

# Bringing alternative protein products to the European Union market – the regulatory framework for novel foods





## Introduction

The pressing challenges of global climate change, rapid biodiversity loss and increasing antibiotic resistance are pushing governments around the world to tackle the unsustainability of the livestock sector.

The Paris Agreement commits its parties to drastically reduce greenhouse gases to keep the rise in global temperatures below 2° Celsius. With the Farm to Fork strategy at the heart of the European Green Deal to make the EU climate neutral by 2050, the EU is supporting the shift to a healthier and more sustainable food system. Increased health concerns and awareness of zoonotic diseases have accelerated this development. The food sector is facing a fundamental change – in Europe and globally.

Alternative protein products such as plant-based meat and cultured meat, as well as plant-based and cultured dairy and egg products will play a key factor in the transition of our food systems. The general perception of what constitutes meat, dairy and egg products will change drastically.

This brochure provides an overview of the regulatory regime for bringing alternative protein products on the market of the European Union under the Novel Food Regulation 2015/2283. It explains the authorization procedure and the instruments available for protection of scientific data and other sensitive information submitted to support a novel food application. It also explores the competitive advantages that may arise from an authorization under the Novel Food Regime.

## What is the regulatory regime for bringing plant-based or cultured alternative protein products onto the EU market?

The placing of food onto the EU market can, in principle, take place without prior authorization, provided that the general provisions of food law are observed. An exception, however, applies to so-called novel foods, for which the Novel Food Regulation 2015/2283 establishes a special authorization regime. In order to exclude health risks for consumers in the EU, novel foods may only be placed on the EU market after prior authorization by the European Commission.

Novel foods in the sense of the Novel Food Regulation are all foods that were not used for human consumption to any significant extent in the EU before May 15, 1997, and that fall into certain categories. The novel food categories include inter alia (in abbreviated form):

- Food with new or intentionally modified molecular structure;
- Food consisting of, isolated from, or produced from microorganisms, fungi or algae;
- Food consisting of, isolated from or produced from plants or their parts by a new non-standard process;
- Food consisting of, isolated from, or produced from cell culture or tissue culture derived from animals, plants microorganisms, fungi or algae.

The European Commission has confirmed that cultured meat may fall under the latter category. The same is likely to be true for cell-based dairy or egg alternatives.

Whether other plant-based alternative protein products fall under the Novel Food Regulation must be assessed on a case-by-case basis, taking into account the ingredients and applied production techniques. Even though fermented foods and beverages have long been part of the human diet, fermented plant-based products, for example, may still require an authorization under the Novel Food Regulation. The Novel Food Regulation may also apply to the starter cultures used in the fermentation process. Food ingredients that are produced by using “new” (meaning not being used for human consumption prior to May 15, 1997) microorganisms in precision fermentation processes may fall under the Novel Food Regulation. The European Food Safety Authority (“EFSA”) maintains a list of microorganisms which have already been assessed. If an assessment concludes that a group of microorganisms does not raise safety concerns, it is granted the qualified presumption of safety (“QPS”) status.

In case of uncertainty about the classification as Novel Food, the competent authority of the member state where the food is to be placed on the market can first be consulted by the food business operator. For example, in Germany the Federal Office of Consumer Protection and Food Safety is the competent authority.



### When does the EU GMO regime apply?

Alternative protein products that contain or consist of a genetically modified organism (“GMO”) are subject to the GMO Regulation 1829/2003. The provisions of the Novel Food Regulation are superseded by the GMO regulation. The GMO Regulation only covers food (and feed) produced “from” a GMO but not food produced “with” a GMO. The determining criterion is whether or not material derived from a genetically modified source material is present in the food. Processing aids that are only used during the food production process are not covered by the definition of food and therefore are not included in the scope of the GMO regulation. Food that is manufactured with the help of a genetically modified processing aid also is not included in the scope of the GMO regulation. Consequently in many cases the GMO regulation will not be applicable to alternative protein products, so its consequences (especially the GMO-specific monitoring and labelling obligations and the 10-year time limit of GMO authorizations) can often be avoided. Again, a case-by-case analysis on the basis of the properties of the respective alternative protein product is necessary.

