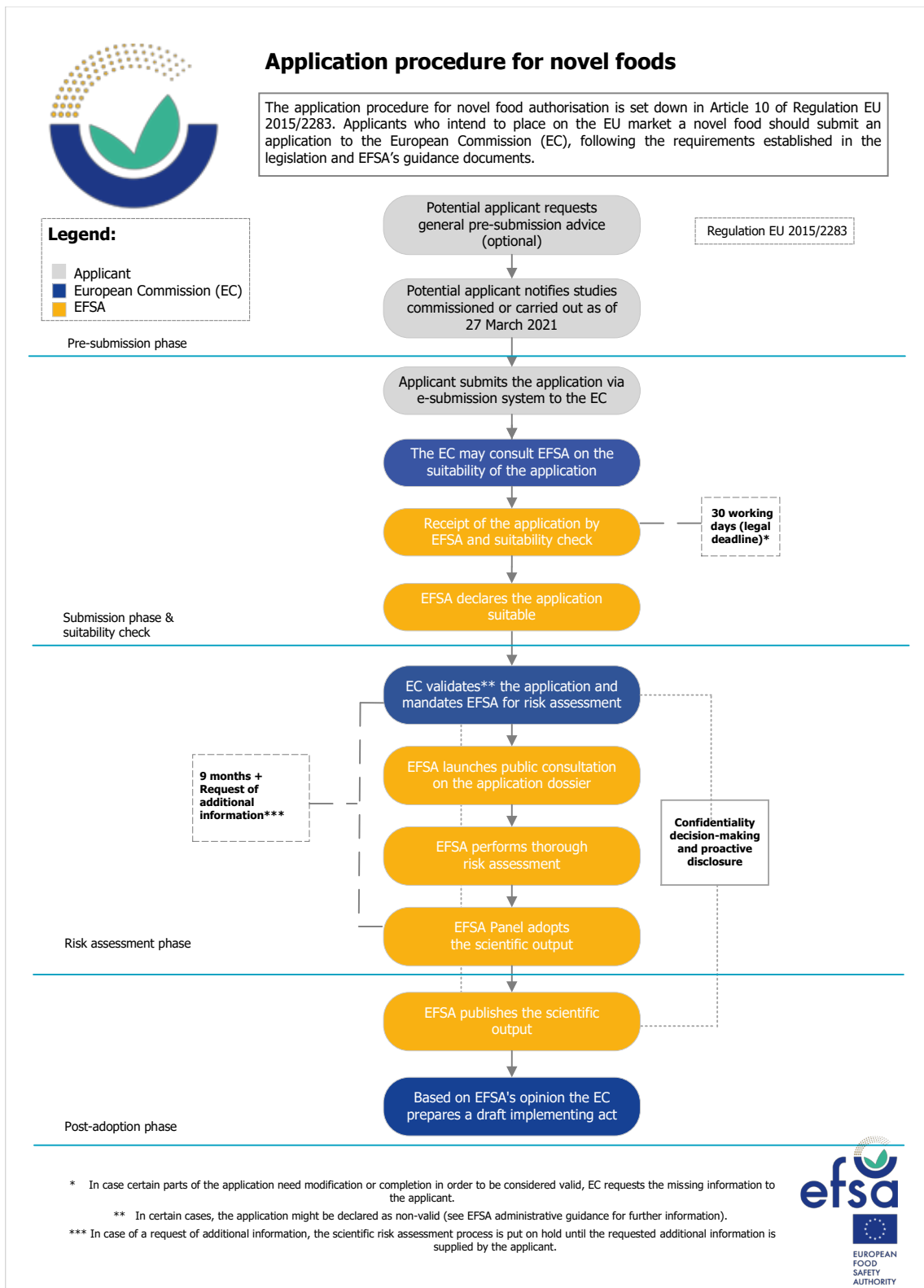


Figure 3. EFSA’s published NF application workflow (Add source)



While the preceding sections provide an overview of the regulatory framework, administrative procedures and scientific requirements for novel protein applications in the EU, understanding how these processes are experienced in practice requires insights from applicants directly involved in the NF approval process. The following section draws on interviews with key stakeholders to explore practical challenges, strategies and perspectives encountered during the preparation and submission of a NF dossier. These firsthand accounts offer a complementary view, highlighting how regulatory guidance is interpreted and applied, as well as the operational realities of navigating the NF authorisation process.

## Identifying challenges and opportunities in the regulation and risk assessment of novel alternative proteins

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The EU NF authorisation process is recognised as one of the most rigorous and comprehensive safety assessment procedures globally. This stringent process plays a crucial role in safeguarding EU consumers by thoroughly evaluating any potential risks associated with new ingredients, carefully assessing their safety and nutritional profile before granting authorisation for entry into the EU market.

However, despite the robustness of the framework, the complex regulatory landscape presents several challenges for applicants impacting timelines for the entry of NFs including new complementary protein products into the market. In particular, the time required to obtain authorisation is frequently longer than the regulated timelines foreseen in the EU NF [Regulation 2015/2283](#). While the Regulation establishes a nine-month period for EFSA's risk assessment, this timeframe is often extended due to additional data requests (ADRs) often referred to as clock-stops. The analysis carried out by Le Bloch et al. (2025) on the timelines for NF applications submitted to EFSA between 2018 and 2024 under Regulation (EU) 2015/2283 show that the average risk assessment timeline is 20.7 months with an average duration of 2.56 years from dossier submission to the publication of EFSA's scientific opinion. Consequently, total timeframes from dossier submission to final authorisation can take several years. Extended timelines create uncertainty for companies, affecting business planning and strategy, investment decisions and delay the introduction of innovative products to the European market.

Driven by consumer demand for sustainable food systems and the aim to diversify protein sources, there has been an increased interest in the development of NFs based on alternative protein sources (NFAPs) in recent years. Companies developing NFAPs also face the regulatory and data-



generation challenges associated with the EU NF framework particularly due to the novelty of such ingredients and limited regulatory precedents.

To gain a further understanding of how current regulations and application requirements influence the development and entry of alternative proteins into the EU market structured interviews were conducted with NFAP developers across the various stages of the EU NF authorisation process covering early development/data generation through the dossier submission, risk assessment and risk management.

These interviews explored participant companies' experiences navigating the EU regulatory framework including interpretation of EFSA guidance, compliance with EU Transparency requirements, interactions with EFSA and the Commission as well how the current procedures have shaped business strategies, investment opportunities and financial planning.

The aim of this study is to provide an evidence-based overview of the main regulatory challenges and opportunities identified by NFAP developers, highlighting areas in which the framework works well and serves current and prospective applicants and where targeted improvements could help streamline the process. The insights gained may help to propose recommendations for further applicant support and potential future policy refinements ultimately contributing to making the EU NF approval process more efficient and better adapted to innovation.

## Methodology

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To generate a shortlist of potential participants to take part in this survey, the [Good Food Institute \(GFI\) Alternative Protein Company Database \(2025\)](#) was used as a starting point. At the time of writing, this database contained a list of 2,089 alternative protein consumer brands, manufacturers and ingredient suppliers based globally.

To reduce this to a manageable number of companies, several filters built into the database were applied along with the following reasoning:

1. **Geographical focus:** Companies that have confirmed operations in Europe were selected, including those with additional operations outside the EU in other territories. This reduced the number of companies to 870.
2. **Additional filters:**
  - **Technology Focus:** Companies categorised under 'End product formulation and manufacturing' and/or 'Ingredient optimization' were selected as these reflect the core focus of NF developers
  - **Protein Category:** Companies working on 'Plant-based', 'Fermentation-derived', 'Traditional fermentation', 'Biomass fermentation' and/or 'Precision fermentation'. These categories most closely correspond to the seven key NFAP products central to the EPIC-SHIFT project: fungi, bacteria, insects, microalgae, macroalgae, food by-products, and aquaculture by-product-derived proteins
  - **Business Model (B2B/B2C):** Companies operating in B2B, or in both B2B and B2C (but not solely B2C), were selected. This aligns with our experience that most NF

developers primarily operate in a B2B capacity, supplying ingredients for use in final products developed by third-party manufacturers

- **Company Focus:** Companies focussing on 'Ingredients and inputs' and 'Contract manufacturing/processing'. Amongst the filters of the database, these were the activities considered to be most widespread among NF developers

A total of 213 records were obtained following the application of the above filters.

These records were further refined by applying selection criteria resulting in a list of 40 companies; the following types of companies were next excluded from the list:

- Companies whose activities do not align with NF development
- Businesses focused solely on final product formulation and manufacturing
- Companies with no indication of involvement in NF activities (e.g. no plans to submit, or no record of having submitted a NF application).

