OVERVIEW

Guide to the authorisation of novel foods in the EU

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The regulations and guidance documents presented in the tables have been used as the source of information for writing this guide.

1. Regulatory framework related to the authorisation of novel foods in the EU

Definition of novel food

Foods and food ingredients which have not been consumed significantly before 15th May 1997 in the EU are considered novel and, thus, require premarket authorisation by the European Commission (EC) and safety assessment by European Food Safety Authority (EFSA). Regulation 2015/2283, Chapter III, defines the authorisation process to be followed. Regulation 2017/2469 is defining administrative and scientific requirements referred to in Article 10 of Regulation 2015/2283.

In many cases it may not be obvious whether a food is novel or not and, thus, subject to the authorisation process. Applicant can follow the consultation approach defined in article 4 of 2015/2283 and the procedure elaborated in detail in Regulation 2018/456 for obtaining a statement from a Member State authority about the novel food status of the product. The statements are published in the **Novel Food Catalogue** (https://webgate.ec.europa.eu/fip/novel_food_catalogue/#).

Authorisation of novel foods

Once authorized, novel food is included in the **Union list of novel foods** according to the Regulation 2017/2470. The authorisation is not holder specific, but any food business operator can place a similar product in the market providing that the specification given in the authorisation is followed. However, the applicant can apply for data protection, which gives the applicant exclusive right for marketing the product for five years.

Foods and food ingredients which have not been consumed in the EU, but are considered traditional foods outside the EU, can be authorised following the specific assessment procedure for traditional foods from third countries as defined in the Chapter III, Section II of Regulation 2015/2283.

Transparency Regulation 2019/1381 came in force as of 27th March 2021. The Regulation has affected the risk assessment process for all regulated products in the food chain, including novel foods, for which an application has been submitted after 27th March 2021. Following the Regulation, all safety and efficacy related studies must be notified to EFSA beforehand, and dossiers are made public for all parts which have not been requested confidential. Guidance and webinars are available on EFSA web site to help to **notify studies in Connect EFSA portal** and to **prepare confidentiality requests in E-submission Food Chain (ESFC) platform**.

Relevant EU legislation related to the authorisation of novel foods are shown in **Table 1**.

Table 1. EU legislation related to the authorisation of novel foods

Regulation (EU) 2015/2283	Novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001
Regulation (EU) 2017/2470	Establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

Regulation (EU) 2017/2469	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 novel foods
Regulation (EU) 2018/456	Procedural steps of the consultation process for determination of novel food status in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods
Regulation (EU) 2019/1381	Transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

2. EFSA Guidance

EFSA scientific guidance related to the authorisation of novel foods are listed in **Table 2** and published on EFSA website (https://www.efsa.europa.eu/en/applications/novel-food-traditional-food/regulationsandguidance). In addition to these main guidance documents, other guidance may be needed to find more detailed instructions for designing specific studies or to building up specific sections of the dossier, for example, dietary intake assessment (useful tools available under Food Improvement Agents on EFSA web pages).

Two product categories for which specific guidance exists are described in **Tables 3-4** and in section 4.2. below.

Table 2. Scientific guidance (EFSA) concerning the authorisation of novel foods in the EU

EFSA, 2021a	Administrative guidance for the preparation of applications on novel foods pursuant to Article 10 of Regulation (EU) 2015/2283
EFSA NDA Panel Guidance, 2021a	Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 (Revision 1)
EFSA NDA Panel Guidance, 2021b	Guidance on the preparation and submission of the notification and application for authorisation of traditional foods from third countries in the context of Regulation (EU) 2015/2283 (Revision 1)

Table 3. EFSA scientific guidance for characterisation of microbial products

EFSA FEEDAP Panel Guidance, 2018	Guidance on the characterisation of microorganisms used as feed additives or as production organisms
EFSA, 2021b	EFSA statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain

Table 4. EFSA scientific guidance for characterisation of products containing nanomaterials

EFSA Scientific Committee, 2021a	Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles
EFSA Scientific Committee, 2021b	Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health

3. Alternative pathways to the authorisation

3.1 Novel foods

3.1.1 Novel food authorisation process

The authorisation process of novel foods is shown in Appendix 1. **EFSA provides general pre-submission advice** with some limitations to help applicants compile the dossiers with adequate information. The questions can be submitted using the pre-application ID which can be obtained in Connect EFSA portal (https://connect.efsa.europa.eu/RM/s/).