### What requirements must be met by the Novel Food in order to be authorized?

Since January 1, 2018, authorized novel foods have been included in the so-called Union list of novel foods. Once a novel food is added to the Union list it is considered as being authorized and it can be placed in the EU market. In summary, the novel food must meet three basic requirements to be authorized. Firstly, only those novel foods are authorized that – on the basis of scientific evidence available – do not pose a safety risk to human health. Secondly, the novel food’s intended use may not mislead the consumer. Thirdly, where the food is intended to replace another food, it may not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.



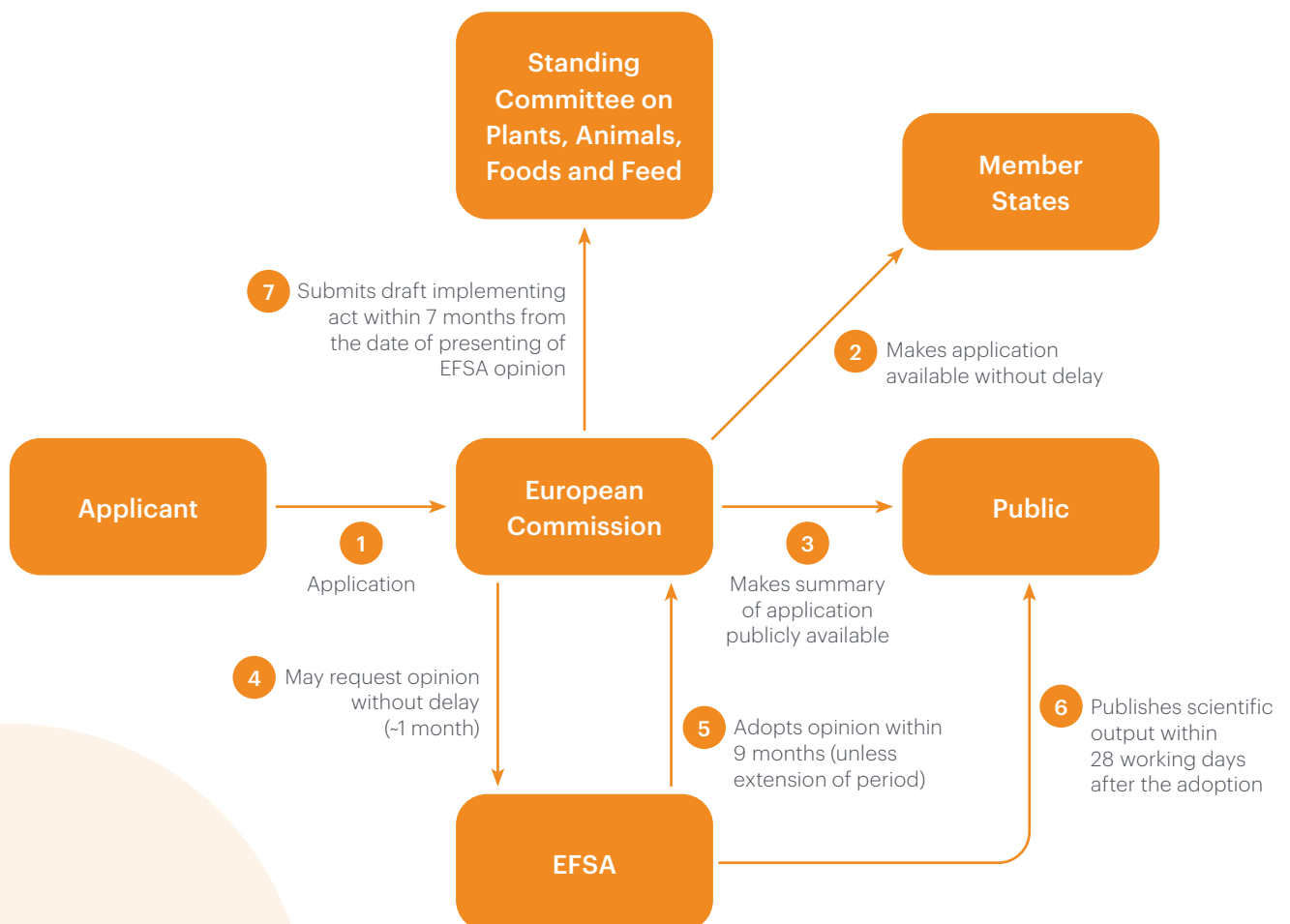
## What competitive advantages arise from the authorization under the Novel Food Regulation?