[Open EFSA](#), the public platform established by EFSA as part of the implementation of the EU Transparency Regulation provides access to information related to EFSA's scientific risk assessments and includes a list of all submitted applications for regulated products for which the EC has sent EFSA a mandate. This platform was used as a complementary resource to identify producers of NFAPs that have submitted an application to the EU to ensure this stage of the approval process was represented in the survey.

Applications submitted following the implementation of the current EU NF Regulation (EU) 2015/2283 (2018) were considered. Re-submitted dossiers, requests for modifications, traditional food applications and applications for ingredients intended solely for use in food supplements were excluded. This resulted in a list of 74 applications.

A final list of 103 NF developers was compiled from the GFI database and OpenEFSA, after removing duplicate company entries between the two sources and excluding repeated references to applicants who had submitted multiple dossiers.

The companies were categorised into seven groups representing different types of NFAP sources: fungi, bacteria, insects, microalgae, macroalgae, agricultural by-products and aquaculture by-products.

Several companies from each category were randomly selected and approached via email or LinkedIn to request their interest in participating. Communications provided an introduction to the EPIC-SHIFT project, outlined its objectives and detailed the procedures for companies wishing to participate. Follow-up correspondence was sent to unresponsive companies, with some contacted up to three times following initial communication. From this list, 15 companies confirmed their interest in participating. Additional efforts were made to identify and engage further suitable companies although no additional participants were ultimately confirmed.

Therefore, interviews were conducted with the 15 companies that expressed interest in participating after completing a participation form and providing consent for their involvement and for the use of the information provided in this study. All data were treated confidentially and both the participants and their companies were anonymised.



# Applicant experiences navigating the EU novel food process

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## Participant company profile and stage in regulatory process

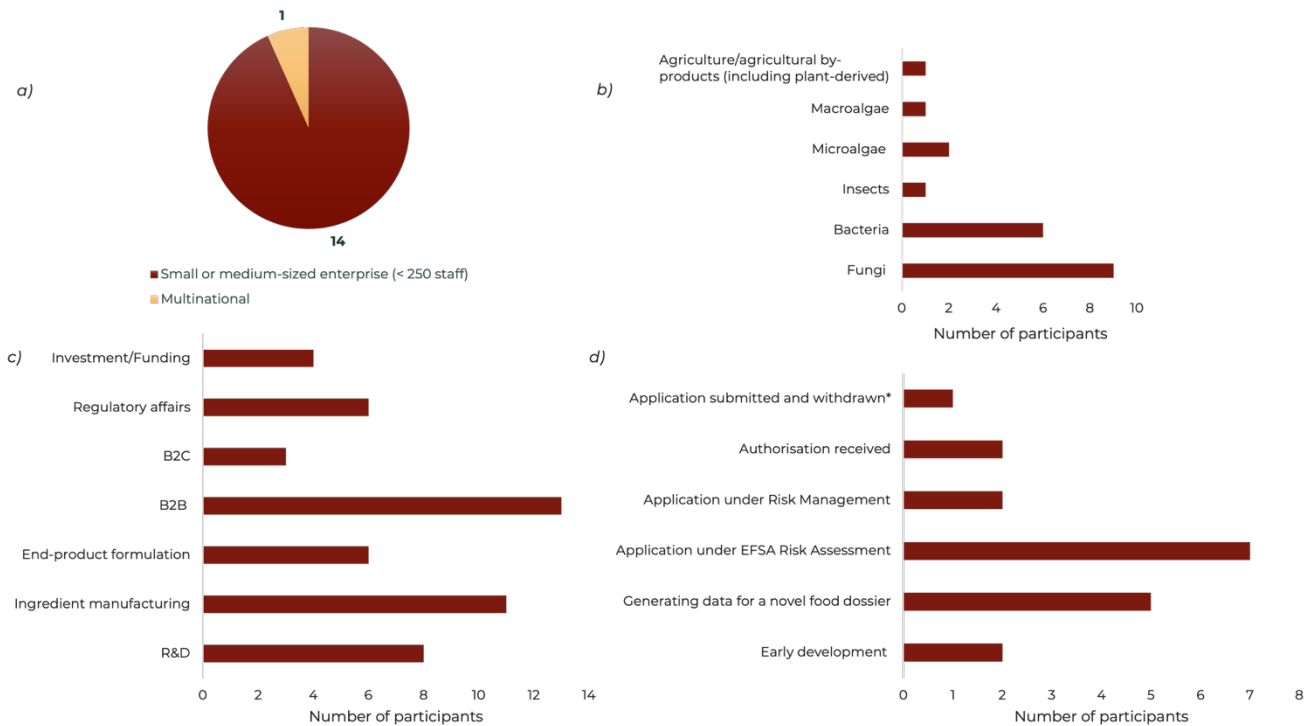
An overview of the profile of the companies that participated in the interviews is provided in *Fel! Hittar inte referenskölla.*, which summarises the company size, areas of focus and business activities and current stage in the EU NF approval process.

Of the 15 companies interviewed, the majority were small or medium-sized enterprises (SMEs), with one being a large multinational corporation.

As outlined in the methodology, the interviews targeted companies developing products based on the specific alternative protein sources that are the focus of the EPIC-SHIFT project. Participants reported working with a diverse range of protein sources. Fungi and bacteria were the most commonly reported categories, encompassing ingredients from both biomass fermentation, where the microbial biomass itself constitutes the NF, and precision fermentation, where microorganisms are employed as production hosts to produce specific target ingredients, in this case proteins (Figure 4b). These were followed by microalgae, macroalgae, insects and plant-derived proteins. Several companies described working across multiple categories.

Companies were involved in a range of activities, from early-stage research and development (R&D) to ingredient manufacturing and regulatory affairs. A total of 13 of the interviewed companies currently supply or plan to supply their products primarily through business-to-business (B2B) channels (Figure 4c). Many companies reported engagement in multiple activity areas.

Of the 15 companies, 14 provided responses specifically related to the EU NF application process. One company reported that, from the outset of product development, they had deliberately structured their activities and ingredient development to ensure that they remained outside the scope of the NF regulation, given the significant time and costs associated with needing to obtain authorisation. While they did not contribute application-specific data, their insights on the overall regulatory process have been incorporated into the discussion. The remaining participants reported their current stage in the EU NF regulatory process, ranging from early concept development through to full authorisation. The majority were at the EFSA risk assessment stage with an application having been submitted to the EC and having passed the initial validation stage. Several participants reported having multiple applications at different stages of the process simultaneously. Of the participants who had begun or completed their NF application, four



**\*Application withdrawn during risk assessment phase**

**Figure 4. Overview of Company Profile and Regulatory Stage: (a) Distribution of company sizes among interview participants. (b) Alternative protein source categories reported by participant companies. (c) Business focus area reported by participant companies (d) Current stage of participant companies in EU NF application process**

submitted their application prior to the implementation of the Transparency Regulation on 27 March 2021 and five submitted after its introduction.



# Navigation of the EU novel food regulatory framework

## *Regulatory support*

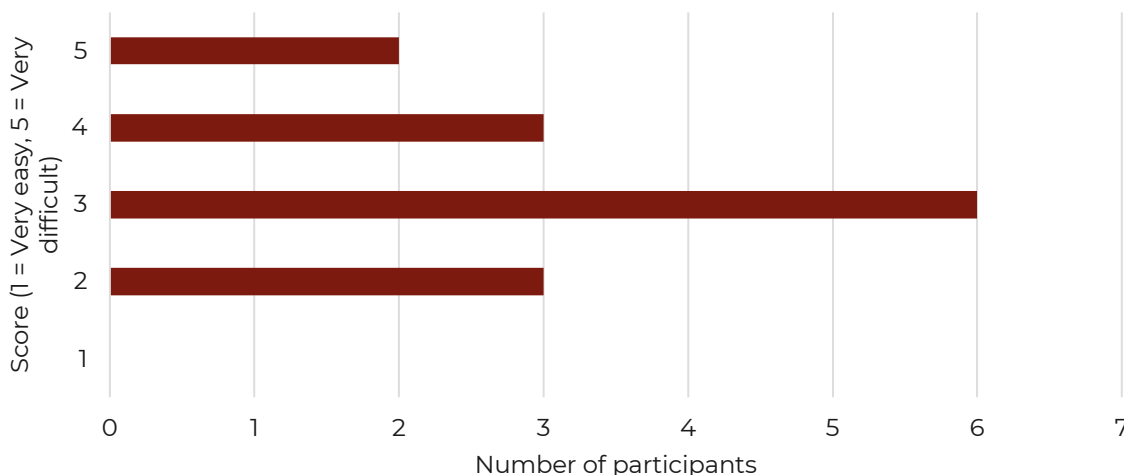
Participants described the types of support used to navigate the EU NF regulatory framework and their dependency on regulatory expertise. The results are summarised in Table 1. The majority of participants (93%, 13/14) worked with an external consultant to support in the preparation and management of their applications. Of these, 57% (8/14) reported using both an external regulatory consulting company combined with in-house regulatory expertise. A small number of participants (14%, 2/14) additionally involved non-regulatory staff as part of their application management. Many participants commented on the importance of an external expert consultancy company being critical to navigating the NF regulatory framework in the EU.

