Like a PRO

Novel Food Regulation

Funded by the European Union

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ABOUT LIKE-A-PRO

LIKE-A-PRO is an EU-funded project that aims to facilitate sustainable and healthy diets by shifting promising alternative proteins and products from niche to mainstream – making them more available, accessible, and acceptable to all population groups. This includes young people, adults, elderly people, and vulnerable groups such as individuals of low socio-economic status, ethnic minorities, and those living in rural areas. The project does this by developing 16 products made from ingredients representing 7 protein sources. These products are designed to be sustainable, EU-based, and to offer improved taste and texture. The work is supported by an active campaign for alternative proteins, co-designed and explored with citizens and community actors across Europe.

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Introduction

Novel foods are defined as foods (which includes ingredients) that were not used for human consumption to a significant degree within the European Union (EU) before 15 May 1997 and that falls under at least one of the 10 categories that are listed in the European Novel Food Regulation (Regulation EU) 2015/2283).[i] A 'novel food' can be a newly developed, innovative food, food produced using new technologies and production processes, as well as a food which is or has been traditionally eaten outside of the EU. Examples of novel foods include several protein sources such as insect proteins, oil from docosahexaenoic acid (DHA) extracted from microalgae, cultured meat, and plant-based protein isolates produced with new technologies. These foods drive innovation in plant-based and novel proteins, enabling improved nutritional profiles, functional properties, and sustainable formulations.

However, bringing a novel food to market can be a time-consuming and resource-intensive process.

In the European Union, the Novel Food Regulation lays down rules for the placing of novel foods on the market within the European Union. Pursuant to this regulation only novel foods authorised and included in the Union list of authorised novel foods may be placed on the market within the European Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein. The European Commission only authorises and includes a novel food in the Union list if it complies with the following conditions:

a) the food does not, on the basis of the scientific evidence available, pose a safety risk to human health;
b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value;
c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Before authorisation, a novel food must undergo a scientific safety assessment carried out by the European Food Safety Authority (EFSA), unless the assessment can rely on a history of safe use for traditional foods from third countries. EFSA's scientists assess potential health risks such as allergens and toxicological effects. They also check to ensure that if a novel food is intended to replace another food, it does not differ in a way that would be nutritionally disadvantageous for the consumer. While this rigorous regulatory framework aims to ensure a high level of protection of human health and consumers' interests, it also requires significant investments in research, data generation, as well as mandatory safety studies, resulting in delayed market entry and requiring investments. Despite these challenges, the novel food regulation ultimately aims to facilitate the safe commercialization within the European Union.

In other countries, such as Singapore and the United States (US) a different regulatory framework applies. As an example, in the US the regulatory concept of GRAS (Generally Recognized As Safe) applies. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any substance added to food is considered a food additive requiring premarket review and FDA approval, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, as having been adequately shown to be safe under the conditions of its intended use, or it is otherwise exempt from the food additive definition. Currently, companies can self-determine GRAS status or submit a GRAS notification to the FDA. Additionally, a notifier may request a pre-submission meeting with FDA to discuss issues that may be relevant to the submission of the notifier's GRAS notice. The FDA defines the criteria for self-assessment and is currently considering eliminating the self-affirmation route due to concerns about transparency. to consumers and to ensure that ingredients being introduced into foods are safe.

In contrast, the EU's Novel Food Regulation does require a centralized premarket authorisation by the European Commission – sometimes preceded by a (safety) opinion from the European Food Safety Authority (EFSA) -, making the process more stringent and generally slower. Overall, GRAS offers more flexibility but still demands and depends on credible safety data.

Aspect	**U.S. (GRAS)**	**EU (Novel Food Regulation)**
Regulatory body	FDA	EFSA + European Commission
Approval type	Self-determined or notified GRAS	Mandatory premarket authorisation
Speed	6 – 18 Months For cultivated meat: no estimate	average 2,5 years, and outliers extending up to six years
Flexibility	High	Low

Table 1: Comparison of U.S. GRAS and EU Novel Food Regulatory Frameworks

Alternative proteins and novel foods in the EU

An overview with further readings

The first step is determining if a product is a novel food Novel Food?

Food business operators are responsible for determining whether or not the food – so the novel food as such, or used in or on foods - which they intend to place on the market within the European Union qualifies as a novel food, which falls within the scope of the Novel Food Regulation. The following step-by-step plan outlines how to make this assessment, using the relevant EU and Dutch national tools.

a. Is your product exempt from the Novel Food Regulation pursuant Article 2 (2) of the Novel Food Regulation, for example because it is a genetically modified food, food enzyme, food additive or food flavouring that falls within the scope of other EU legislation.[ii]

   - If the answer is YES: the Novel Food Regulation does not apply. The product must, however, comply with its own product-specific legislation, as well as general food legislation, such as the General Food Law.
   - If the answer is NO: the product may fall under the Novel Food Regulation → proceed with b.

b. Is your product included in the Union List of authorised novel foods (Regulation (EU) 2017/2470)?