Without an authorization, cultured meat, cell-based dairy or egg alternatives or other alternative protein products falling under a novel food category may not be placed on the EU market. The authorization is granted with regard to a specific novel food and not with regard to the product of a specific applicant. This means that an authorized novel food may in principle be put on the EU market by any food business operator and not just the applicant. Taking into account the differences in ingredients and production processes, it however remains to be seen if other companies will be able to bring their own product to the EU market on the basis of an authorization obtained by another food business operator.

However, other food business operators may in principle be able to rely on scientific evidence and data provided by another food business operator in

a previous authorization procedure, at least to the extent as the scientific evidence and data has been made publicly available. This would be annoying for applicants, as carrying out the authorization procedure and providing the necessary scientific studies involves considerable effort and costs. To recognize these efforts the European Commission therefore under certain conditions and upon request grants the applicant not only an exclusive right with regard to the authorized novel food but also protection with regard to the scientific data on which the application is based. To be granted protection the application must be based on newly developed and proprietary scientific evidence and data. If protection is granted, for a period of five years only the applicant may place the authorized novel food on the EU market. Another company can only obtain a novel food authorization without reference to the protected scientific evidence and data of the initial applicant or with the agreement of the initial applicant.

## Novel Food authorization procedure – Overview



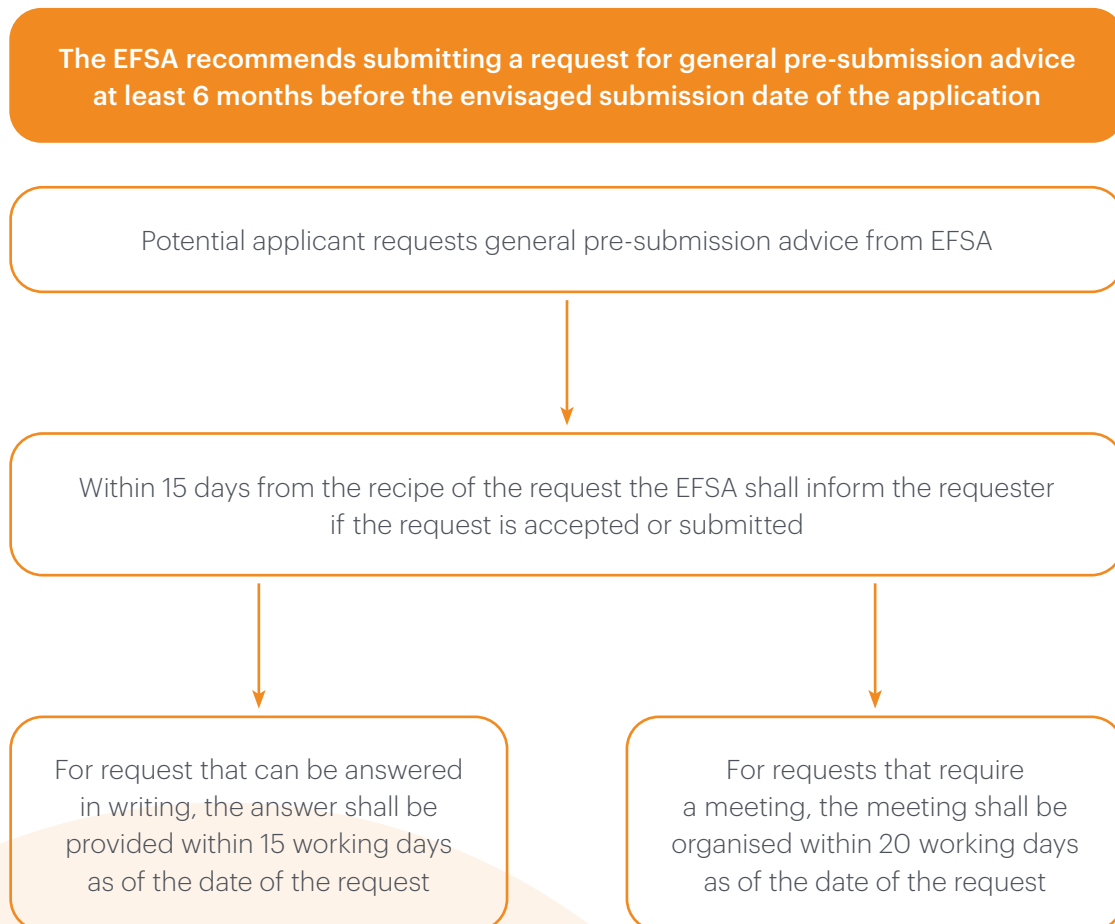
## Which authorities are involved in the application for admission?