<b>Table 1. Type and combinations of support used by participating companies to navigate the EU NF regulatory framework</b>	
<b>Individual types of support</b>	<b>Number of companies</b>
External consultant	13
In-house regulatory team	10
In-house non-regulatory staff	2
<b>Combination of support</b>	
External consultant only	3
In-house regulatory only	1
External consultant + in-house regulatory	8
External consultant + non-regulatory staff	1
External consultant + in-house regulatory + non-regulatory staff	1

## *Use of available resources*

Participants were asked to assess the ease of navigating published resources applicable to NF applications. This included access to the relevant guidance documents outlining the data requirements and procedural steps, applicable legislation and the various online tools available on the EFSA website including the applicable portals for pre-submission activities, explanatory material on what constitutes a NF, the role of the risk manager and risk assessor and other information to help applicants understand the regulatory obligations before preparing and submitting a dossier.

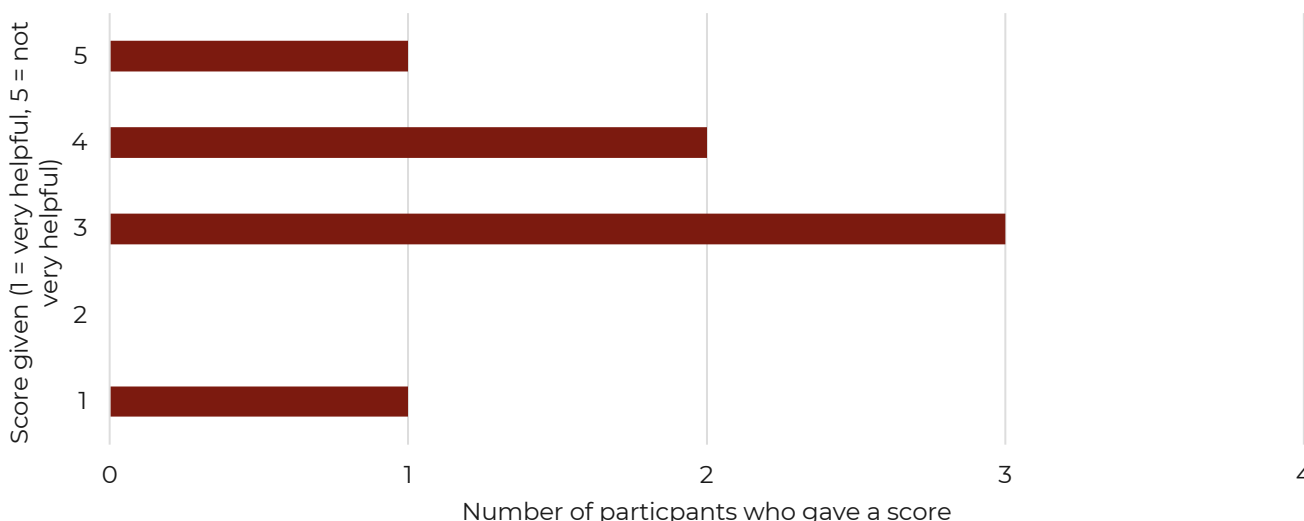
Participants were asked to give a score out of five of how easy they found it to navigate the various resources published by EFSA where one was very easy and five was very difficult. Six out of the 15 participants gave a score of three, three participants gave a score of four and two participants gave a score of five. Only three participants gave a score of two and no participants gave a score of one (Figure 5).



**Figure 5. Responses for how easy it was to navigate the various resources published by EFSA**

EFSA has been offering GPSA to companies applying for the approval of certain regulated products including NF applications since 2021. This was introduced as one of the new procedures under Transparency Regulation. Out of the participants who had the opportunity to consult with EFSA pre-submission, seven participants consulted with EFSA for GPSA. One of the participants had not started to generate data for submission yet but expressed that they would consider requesting EFSA GPSA in the future. One participant was able to consult EFSA but chose not to as they felt the advice given would be too generalised.

The participants who did seek GPSA were asked to give a score out of five of how helpful they found the pre-submission advice where one was very helpful and five reported that the advice given was not very helpful (Figure 6). The majority of participants gave a score over three indicating that they did not find the pre-submission advice meeting particularly helpful.



**Figure 6. Responses for how helpful the EFSA pre-submission meeting was for participants**



## Transparency Regulation

Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain, implemented on 27 March 2021, was introduced to strengthen EFSA's ability to carry out its risk assessment in accordance with the highest transparency standards. This Regulation introduced new requirements for applicants including the notification of certain studies to EFSA prior to the study start date, the preparation of both confidential and non-confidential versions of the application and stricter rules for confidentiality requests. The latter requires applicants to justify each request on specific legal grounds as laid out in Articles 23 and 39 of the Regulation and the submission of applications through the E-submission Food Chain Platform (ESFCP).

Participants were asked to attribute a score for how challenging they found the notifications of studies (Figure 7 **Fel! Hittar inte referenskölla.**), the confidentiality requests (Figure 8) and navigating the ESFCP (Figure 9). Participants noted that both the notifications of studies and confidentiality request requirements were challenging to navigate and that without external consultants the process would have been much more difficult. In Figures 7 and 8 this is evidenced with the majority of participants giving a score over 3.

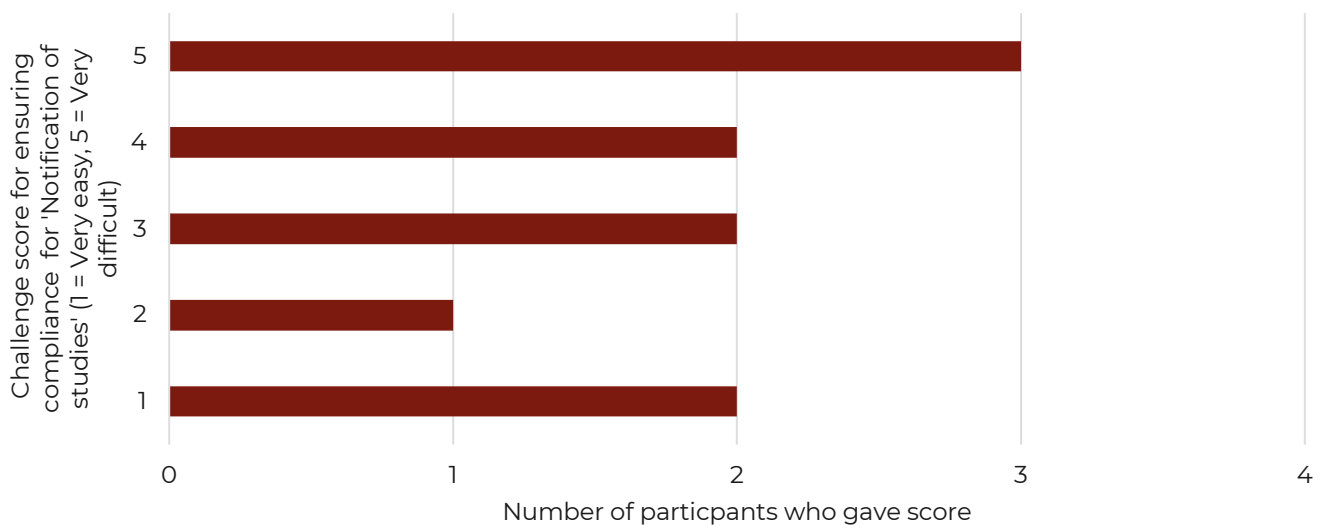
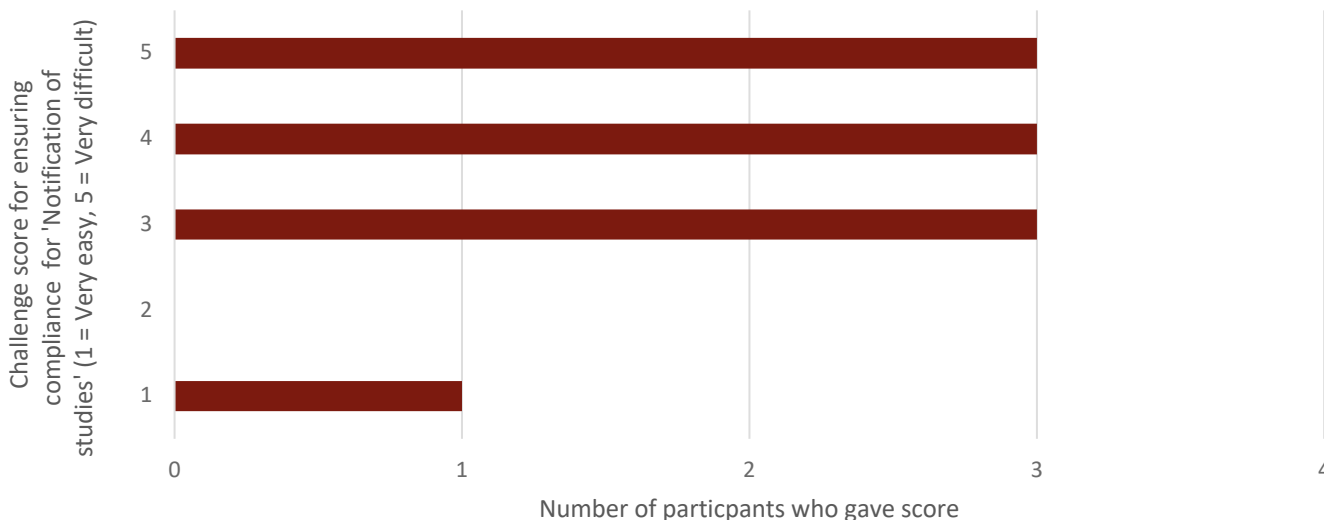
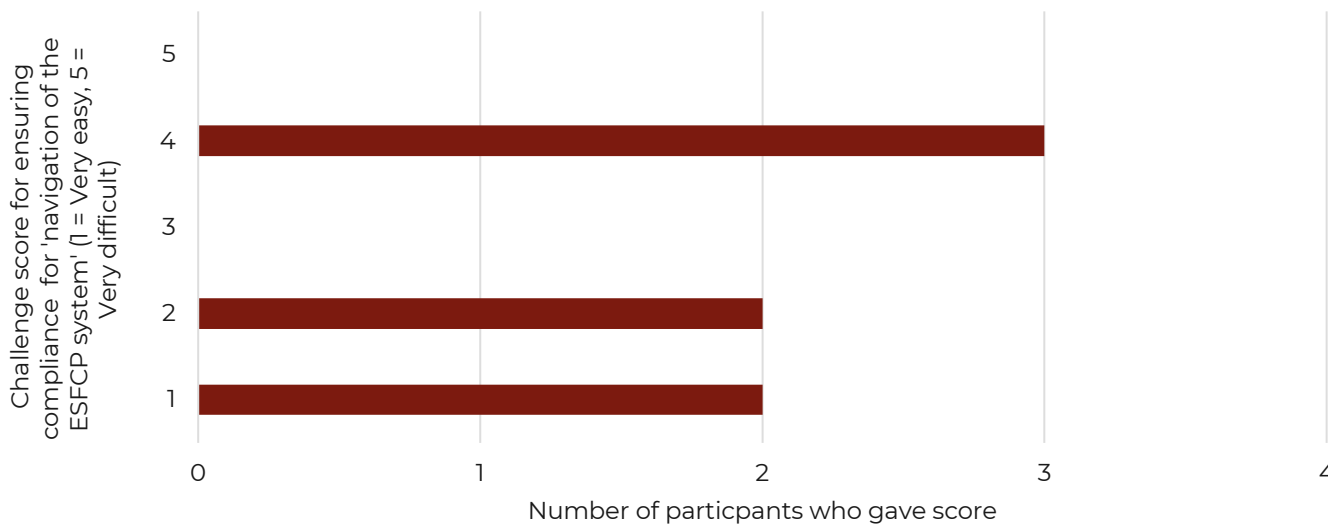