   The Union List of Novel foods is an overview of novel foods, authorized to be placed on the market within the European Union. You can find the Union list here: Union List of authorised novel foods (Implementing regulation 2017/2470). Please make sure to always consult the most updated version and read it to learn more about the conditions under which the novel food may be used, labelling- and other requirements. After all, the European Commission regularly updates the Union list. As, only novel foods authorised and included in the Union list may be placed on the market within the European Union as such, or used in or on foods, in accordance with the conditions of use and the labelling requirements specified therein.

   In table 2 you can find an overview of some of the approved novel foods relevant for the protein transition:

Source	More information
Duckweed: Wolffia arhiza or Wolffia Globosa	Implementing regulation - 2021/2191 - EN - EUR-Lex
Protein concentrate from Lemna minor and Lemna gibba	Implementing regulation - EU - 2024/1048 - EN - EUR-Lex
Mycelial extract from Shiitake mushroom (Lentinula Edodes)	Implementing regulation - 2018/1023 - EN - EUR-Lex
Pea and rice protein fermented by Lentinula edodes (Shiitake mushroom) mycelia	Implementing regulation - 2023/6 - EN - EUR-Lex:
Partially defatted rapeseed powder from Brassica rapa L. and Brassica napus L.	Implementing regulation - 2021/120 - EN - EUR-Lex
Mung bean protein (Vigna radiata)	Implementing regulation - 2022/673 - EN - EUR-Lex
Partially hydrolysed protein from spent barley (Hordeum vulgare) and rice (Oryza sativa)	Implementing regulation - EU - 2024/2046 - EN - EUR-Lex
Coagulated potato proteins and hydrolysates thereof	Decision - 2002/150 - EN - EUR-Lex
Frozen, dried and powder forms of *Acheta domesticus* (house cricket)	Implementing regulation - 2022/188 - EN - EUR-Lex

Table 2: An overview of some of the approved novel foods relevant for the protein transition

If the answer is YES, so your product is included in the Union List, the product is an authorised novel food. An authorised novel food may, in principle, be placed on the market by anyone in all Member States, provided that the conditions set out in the Union List are met, such as labelling requirements, permitted food categories, and the product specifications.

If the answer is NO, so your product is not included in the Union list, your product could qualify as a (non-authorised) novel food. See step c.

c. Has your product been used for human consumption to a significant degree in the EU before 15 May 1997?

If the answer is YES: the product is not a novel food, as a result of which the Novel Food Regulation does not apply. However, the product must comply with European and national food legislation. We advise companies to make document so that you can demonstrate to the Netherlands Food and Consumer Product Safety Authority (NVWA) upon request that and why the product does not qualify as a novel food. The following documents may be used, among others, to demonstrate that your product was consumed in the EU before 15 May 1997:

- a statement from the competent authority of a Member State confirming that the product is not a novel food;
- sales invoices;
- import documents;
- literature data on consumption; and/or
- labels/packaging showing a date.

Keep in this regard also the following pointers:

- a combination of documents is often needed to demonstrate this history of use;
- there must be a clear link between the evidence and the product in question, for example by indicating the ingredients or composition to avoid confusion with another product;
- documents such as invoices must be addressed to food business operators so it is clear that the product was used as a food;
- the history of use must relate to the part of the organism used as the product (e.g. a plant part). A significant history of use for one part of a food does not automatically apply to other parts or to extracts;
- the product must be exactly the same, or the same part of the product—be cautious with derived products or comparable products from a different source;
- consumption of a product as (part of) a medicinal product cannot be used as evidence of a history of use.

If the answer is NO**:** then your product may still be a (non-authorised) novel food. You must investigate this further. There are various tools in this regard:

(i) the European Novel Food status Catalogue, which you can find here: Search Novel Food status Catalogue. This European catalogue contains a non-exhaustive list of products indicating whether they are considered novel foods, based on the information available at the time of assessment to the European Commission and the Member States. The Novel Food Status Catalogue can be used by Member States and businesses as an orientation tool to obtain an initial indication of whether a product may or may not be a novel food. It is a non-binding tool.

(ii) Use the Europese Information and Guidance document on human consumption to a significant decree: European Information and Guidance Document The European Guidance document explains how to

substantiate that a food is *not* a novel food because it was already marketed and consumed to a significant degree in at least one EU Member State before 15 May 1997. Although published under the former Regulation (EC) No 258/97, the document still provides useful criteria and considerations. The document addresses, among other things, quantities consumed (which may vary by product, e.g. smaller amounts for herbs than for fruits), and the use of other forms or parts of the food. It also includes a decision tree and a questionnaire to help determine whether a product was consumed to a significant degree for human nutrition in an EU Member State before 15 May 1997.