In order to be included on the list, the novel food must go through the authorization procedure, which is carried out by the European Commission. The European Commission shall conduct the procedure with the involvement of the European Food Safety Authority ("EFSA"). The EFSA is an independent agency responsible for the risk assessment. The member states are not involved in the procedure but are kept informed about its progress by the European Commission. Applications for authorization of plant- or cell-based novel foods must be submitted through the electronic submission system of the European Commission, the E-Submission Food Chain Platform.

## What is the pre-submission phase?

Before the application is submitted, the EFSA can provide general pre-submission advice to the potential applicant. This engagement with the EFSA is not mandatory but can be helpful to prepare a complete application and avoid queries later on. The pre-submission advice shall relate to the rules applicable to the application and the information to be provided in the application. However, the advice does not go beyond the information already provided by the regulations, guides and guidelines on how to apply. In particular, the advice does not relate to the design of the studies, the hypotheses to be tested or the risk management. Requests for pre-submission advice shall be submitted via the EFSA website. In principle, the pre-submission advice takes place in such a way that the authority answers the questions in writing. However, a meeting (also by telephone or video conference) is possible.

## General pre-submission advice







### What is the obligation to study notification?

Upon the implementation of the Transparency Regulation 2019/1381, the EFSA maintains a database of studies commissioned or carried out by companies to support applications for which the EFSA is required to provide a scientific opinion under EU law. All studies which shall be used to support a novel food application and which are commissioned or carried out after March 27, 2021, need to be notified to the EFSA before the starting date of the study. If study notifications are only made after the start date of the study, the reasons for the delay must be communicated. The notification obligation ensures that applicants cannot withhold studies with unfavorable results. It applies not only to applicants, but also to laboratories and external research institutions in the EU. Laboratories and external research institutions in third countries may also become subject of the notification obligation if the EU concludes respective agreements with the third country.

Failure to comply with notification obligations can trigger significant time delays in the application process. Novel food applications are considered invalid if they contain non-notified studies or if the reasons given for late notification are not considered sufficient by the EFSA. Applications are also invalid if notified studies are not included in the application and the applicant cannot provide a valid justification for this. In both cases the application must be re-submitted. The assessment of the validity of the re-submission shall commence six months after the correct notification or the submission of the studies.

For companies in the sector that target markets worldwide, it is important to know that the study notification must be made without delay as soon as the European Union becomes the potential market for the novel food to which the study relates. Therefore, even if the novel food shall initially be put on a market outside the EU, the food business operator should consider whether the studies should be also be notified to the EFSA.