Figure 7. Responses for how challenging the notification of studies were for participants



**Figure 8. Responses for how challenging the confidentiality requests were for participants**

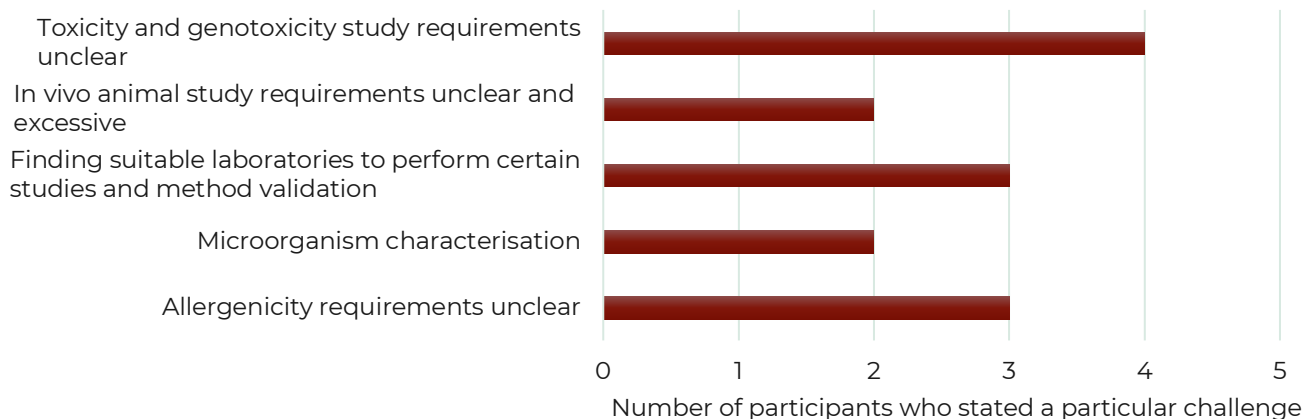
Using the ESFCP was, in contrast, deemed easy or moderately challenging to navigate for those participants who had so far used it with most reporting it was a high administrative burden rather than technically challenging (Figure 9).



**Figure 9. Responses for how challenging the E-Submission food chain platform was for participants**

## Challenges in data generation and interpretation of guidance

Of the participants who had begun, completed or were planning to generate data, all reported that there were aspects of the data requirements they found difficult to interpret or meet. Recurrent themes are summarised in Figure 10.



**Figure 10. Recurrent aspects of data requirements found difficult to meet by multiple participants**

### Additional Data Requests

Following dossier submission, applicants may receive an additional data request (ADR) from the authorities during the validation stage or during the EFSA risk assessment phase after validation. An ADR may request clarification on the information provided in an application or additional data needed to complete the scientific evaluation. ADRs are often informally referred to as “clock-stops,” because the assessment timeline is stopped and resumed once the applicant provides the requested information. There is no limit to the number of ADRs that can be issued at each stage and a single ADR typically contains multiple questions that the applicant must address.

All participant companies in the Risk Assessment phase of their NF application reported receiving at least one ADR. Several companies further reported the number of ADRs received. For those participants, the mean number of ADRs was six (Table 2)**Fel! Hittar inte referenskölla..**

Table 2. Number of additional data request reported by each participant during the EFSA Risk Assessment phase	
Participant	Number of ADRs
1	5
2	7
3	6
4	9
5	3
6	10
7	4
<b>Mean</b>	<b>6</b>

The common challenges reported by applicants in relation to the ADRs received are summarised below:

- Time taken to respond to certain questions if new studies needed to be performed or new methods of analysis had to be developed and validated
- Several applicants expressed surprise at the depth and level of detail of the questions received
- Large number of questions in each ADR
- Certain questions appear as more academic or exploratory in nature rather than clearly risk-based with justifications for some requests were not always provided

## Impact on budgeting, funding and investor relations

The participants were asked whether the regulatory requirements influenced their financial planning, including budgeting, funding strategies and investor relations during the development of their NF in the EU and application process. Separate questions were directed to companies' dependent on external investment (e.g. start-ups and SMEs) and to self-funded companies to capture differences in impact.

### *Investor-dependent companies*

The majority of participants planning to submit or who had submitted a NF application (13 out of 14) reported that regulatory requirements influenced their overall budgeting and financial planning. A common theme was the need to revise and increase budgets after they had been set, often due to additional studies that needed to be performed that were not originally envisaged. The requirement for performing additional studies came from ADRs which also can incur additional costs through consultancy fees if external support is needed to help navigate the questions received in an ADR. For the remaining company, although an application had been submitted and was undergoing risk assessment, no ADRs had been received at the time of the survey. As a result, their initial budgeting and financial planning remained sufficient and had not yet required adjustment.

All participants reliant on external investment reported difficulties in attracting funding as a direct result of the regulatory framework. Investor concerns were primarily related to the long timelines and high costs associated with the EU approval process.

### *Self-funded companies*

One company was self-funded i.e. primarily financed through its own profits and internal capital. Regulatory requirements led to the need for increased financial allocations to continue the

application process, as stopping the application would have resulted in greater financial losses. This reallocation created internal financial strain.

## Market entry and product development strategies

Participants were asked whether the EU regulatory framework and data requirements had influenced their market entry planning and product development strategies. Specifically, companies were asked about their decisions regarding launch markets, any delays or changes to product development and whether regulatory considerations had led them to prioritise approval in non-EU jurisdictions.

A total of 11 participants reported that the EU regulatory framework and data requirements had impacted their company's go-to-market strategy and which countries to target first for launch.