(iii) Website of European Commission with outcomes of consultation procedures. On this European Commission website (Consultation process on novel food status), the outcomes of the consultation procedure are published. The website also includes a brief justification explaining why a product is or is not considered a novel food. This offers background information on how such assessments are substantiated. It may also provide useful insights into the status of your own product if you are assessing whether a similar product is a novel food.

(iv) Consult a lawyer specialised in food law

(v) Consultation process. When a food business operator is unsure whether or not a food which they intent to place on the market in the European Union qualifies as a novel food, it is an option to consult the competent authorities of the EU Member State where this operator first intends to place the food on the market. The steps for the consultation process for determination of novel food status are described in Implementing Regulation (EU) 2018/456. This implementing regulation describes the information that must be included in the consultation request and the corresponding procedural steps. If the outcome is that the product is not a novel food, the Novel Food Regulation does not apply. However, please do not forget that in that event the product must comply with other European and national food legislation, for example General Food Law.

The contact details of the authorities responsible for the consultation process in the member states can be found on the European Commission website. In the Netherlands, a consultation request with a technical dossier can be sent to the Bureau Nieuwe Voedingsmiddelen (Novel Foods Unit (NFU)), which is part of the Medicines Evaluation Board (MEB). The Bureau Nieuwe Voedingsmiddelen advises the Dutch Minister of Health, Welfare and Sport. The steps in the consultation process in the Netherlands are stated in the Commodities Act on the consultation procedure for novel foods. An infographic with the steps can be find here: Determination of novel food status | Medicines Evaluation Board

Application process

An application for market authorisation in the European Union of a novel food must be submitted electronically to the European Commission. There are two different application procedures: one is for the authorisation of a novel food and one is for the authorisation of a traditional food from a third country that have a history of safe use in a third country.

They differ extensively in the data and information requirements establishing the safety of the novel or of the traditional food. The application for the authorisation of a novel food must contain extensive safety data and (toxicological) studies supporting the safety of the novel food. The notification of a traditional food puts weight and emphasis on establishing the safety of the traditional food on the history of consumption of the traditional food in a third country.

Application procedure for a novel food and updating the Union list

In order to place a novel food on the market in the European Union you can choose the application procedure for a novel food and updating of the Union list.

The application procedure for novel foods entails four consecutive processes, as shown below figure.

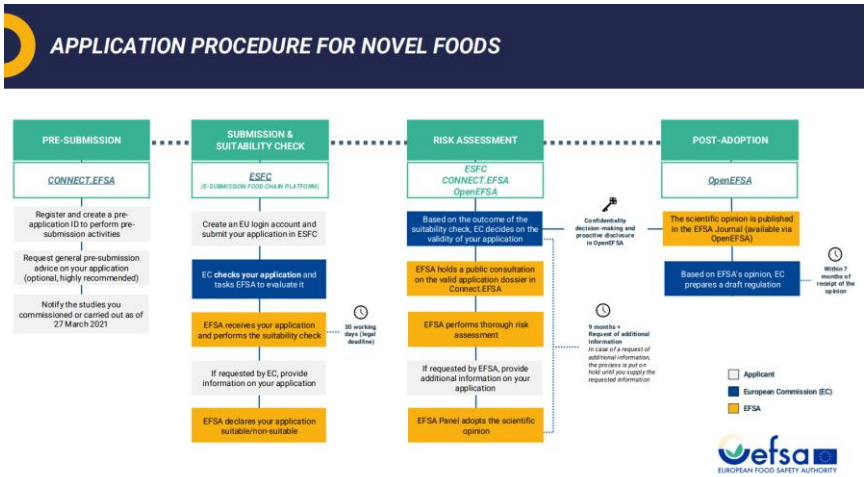

Figure 1: application procedure for novel foods

See also for more information: Novel food application procedure | EFSA, which also refers to various tools to help you build an application dossier for example

The online application has to be in line with the requirements set in the Novel food Regulation.

The administrative and scientific requirements for this application are described in Implementing Regulation (EU) 2017/2469.

The European Food Safety Authority (EFSA) has prepared a guidance on the preparation and presentation of an application for authorisation of a novel food.

Please note that these guidance documents are updated regularly by EFSA, reflecting the experience it has gained in the assessment of novel food applications over the past years. So applicants should check that they are using the latest version before submitting an application. Applicants must submit their dossier online to the European Commission. Information on this can be found via e-submission in accordance with the new Novel Foods regulation - Food Safety.

With regards to timing, please note that the duration of the authorisation procedure varies significantly depending on the product and the application. Key factors that impact the timing include the completeness and quality of the submitted application, including its technical dossier. Requests for additional information can lead to clock stops and therefore often lead to substantial delays. The key recommendations are: ensure you are fully aware, well in advance, of the requirements for an application and verify that the dossier meets all applicable requirements. Make use of the available guidance documents. Speaking with businesses that have already gone through the procedure can also provide valuable insights.