## How does the authorization procedure work?

After the application has been submitted, the European Commission can request the EFSA to issue a scientific opinion evaluating the safety of the novel food. It is to be expected that the European Commission will practically always make use of this possibility with regard to novel food authorization applications for alternative protein products. Even though the EFSA issues a scientific opinion, it remains the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (including both data in favor and not in favor) that are pertinent to the safety of the novel food.

The EFSA has prepared a “completeness checklist” which corresponds with the necessary content of the scientific opinion the EFSA must prepare. The EFSA expects detailed information about the identity of the novel food (depending on the applicable novel food class), the production process, compositional data, specifications, the history of the novel food and / or its source, the proposed uses and use levels and anticipated intake, ADME (absorption, distribution, metabolism and excretion), nutritional information, toxicological information and information about the allergenic potential. The results of the scientific studies shall be summarized in summary tables.

The EFSA shall adopt its opinion within nine months for the date of receipt of the application. The period may be extended where the EFSA requests additional information from the applicant. The EFSA aims to publish its scientific output relating to the risk assessment of the application within 28 days after the adoption. Within 8 months from the date of the publication of the opinion of the EFSA, the European Commission submits a draft implementing act to the Standing Committee on Plants, Animals, Food and Feed.

## How is the confidentiality protected of any scientific data and other sensitive information submitted to support a novel food application?

EFSA shall carry out its tasks of risk assessment in the food chain in an open and transparent manner towards consumers, businesses and the public. For this reason the EFSA must proactively make publicly available all information submitted by applicants for the purposes of the EFSA’s scientific evaluation of the novel food. The EFSA is to make publicly available *inter alia* the following information:

- All its scientific outputs;
- Scientific data, studies and other information supporting applications, including additional or supplementary information requested during an assessment, as well as other scientific data and information requests from the European Commission and the member states for scientific output;
- The information on which its scientific outputs are based;
- A summary of the advice provided to potential applicants at pre-submission phase.

It is clear that these far-reaching transparency requirements run counter to the applicant’s interest in protecting its trade secrets. Upon request of the applicant, the EFSA may therefore grant confidentiality status to certain elements of application dossiers, provided applicants submit a verifiable justification and the EFSA accepts the confidentiality request. In the case of applications for a novel food authorization, the following information may be accepted as being confidential:

- The manufacturing or production process, including the method and innovative aspects, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the safety assessment;
- Commercial links between a producer or importer and the applicant;
- Commercial information revealing sourcing, market shares or business strategy of the applicant;
- Quantitative composition of the subject matter or the request, except for information which is relevant to the safety assessment;