Nine companies stated that they were targeting either a combination of non-EU markets or specific non-EU jurisdictions prior to targeting the EU. These markets included the US, Canada, Singapore, Southeast Asia, Japan, the UK and Switzerland.

The reasons cited for prioritising these markets targeted were:

- Faster timelines to market
- More comprehensive opportunities for early engagement with regulatory authorities, enabling applicants to clarify requirements, obtain detailed pre-submission advice and prepare higher-quality dossiers lowering the likelihood of receiving extensive requests for further information following dossier submission
- Fewer product batches required for analysis
- Overall costs were perceived to be lower

One participant stated that from their perspective, obtaining NF authorisation in their domestic market is an important step prior to exporting and that securing their approval in the EU first can support their export strategy and facilitate market entry abroad. In the context of the EU, authorisation under Regulation (EU) 2015/2283 is only required for placing a product on the EU market and is not a legal prerequisite for exporting. The company's position therefore reflects a strategic choice rather than a regulatory necessity, suggesting that they view domestic authorisation as a way to strengthen their regulatory standing and potentially streamline engagement with international partners and regulators.

One participant decided to target the EU animal feed market with their product and plans to sell their ingredient for use in pet food and aquaculture. Since their product when used as a feed material does not require a pre-market authorisation, this pathway is perceived as a faster route to market with fewer regulatory hurdles. The company's intention is to generate an income to provide investors with some confidence whilst their NF application is ongoing.

## Overall Reflections on the Dossier Preparation Process

Participants were asked to provide overarching reflections on their experience with the EU NF process. Specifically, they were asked to identify the principal challenges encountered during dossier preparation, aspects of the regulatory procedure that they considered work well and the types of support, guidance or information that could have facilitated the process. Their feedback gives a clear picture of both the scientific and administrative challenges faced by applicants and highlights common difficulties, useful tools and practices, and offers ideas on how things could be improved to better support future applicants.

### *Key challenges encountered*

Participants were asked to indicate which specific aspects of the dossier preparation and assessment process presented the greatest difficulties. Participants were asked to select all relevant challenges from a list of potential issues, which covered scientific, procedural and administrative aspects. A breakdown of the frequency of the reported challenges is provided in Table 3.

<b>Challenge</b>	<b>Frequency</b>
Generating the required scientific data	13
Interpreting/understanding EFSA guidance	8
Number of clock-stops	6
Number of studies required	5
Validation timeline	5
EFSA risk assessment timeline	5
Compliance with the Transparency Regulation <sup>†</sup>	4
Overall transparency of the process	3
Navigating EFSA tools	3
Risk management timelines	2
Time required for dossier preparation	2
<sup>†</sup> Including managing confidentiality requests and submission via the ESFCP	

The main challenge identified was generating the required scientific data, cited by nearly all respondents (87%).

Interpreting and understanding EFSA guidance was reported by eight respondents (53%).

Six participants (40%) reported the number of ADRs (clock-stops) they experienced as being a major challenge. Along with the number of studies required (33%), validation timelines (33%) and EFSA's risk assessment timeline (33%), this feedback points to how extensive data requests and lengthy timelines can make managing dossier submissions more complex.

Concerns regarding compliance with the Transparency Regulation, including the management of confidentiality requests and submission via the ESFCP was selected by four participants.

Overall, most participants felt they had a good understanding of the NF framework and application process. They were generally aware of the need to follow specific guidance when preparing applications, the different stages involved and the respective roles of the risk assessor and risk manager although three participants cited this as lacking clarity for them.

Operational issues such as navigating EFSA tools (21%, 3/14), the EC risk management timeline (14%, 2/14) and time required for dossier preparation (14%, 2/14) were less frequently reported but were highlighted as factors contributing to prolonged application preparation and time to obtain final authorisation following EFSA's Opinion.

### *Positive aspects of the regulatory process*

Participants were asked what they thought worked well and which tools they found particularly useful.

Feedback indicated that EFSA's guidance documents were widely valued, as they provide clear information on both administrative and scientific requirements. Several participants indicated that the Transparency Regulation provided greater clarity regarding the submission process and the management of confidential information. The opportunity to speak directly with EFSA in a clarification teleconference during the completeness/suitability check and the risk assessment phase (following the issue of an ADR) was considered particularly valuable. These calls allow applicants to clarify EFSA requests for missing information the scientific rationale behind specific questions and ensure a shared understanding helping to reduce the need for prolonged email exchanges.

Multiple participants emphasised the usefulness of EFSA's technical tools. The EFSA Dietary Exposure (DietEx) tool, used by applicants to estimate chronic dietary exposure, was cited repeatedly as a key resource that improved the efficiency of the process, with some noting that equivalent tools are not available in other jurisdictions. Open EFSA was also valued for enabling applicants to view previous applications submitted and access EFSA's scientific opinions

published in the EFSA Journal to help guide applicants submitting applications for similar products and proposed uses.

Participants noted that, despite the guidance documents not being overly prescriptive, the structured guidance and supporting tools generally made the process more navigable and predictable compared with other jurisdictions. That being said, several participants emphasised that without external consultancy support, navigating the dossier preparation process would have been extremely challenging.

### *Participant feedback*

Participants were asked what types of support, guidance or information would have made the process easier. Their suggestions are summarised below and discussed further in the discussion section.

- Funding grants or regulatory sandboxes for companies developing and planning to submit applications for NFs
- Clearer guidance to reduce ambiguity regarding tiered testing, testing requirements and endpoints
- Streamlined guidance that is less administrative
- Greater prioritisation of *in vitro* or *in silico* trial validation and recognition of new approach methodologies to reduce reliance on animal testing
- More meaningful pre-submission advice on the studies required and appropriate methods
- Reduction in the number of batches required for initial submission, with the agreement to produce and submit further batches during the risk assessment process
- A submission platform that allows multiple documents to be uploaded simultaneously to reduce dossier submission time
- Increased transparency regarding certain questions asked in ADRs
- Statutory limits on the number of ADRs
- Clearer transition period following the implementation of new guidance, not being held to draft guidance prior to implementation or required to update dossiers submitted before updated guidance comes into effect
- More in-depth scientific dialogue with EFSA Scientific Officers on the rationale behind specific data or study requirements, including clarification where applicants may not fully understand why certain studies are being requested in ADRs



# Discussion

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Although the participants in this study represent a relatively small number of NF companies working in the alternative protein space, they provide meaningful insights into key trends and challenges in entering the EU market.

Most of the participants interviewed were involved in the development of ingredients from microbial fermentation, particularly precision fermentation and biomass fermentation. Recent industry data indicate that Europe remains a key region for fermentation-enabled alternative protein development, with a significant increase in investment into companies working on precision fermentation in 2024 and a 10% increase in investment into European biomass fermentation companies compared to the previous year as reported by GFI Europe (GFI, 2025). At the time of writing, 70 applications for NFAPs have been submitted to the EU authorities since 2018. This may appear to be a low number of applications given the timeframe (7 years) however, this may reflect a combination of factors including companies' reluctance to submit an EU NF dossier due to the costs and timelines associated with the process particularly for complex ingredients along with the prioritisation of other strategic markets with perceived faster and easier routes to market before engaging in the EU regulatory pathway.

The companies interviewed predominantly operate through B2B supply chains, with the majority being SMEs. This aligns with broader industry trends, as SMEs constitute a significant portion of the alternative protein sector in Europe.

Seven of the companies had submitted dossiers that are currently under EFSA risk assessment. Of these, two companies had already secured approval for at least one other ingredient. One company, which previously obtained a NF authorisation, had submitted an additional application for a different product that is now in the risk management stage following the issuance of an EFSA Opinion. Another company, which had also received authorisation, had submitted a separate dossier that is currently under risk management. One company had held NF approval for many years for an ingredient not considered an alternative protein source and submitted a new dossier for an alternative protein source but later withdrew it three years after submission whilst it was under risk assessment by EFSA. Finally, three companies are in the process of generating data for their dossiers, while two remain at the early development stage.

Of the companies with active applications under risk assessment, five submitted their dossiers in 2022 or earlier, showing that these applications have been in progress for more than three years. One application has been under consideration since 2019. According to the legislation, EFSA has nine months to complete its risk assessment once a submitted dossier has been validated; however, this timeline can be extended if ADRs are issued. All applicants that had submitted a dossier reported receiving at least one ADR, with an average of six ADRs per applicant however,



Le Bloch et. al reported an average of three ADRs issued by EFSA per application from a larger sample size (93 applications) ranging from zero to eight requests (Le Bloch et al., 2025). The frequency reflects the level of scrutiny applied during EFSA's assessment. An internal, unpublished analysis of NFAP applications submitted since 2018 shows that the average time from submission to validation is 8 months and 23 days and the average time from validation to publication of EFSA's Opinion is 2 years and 14 days. However, this average takes into account several insect-related applications which had notably longer timelines. Two applications (mealworm (*Tenebrio Molitor*) [EFSA-Q-2018-00746](#); house cricket (*Acheta domesticus*) [EFSA-Q-2018-00543](#)) each took over six years from dossier submission to EFSA Opinion, with the latter remaining in the validation stage for more than four years. Another three applications ([EFSA-Q-2021-00262](#); [EFSA-Q-2018-00282](#); [EFSA-Q-2019-00748](#)) had a timeline of at least four years from submission to EFSA's Opinion. Finally, an application for migratory locust (*Locusta migratoria*) [EFSA-Q-2018-00513](#)) as a novel food which currently remains under the risk assessment phase was not considered valid until six years after the dossier was first received by EFSA.