Please note that applicants may request confidential treatment of certain information submitted under the Novel Food Regulation where disclosure of such information may harm their competitive position. For this purposes, applicants need to indicate which parts of the information provided they wish to be treated as confidential and provide all the necessary details to substantiate their request for confidentiality. Verifiable justification shall be given in such cases. Confidentiality shall not apply to (a) the name and address of the applicant; (b) the name and description of the novel food; (c) the proposed conditions of use of the novel food; (d) a summary of the studies submitted by the applicant; (e) the results of the studies carried out to demonstrate the safety of the food; (f) where appropriate, the analysis method(s); (g) any prohibition or restriction imposed in respect of the food by a third country.

In order to stimulate research and development within the agri-food industry, and thus innovation, the legislator considered it appropriate to provide an option, to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food. Therefore, the Novel Food Regulation gives the option for the European Commission to grant more or less an individual authorisation for five years based on protected data. However, applicant must request for data protection if they want this. When requested, and where supported by appropriate and verifiable information included in the application, newly developed scientific evidence or scientific data supporting the application

may not be used for the benefit of a subsequent application during a period of five years from the date of the authorisation of the novel food, without the agreement of the initial applicant. If requested, data protection is granted by the commission where the following conditions are met:

(a) the newly developed scientific evidence or scientific data was designated as proprietary by the initial applicant at the time the first application was made;
(b) the initial applicant had exclusive right of reference to the proprietary scientific evidence or scientific data at the time the first application was made; and
(c) the novel food could not have been assessed by the Authority and authorised without the submission of the proprietary scientific evidence or scientific data by the initial applicant.

Please note that the initial applicant may agree with a subsequent applicant that such scientific evidence and scientific data may be used. For example, by means of a licence, allowing the original investor/application to recover part of its costs.

Please also note that a party can also choose to join forces and to submit an application together. This in order to share the time investment and costs of an application. If multiple parties can reap the benefits of an application, then it is also fair to share the costs. To prevent potential disputes, it is advisable to make clear agreements about such cooperation in advance.

Procedure for notification of a traditional food from a third country and updating the Union list

A 'traditional food from a third country' means a novel food – with some exemptions[iii] - which is derived from primary production as defined in the General Food Law, with a history of safe food use in a third country. And a 'history of safe food use in a third country' means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification of a traditional food from a third country.

If you wish to market a traditional food from a third country in the European Union, you can choose the procedure for notification of a traditional food from a third country. Also such notification should comply with the requirements set in the Novel Food Regulation.

The administrative and scientific requirements for this application are described in Implementing Regulation (EU) 2017/2468. The EFSA has prepared a guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries.

Upon reception of a notification the Commission assesses the validity of the application, its completeness and the presence of the required information. The Commission then forwards the valid notification to the EU countries and to EFSA. Within four months, Member States or EFSA may submit to the Commission duly reasoned safety objections to the placing on the market of the traditional food concerned. Where no duly reasoned safety objections have been submitted, the Commission will authorise the placing on the market of the traditional food and update the Union list. If one or more EU countries or EFSA submit duly reasoned safety objections, the Commission cannot authorise the placing on the market of the traditional food concerned or update the Union list. In that case, the applicant may submit an application to the Commission following the requirements of Article 16 of the new novel food regulation.

References

[i] The categories 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 microorganisms, 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 used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013, where:

— a production process not used for food production within the Union before 15 May 1997 has been applied as referred to in point (a) (vii) of this paragraph; or

— they contain or consist of engineered nanomaterials as defined in point (f) of this paragraph;

(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements as defined in point (a) of Article 2 of Directive 2002/46/EC.

[ii] Pursuant to Article 2 (2) of the Novel Food Regulation, the Novel Food Regulation does not apply to:

(a) genetically modified foods falling within the scope of Regulation (EC) No 1829/2003;

(b) foods when and in so far as they are used as:

(i) food enzymes falling within the scope of Regulation (EC) No 1332/2008;

(ii) food additives falling within the scope of Regulation (EC) No 1333/2008;

(iii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;

(iv) extraction solvents used or intended to be used in the production of foodstuffs or food ingredients and falling within the scope of Directive 2009/32/EC.

[iii] After all it are novel foods as defined in Article 3(a) of the Novel Food Regulation, other than novel food as referred to in points (a) (i), (iii), (vii), (viii), (ix) and (x) thereof, which is derived from primary production as defined in point 17 of Article 3 of Regulation (EC) No 178/2002 with a history of safe food use in a third country. See also end note 1 of this document, in which (i), (iii), (vii), (viii), (ix) and (x) are mentioned.