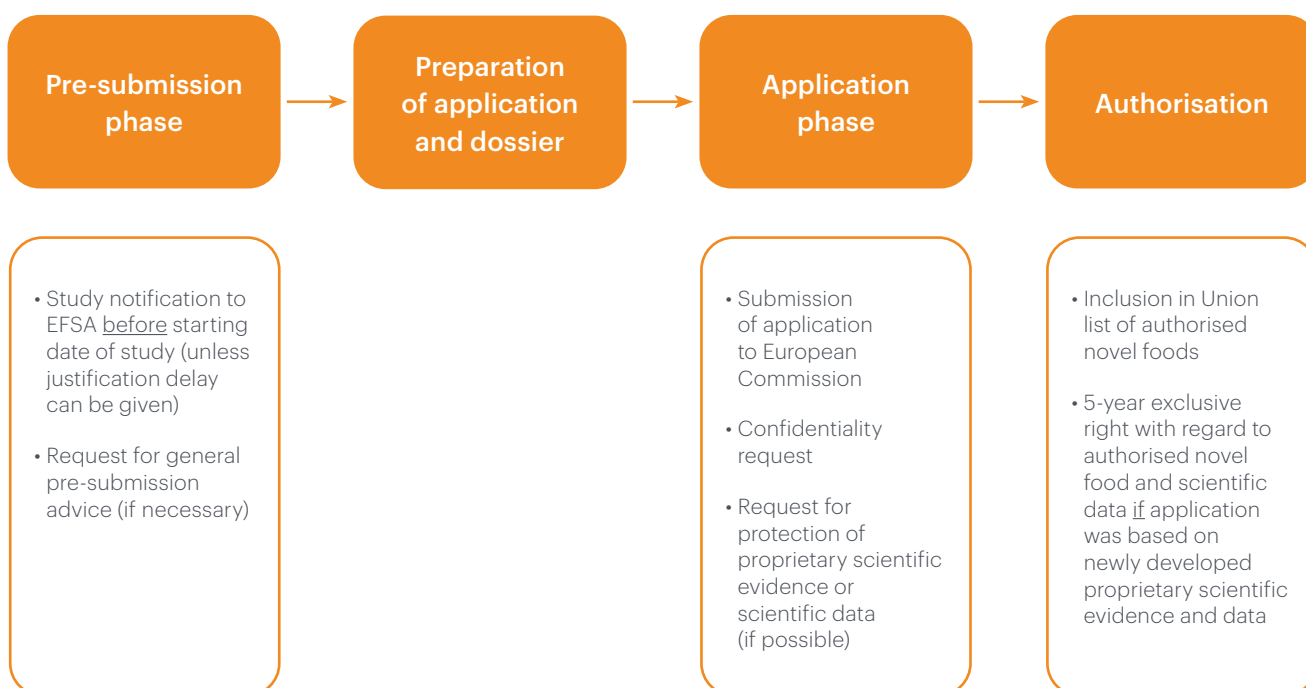
- Information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the novel food, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use that novel food, except for information which is relevant to the safety assessment;
- Detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the safety assessment;
- Certain personal data.

Several requirements apply to the confidentiality request. In particular, the information concerned must be precisely identified and full reasons must be given as to why the information is to be treated as confidential. The applicant must submit a confidential and a non-confidential version of the respective document. The non-confidential version will be made publicly available on the EFSA-Portal as soon as the application is declared valid. The EFSA will assess the confidentiality request and produce a “sanitized” version of the documents, which means that it will mask or unmask scientific data, studies or other information in accordance with the confidentiality request or its confidentiality decision. Prior to the adoption of a decision rejecting the applicant’s

confidentiality request in part or in full, the EFSA will share the draft decision with the applicant, which may share its comments within two weeks from the receipt of the draft decision. The EFSA will assess the comments, modify the draft as appropriate and adopt the decision.

If the confidentiality request is rejected, the applicant may withdraw the novel food authorization application within two weeks or submit a confirmatory application for the review of the confidentiality decision for the attention of the executive director of the EFSA. During the time the confirmatory application is assessed, the implementation of the confidentiality is put on hold. The reasoned confirmatory decision shall be issued by the executive director no later than three weeks from the receipt of the confirmatory application. If the confidentiality request is not granted in the confirmatory application, it again is possible to withdraw the novel food authorization application. The applicant may also bring an action challenging the legality of the confirmatory decision before the European Court of Justice (“ECJ”). Such an action before the ECJ generally has no suspensory effect. If the necessary circumstances are demonstrated, the ECJ may however order that the application of the contested confirmatory decision is suspended.

## Roadmap – Bringing alternative protein products on the EU market under the Novel Food Regime





### **What other regulations must be observed when bringing alternative protein products onto the EU market?**

The manufacture and placing on the market of food is comprehensively regulated both at EU and member state level. The applicable laws address every step from production, packaging and labelling to hygiene, transport and storage. The regulations for labelling are of particular significance for alternative protein products. Food business operators must find a balance between, on the one hand, a name that is understandable to the consumer as well as attractive and suitable for marketing and, on the other hand, a name that is not misleading. The labelling regime in the dairy sector is especially strict. Careful consideration must be given to the way in which designations based on dairy products may be used for plant-based or cell-based dairy alternatives. If alternative protein products shall be marketed as healthy alternatives to meat or dairy products using nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods, the specific regulations of the Health Claim Regulation 1924/2006 will apply.

*Disclaimer: The legal terms used in this article are defined by the EU Regulation (EU) 2015/2283.*



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