The EU is renowned for its comparatively longer risk assessment timelines relative to other jurisdictions. For example, many applicants seeking NF approval in the EU also pursue regulatory clearance in other markets, such as the United States through the Generally Recognized as Safe (GRAS) pathway or in Singapore under the Singapore Food Agency (SFA) NF framework. While both processes remain thorough in their review, particularly for new and complex products, the average review timeline in the US and Singapore is typically around 9–12 months.

It is important to note, however, that while applicants often refer to the GRAS process for comparison, it operates under a fundamentally different procedure compared to the EU NF authorisation route. GRAS is not a formal pre-market approval system but rather process in which a company concludes, based on established scientific evidence, that the use of a substance is safe under its intended conditions of use. Companies may choose to notify the US Food and Drug Administration (FDA) of their GRAS conclusion. Following its review of the submitted information, if satisfied, it will issue a “no-questions” letter, indicating that it has no further concerns regarding the notifier's safety conclusion.

This difference in timelines can have significant implications for companies, particularly start-ups that have invested years in product development and have limited financial resources. For such companies, prioritising faster-to-market jurisdictions can be critical to generating revenue and sustaining operations, while EU applications proceed in parallel.

The combination of high costs, extensive dossier requirements and prolonged EU review timelines frequently constrains investment and budgeting decisions. Several participants noted that investors were reluctant to commit to providing their support until there was greater clarity on regulatory outcomes i.e. clear precedents of successful applications, with some explicitly declining investment upon learning the scope and duration of obtaining final EU authorisation. Even companies that secured funding reported ongoing pressures, including repeated demands for



updates and justifications for delays from investors as the process extended over multiple years. The self-funded company interviewed, similarly reported that regulatory requirements necessitated unforeseen financial reallocations, including additional studies requested during ADRs, external consultancy fees and internal costs and that halting the application was not feasible given the resources already invested.

These financial and regulatory pressures are closely linked to companies' market entry strategies. Many prioritise jurisdictions with faster and more predictable approval pathways, such as the US or Singapore, to generate early revenue, demonstrate proof of concept and maintain investor confidence, while EU applications are submitted or being prepared in parallel. Several participants reported submitting in multiple regions simultaneously to mitigate risk. While the EU represents one of the largest potential markets for many novel ingredients, the stringent data requirements and lengthy timelines often mean that it is approached later in the launch sequence.

Conversely, some companies maintained that EU approval was unavoidable for achieving large market access, reflecting a strategic necessity: "Because we want to market in the EU, we have to accept the longer regulatory process". As mentioned in the results section, some companies have proceeded with and are exploring the possibility of other regulated product pathways in the EU to access the market faster such as the animal feed or cosmetic route to generate revenue whilst their NF application progresses.

Building on these insights, the findings on regulatory support and use of resources to build and submit an application further clarify how companies navigate the EU NF pathway.

Participants overwhelmingly reported relying on external consultants to navigate the complex framework, with most combining external expertise with in-house regulatory teams. This reflects the perception that in-house capacity alone is often insufficient, particularly for smaller or less experienced organisations. As one participant explained, "the consultants we work with provide most of the advice and experience, even from the initial stages helping us understand which regulations and guidance are applicable through to the final stages of submitting dossiers." Consultants were described as "very important" due to their ability to "answer quickly and concisely," particularly when timelines are tight and even the submission process is administratively demanding and time-consuming. While consultants provide critical support for many companies, participants noted that these services come at considerable cost, which can be difficult for smaller companies. This reliance may also reflect a broader need for clearer guidance or greater regulatory support mechanisms within the sector.

Another area where companies may typically rely on experienced regulatory staff or consultants is the interpretation of guidance. Participants emphasised that understanding and applying EFSA's scientific and administrative requirements often required external expertise to ensure compliance. Even with consultant support, applications can still take considerable time to progress through validation and companies frequently receive requests for additional data



(ADRs). This highlights that consultants, whilst highly valuable, do not have complete knowledge of every expectation from EFSA.

In terms of administrative requirements, participants who had experience needing to comply with the EU Transparency Regulation shared a range of perspectives. While the Regulation aims to enhance openness and public trust, its implementation was often described as burdensome and at times, unclear. Several companies highlighted that the notification of studies requirement, though conceptually straightforward, was difficult in practice particularly during early development stages when study plans were still evolving and it is unclear whether such studies will be used for a future application or simply internal research purposes. Participants noted that “to actually do it is easy, but to ensure compliance is difficult” reflecting uncertainty over what qualifies as a notifiable study and when exactly notification obligations begin despite the definition of “study” and “study start date” being outlined by EFSA in its [Questions and Answers on EFSA Practical Arrangements](#) (last updated in 2023) with some examples of studies that would constitute notification but no clear closed list. Another concern was the requirement to prepare justifications that would be accepted by EFSA for studies not notified accordingly or that were not originally intended to be used for EU submission and therefore, risk receiving a penalty in which EFSA deems the dossier non-valid, resulting in the applicant having to re-submit the application and being hit with a six month penalty. A six-month delay can be make or break for SMEs who have limited financial runway and are dependent of meeting critical investor milestones (such as dossier validation) or receiving regulatory approval to unlock additional funding.

Drafting confidentiality requests were also perceived as “painful” and “time-consuming,” primarily due to the need to prepare both redacted and non-redacted versions of documents and to justify each request against specific legal grounds. By contrast, navigation of the ESFCP was generally viewed as more manageable, with challenges framed as administrative rather than technical with some appreciating the possibility of being able to track their application directly through this platform.

In terms of scientific data requirements, participants identified this as the most significant challenge in preparing their NF application. Participants emphasized the uncertainty over generating the “right sort of data” expected by EFSA, particularly for innovative or complex products where existing guidance was considered too general or not directly applicable. This was particularly evident in areas such as toxicological study requirements, where decisions about study design, selection of the correct test item, data generation or the level of evidence required were described as highly case-dependent and often unpredictable. While *in vitro* and *in silico* approaches are available, participants noted that it was often unclear under what conditions these methods would be accepted in place of *in vivo* studies. Comments were raised concerning the high costs, time and ethical considerations associated with animal testing where such studies are required or requested. As one company noted, “they say they want to reduce animal use, but then they say, ‘this is so novel, you must still do the studies’”. This was a particular tricky point raised

by three companies who, as developers of alternative protein products, want to distance themselves from all involvement of animal testing in line with their company's mission.

A common theme related to the lack of clarity and specificity in EFSA's scientific guidance, which often led to inconsistent interpretations during dossier preparation. Several participants reported being asked to generate data for specific food matrices, endpoints or analytical methods for which no validated protocols existed, requiring the development and validation of new methods either using external laboratories or in-house. As one applicant explained, "for the first application, we needed to find a company who could develop a new validated method, it took a lot of time." Others described being instructed to use specific analytical methods that lacked formal validation, or to apply draft guidance documents that were "not well described for our product," and in some cases, considered unsuitable. This added further uncertainty, as companies were required to develop in-house standards or adapt methods mid-process to align with evolving regulatory expectations.

Understanding the requirements for addressing allergenicity was the most commonly cited challenge, which is especially significant given that the allergenic potential of new protein sources is a critical safety concern. Despite the 2024 update to EFSA's scientific guidance, which provides a more detailed, tiered approach for assessing allergenicity, participants still reported uncertainty regarding the amount of data required, interpretation of guidance on cross-reactivity testing and bioinformatic analysis for non-experts and which methods were most appropriate for their specific products were key challenges. One company reflected on how they think that they "over-submitted" information to address allergenicity and "aimed to provide as much data as possible" including expert input, but this approach ultimately generated a cascade of follow-up questions from EFSA which they may have been able to avoid by submitting more targeted information from the beginning.

With several applicants producing ingredients derived from microorganisms, some explained that, as is routine in industry, they continuously work to modify and improve the efficiency of their production strains over time and would also be the case following approval. This ongoing strain optimisation raised uncertainty about whether such changes would require dossier re-submission or additional data to be submitted to the Commission and EFSA. While such process adjustments may not fall within EFSA's remit, participants noted that any modification affecting the product's safety profile could still trigger the need for renewed assessment, creating ambiguity about where the regulatory boundary lies.

A further issue concerned the Qualified Presumption of Safety (QPS) approach. QPS provides a framework through which microorganisms with a well-established record of safe use in the food chain can benefit from a simplified safety assessment. However, as there is no pre-assessment process to confirm QPS status before submission, applicants must still provide a full safety dataset upfront for microorganisms that are not already included in the QPS list. One company reflected that, although their strain had not yet been assessed as QPS, "it would be good to have this evaluation first," noting that an early determination could help tailor data generation and avoid



unnecessary studies. While such an approach might reduce some study costs if determined to be suitable for QPS status, adding this extra review step would actually increase overall timelines as in current practice, EFSA carries out its own, separate QPS assessment of microorganisms that are part of regulated product applications in parallel to the NF dossier evaluation.

Another significant challenge reported by some participants was the requirement to produce five independent batches of their NF for compositional analysis while other regulatory regions typically request three non-consecutive batches. For smaller companies or those developing ingredients at pilot scale, producing five batches can be technically and financially demanding. However, it can simultaneously be argued that EFSA's request for five independent batches reflects its approach to ensure robust and reliable safety data across independent production runs.

With regards to composition, one company also highlighted the additional complexity of new ingredients such as biomasses, which are not just sources of protein but also contain significant levels of minerals, vitamins and other bioactive components. As outlined in the section on scientific data requirements earlier in this report, NFs must not be nutritionally disadvantageous meaning that their consumption under the proposed conditions of use should not lead to an excess intake of nutrients for one or more population groups. EFSA has become increasingly focused on the exposure of micronutrients relative to established Dietary Reference Values (DRVs). Applicants must be aware of nutrient levels during product development particularly when using different inputs or process variations and anticipate the potential implications if levels approach or exceed DRVs meaning that the NF could be concluded as nutritionally disadvantageous. Exceeding these values may require refinements to proposed food categories to reduce micronutrient exposure levels or additional justification in the dossier. This company also cited the uncertainty arising from the possibility that DRVs could be updated over time, which could impact exposure.

For applicants that had submitted a NF application, in line with the abovementioned difficulties with adhering to the scientific study requirements outlined in both the guidance and in ADRs, many were dissatisfied with the time elapsed before clock stop questions were actually sent. Several commented that had EFSA been able to be more open in its communication or greater transparency was provided earlier on in the process about what type of questions may be expected and perhaps issuing questions to applicants as early as possible when concerns arise, the company would have been able to answer these more quickly and in more manageable chunks. In one particular case, an applicant whose dossier had been under risk assessment for more than four years and who had already received two extensive ADRs reported that EFSA subsequently determined the data submitted were insufficient to fully rule out potential genotoxicity concerns. As a result, the applicant was requested to conduct an additional genotoxicity study using a different test item, a requirement introduced only in EFSA's updated 2024 scientific guidance and therefore not referenced or applicable at the time the dossier was originally submitted. Such a request was perceived as particularly challenging, as it required the applicant to undertake a costly and time-intensive study several years into the process, in accordance with guidance that

had not been in place when the dossier was originally submitted. On the other hand, this may reflect EFSA's efforts to align with technological advances and evolving scientific approaches for assessing certain areas of safety, ensuring that evaluations remain in line with the most current understanding of safety. One further applicant submitted an application and after 1.5 years received the first ADR, after which a further three ADRs over the course of two years ultimately led to the dossier receiving a negative opinion from EFSA without a clarification call. Communication from EFSA prior to this may have allowed the applicant to add additional information to the dossier allowing a positive opinion to be formed.

Beyond timing, several participants also expressed concern about the scope and depth of questions included in ADRs. In one example, an applicant explained that they were unexpectedly requested to generate analytical data for certain undesirable substances that published literature had already shown to be absent or insignificant in well-characterised comparable food matrices. Such questions were characterised some of the questions as “more academic than risk-based”. Their first round of more than 70 questions reportedly covered all sections of the dossier, with follow-up queries on the same dossier sections issued despite detailed initial responses. The company further noted that EFSA did not always provide clear risk-based justifications for certain data requests and did not appear receptive to scientific explanations submitted by applicants, which contributed to a sense of procedural imbalance and uncertainty.

Many participants also noted that inevitably external consultant costs rise with each ADR as the number and complexity of questions is impossible to predict. Therefore, not only is there a delay in the application process but there is also a cost implication to the company and its investors aside from additional study costs.

The findings from this study suggest that there is a disconnect between what the applicants are doing and how they interpret the guidance versus what EFSA wants to see, leading to dossiers that are not fully compliant and take longer to validate and risk assess because of key gaps.

It becomes clear that these gaps need to be identified and addressed to increase the quality of dossiers and reduce timelines to market.

One potential approach to address the gaps could be the establishment of regulatory sandboxes - controlled environments where companies can test new products or processes with regulatory guidance and oversight directly from authorities before market entry. In 2024, the UK Food Standards Agency (FSA) launched a regulatory sandbox for cell-cultivated products (CCPs) to gather scientific information to help the FSA to assess such applications efficiently and ensure their complete safety before they are sold to consumers. The programme will also offer clearer guidance to businesses and address essential questions prior to market entry, with the goal of completing full safety assessments for two CCPs within the next two years.



Additionally, a summary of the main gaps in support, guidance and information referenced by the participating companies is shown in Figure 11.

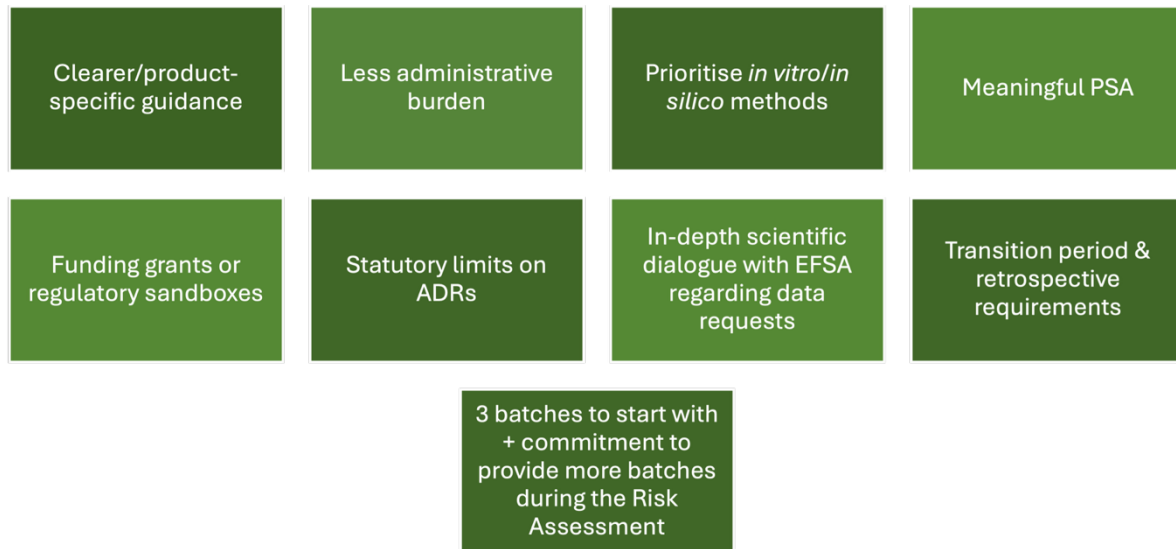


Figure 11. Summary of gaps in support, guidance and information from participant feedback

## Conclusions & recommendations

EFSA has consistently emphasised its commitment to performing thorough and reliable risk assessments, underpinned by the latest scientific advancements to ensure its mission of safeguarding public health and ensuring the safety of the EU food and feed chain. While this study primarily captures the perspectives of NF developers working in the alternative protein sector, it is important to note that EFSA has also highlighted factors that can make their review of submitted NF applications challenging and lead to detailed requests for data and therefore the increase in risk assessment timelines. EFSA discussed and published their main observations on submitted dossiers during their recent [158th Nutrition, Novel Foods and Food Allergens \(NDA\) Panel meeting](#).

They found that regulatory requirements are at times misinterpreted or appear to be neglected by applicants. They strongly encourage applicants to review existing scientific opinions for similar products along with relevant regulatory outputs as a good source of information of EFSA's expectations from companies. Moreover, general guidance materials may be applied unevenly or to an insufficient extent. In certain cases, data collection concerning the NF and its safety-related properties lacks thoroughness with compositional analyses cited as a particular area which is often incomplete or inconsistent with published literature. Additionally, discrepancies are sometimes observed between study results presented in laboratory documents (such as certificates of analysis) and the corresponding data provided in the main dossier. EFSA has cited these reasons for delays in the application process.

Further points from EFSA highlight issues often observed in applications:



- **Over-reliance on history of use or non-representative literature-based toxicological data:** Applicants may depend heavily on historical use data or literature that does not adequately represent the NF's characteristics or potential risks
- **Studies not submitted without a scientifically sound justification:** In some cases, applicants fail to submit required studies without providing adequate scientific reasoning for their omission
- **Incorrect or incomplete application of the tiered toxicity testing approach:** The tiered approach, designed to limit animal testing, may not always be correctly or fully applied, leading to data gaps
- **Insufficient interpretation or elaboration of study results:** Submitted study results may lack sufficient interpretation or elaboration, making it difficult to assess their relevance and reliability
- **Lack of contextualisation within the broader scientific or regulatory framework:** Findings may not always be clearly contextualized under the specific NF scope
- **Inconsistent integration of evidence across dossier sections:** Lack of clear connected between data and information included across the dossier leading to a fragmented assessment approach

Recognising both applicant experiences and EFSA's observations provides a more balanced understanding of the complexities inherent in the EU NF regulatory framework and demonstrates the need for continued dialogue and clarity to facilitate efficient and robust risk assessments.

## Pre-submission advice

One way of achieving further transparency is the establishment of more meaningful pre-submission advice which was proposed by nearly all the companies interviewed. In certain jurisdictions, such as the US, Australia and New Zealand, Canada and Singapore, regulatory authorities strongly encourage prospective applicants to engage with them before submitting their dossiers. This early interaction allows companies to introduce themselves, their technology or ingredient and their proposed strategy for meeting application requirements. These authorities are able to offer highly tailored feedback, including comments on preliminary data, planned studies, study design and guidance on any additional information they would like to see included in their application.

Whilst EFSA currently does not offer tailored pre-submission advice, it actively encourages applicants to seek its GPSA, where the scope is focussed primarily on general questions regarding administrative and scientific guidance documents rather than providing the detailed, product-specific feedback that applicants would find most valuable. EFSA has emphasised that their ability to provide more in-depth pre-submission advice is limited due to the scope of the GPSA which is defined in Article 32a of the General Food Law Regulation (EC) No 178/2002. As shown in the results above, participants who sought EFSA's GPSA rated its helpfulness on a scale of 1 (very helpful) to 5 (very unhelpful): one company gave a score of 1, three gave 3, two gave 4 and one gave 5. The majority of scores at 3 or above indicates that, while the advice could be somewhat useful, it often fell short of expectations. One participant who took part in a teleconference with



EFSA to obtain GPSA (through an expression of interest (EOI) for SMEs working in the area of NFs, an initiative first launched in June 2024) reported that, although the interaction was useful for introductions and understanding EFSA's structure, it offered limited substantive guidance.

More thorough pre-submission advice could help address the issues with submitted applications observed by EFSA and improve the quality of submitted dossiers by clarifying expectations and appropriate testing strategies which would also allow applicants to be better positioned in avoiding costly errors or misunderstandings. Although not an alternative protein source, a clear example is EFSA's Scientific Opinion on apple fruit cell culture biomass as a NF (EFSA, 2023) where the applicant was required to repeat genotoxicity tests because the initial test material largely consisted of the carrier isomalt rather than the NF itself. These tests are both time-consuming and expensive and such duplication could likely have been avoided if the testing approach had been discussed with EFSA in advance.

Targeted pre-submission advice could also be a great benefit to EFSA itself as it would allow them to familiarise themselves with upcoming applications and new, developing technologies that are being used to produce food ingredients and therefore anticipate challenges earlier.

The general costs associated with submitting a dossier are already high, but uncertainties regarding budget and timeline can create additional challenges. Participants cited these uncertainties as reasons why investors may be reluctant to fund an EU application or why self-funded companies may struggle due to budgeting issues or the need to reallocate funds. Delays due to clock-stops and requests for larger studies later in the application process can also frustrate investors and mean that submission milestones are not met. Whilst the participants accept that safety is paramount and they are more than happy to accommodate requests for studies, participants have stated that it would be helpful if those requests came sooner in the application process to be able to inform investors earlier of such increases in budget and time delays. For example, if required a 90-day subchronic toxicity study may cost in the region of 30,000€ with the timeline to the final report being 9-12 months. This is a significant cost which may not have been initially budgeted for due to an applicant's interpretation of the guidance. moreover, some applicants invest in the 90-day sub-chronic toxicity study when it is not needed, as was the case for the apple fruit cell culture biomass. In this case, the applicant performed the sub-chronic toxicity study in rate, but in their scientific opinion, EFSA said that the sub-chronic toxicity study was not needed to conclude on the safety of the NF, underscoring the waste of time and money and more importantly, the unnecessary use of animals.

However, it is also important to note that the legal framework established by Article 32a currently restricts EFSA's ability to provide more detailed advice, meaning that a more comprehensive form of pre-submission engagement would require some form of regulatory adjustment or clarification.



## Enhancing communication and clarity in risk assessment

A common area of feedback from participants was the desire for deeper engagement with EFSA scientific officers when requesting GPSA and during post-submission clarification calls rather than more administrative staff, particularly to clarify the rationale behind certain data requests. Some participants felt that certain requests appeared to reflect academic curiosity rather than direct safety concerns, placing unnecessary burdens on companies. They suggested that formal explanations for why specific questions are asked could help applicants respond more effectively and reduce inefficiencies.

Participants also commented on the lack of clarity on when clock-stops may be issued and what is likely to be included in an ADR. Whilst there are statutory guidelines in place, these are often vague and allow a large buffer of time for EFSA. The participants suggested that establishing formal clock-stop points for each section of the dossier be mapped out ahead of time in a consecutive order and that more effort is made to issue requests for large studies much earlier in the risk assessment phase. They also suggest that information on previous clock-stops could be made publicly available (in a confidential form akin to the non-confidential dossiers published on Open EFSA) to enable potential applicants to plan better.

## EU support for alternative protein innovation, addressing funding gaps and investor education

The EU has acknowledged the growing importance of alternative proteins in promoting sustainability and reducing the environmental impact of traditional animal agriculture. Initiatives such as the European Green Deal aim to foster the development and scaling of alternative protein sources. For example, the European Innovation Council (EIC) has reportedly allocated €50 million to support startups in scaling the production of foods derived from fermentation and algae. In addition, the European Investment Bank (EIB) has provided venture debt to companies such as Formo in Germany, which develops fermentation-based cheese alternatives and Heura Foods in Spain, which produces 100% plant-based meat alternatives, to help advance the production of innovative alternative protein ingredients.

However, despite these efforts, many startups producing particularly novel ingredients continue to face financial challenges. Some participants have suggested the possibility of additional funding mechanisms, regulatory sandboxes or finance models to bridge the funding gap and support the growth of the alternative protein sector. These measures could help de-risk investments enabling startups to scale their operations and contribute to a more sustainable food system. Along with this is the suggestion to establish sources of education for investors to help them understand the



overarching principles of the EU NF framework including its timelines and data requirements, which would help align expectations and facilitate informed investment decisions.

## Improving access to expert support

It was notable that most participants relied on external consultants, reflecting the complexity of navigating the NF application process. Even with experienced support, both applicants and their consultants sometimes struggled to determine the most appropriate approach for certain testing requirements. Several participants suggested that it could be helpful to have a publicly available list of consultants with demonstrated experience in preparing NF dossiers, compiled by Member States or another neutral body, to support companies in managing the process more effectively.

## Targeted technical guidance

Finally, some companies called for more tailored and specific guidance for different types of novel ingredients such as clearer instruction on testing tiers, allergenicity assessment and acceptable compositional ranges would allow applicants to design studies more efficiently and avoid unnecessary duplication. Having a clearer opinion on the likely acceptability of New Approach Methodologies (NAMs) such as *in vitro* or *in silico* alternatives to animal studies would also help address ethical concerns. This aligns with EFSA's commitment to applying the 3Rs principle of replacement, reduction, and refinement of animal use, and reflects the European Commission's roadmap for phasing out animal testing. Targeted guidance on NAMs would be particularly valuable for alternative protein developers, supporting innovation while ensuring robust safety assessment without unnecessary reliance on *in vivo* studies.

In summary, the findings of this work highlight several overarching themes that shape applicants' experiences with the NF process:

- **Applicants want to prepare high-quality dossiers**, but often struggle to do so with the demanding requirements
- **EU regulatory requirements remain complex and difficult to navigate**, particularly for smaller or less experienced organisations
- **Existing guidance documents provide valuable direction**, yet important gaps persist, leaving applicants uncertain on key aspects of data generation and assessment expectations
- **Pre-submission engagement and clearer scientific dialogue would considerably reduce ambiguity**, helping applicants understand expectations and design appropriate studies from the outset
- **Unanticipated costs, clock-stops, and extended timelines after submission create substantial burdens**, especially for SMEs and companies operating with limited resources



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