An application with a scientific dossier is submitted to the European Commission (EC) in the ESFC. The Commission will forward the application to the Member States and to EFSA. The summary of the application is also made public. The application is checked for validity by EFSA within 30 working days. However, this period can be longer if additional information or clarifications are requested from the applicant. **EFSA NDA (Dietetic Products, Nutrition and Allergies) Panel** should formulate its opinion on the safety of the novel food within **nine months** after receiving the valid application. Again, in cases, when EFSA requests additional data, a clock stop is applied, and this nine month's period may be extended.

EFSA will forward its opinion to the Commission and Member States. Within seven months after the receipt of the EFSA opinion, the **Commission shall draft a decision on the authorisation** of the novel food and on its addition to the Union list of novel foods. This draft decision is subjected to the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) for approval. In this committee the Member States are represented, and it makes its decisions by qualified majority (a positive decision should be backed both by the majority of the Member states and the majority of the EU population). After a positive decision the food is included in the Union list of novel foods.

3.1.2 Contents of novel food dossiers

The applicant should submit to the Commission an application containing the following information:

- the name and address of the applicant
- the name and description of the novel food
- the description of the production process(es)
- the detailed composition of the novel food
- scientific evidence demonstrating that the novel food does not pose a safety risk to human health
- where appropriate, the analysis method(s)
- a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

The detailed instructions on the information to be included in the application and the accompanying technical dossier are given in the guidance document of the EFSA panel on Nutrition, Novel Foods and Allergies (NDA) (EFSA NDA Panel, 2021a).

The requirements concerning novel food applications are discussed in section 4 below.

3.2 Traditional foods from third countries

3.2.1 Traditional food notification process

In case an applicant wishes to place on the market **a food traditionally consumed in a third country** (any non-EU country) a notification should be made to the Commission. The notification workflow is presented in Appendix 2. A notification is different from the application, the latter of which is only required if safety issues are pointed out in the assessment of the notification (see below).

After receiving the notification and the verification of its completeness, the Commission sends it to the Member States and to EFSA within one month. If neither the competent authorities of the Member States nor EFSA raise any reasoned safety objections within **four months** after receiving the notification, the Commission places the food into the Union list of Novel Foods specifying the entry a traditional food from a third country.

What if reasoned safety objections emerge? The applicant may submit an application completed with the data addressing the safety concerns of the Member states and/or EFSA. EFSA is expected to complete its assessment within six months after receiving the application. EFSA may ask for more information, and this may extend the six-month period. The EFSA opinion will be made available to the Commission and to the Member states.

Within three months the Commission will draft an authorisation decision and the decision process proceeds as it is for novel foods described above.

In conclusion, the process for the authorisation of traditional foods from third countries is shorter than the process for authorisation of real novel foods.

3.2.2 Contents of Traditional food notifications

The identity, composition (including microbiological and chemical impurities) and the production process of the traditional food should be described, using, where appropriate, literature surveys to complement the analytical compositional data. The stability of the food should be established, paying attention to properties that might be subject to changes or degradation in storage conditions. On the basis of the analytical data, specification for the traditional food should be proposed.

The central element of the evaluation is the **documented history of use** and the experiences obtained in the third country: The extent of use, characterisation of the typical consumer segment, role in the diet, any precautions or restrictions of use and any documented safety-related human data.

The proposed use in the EU, target population, intended use levels, role in the diet, and any precautions and restrictions should also be described.

No toxicological or safety studies are required unless the reasoned safety objections arising during the evaluation process make them necessary.

3.3 Novel food consultation process

What to do if novel food status is unclear? Business operator is responsible for confirming the traditional status of the food or ingredient and demonstrate the history of consumption and safe use if required when bringing a product to market. There is a possibility to use a consultation process defined by Regulation 2018/456 if the status of the product is not evident based on the history of the use in the EU or in third countries. To confirm the status of the food (novel or traditional) to be put into market, the applicant can consult the **Competent Authority of the Member State** in which the marketing is to start (for the list of competent authorities, see: https://food.ec.europa.eu/system/files/2023-06/fs_novel-food_leg_list_comp_auth_reg_2018_en.pdf

The consultation request should contain i) the cover letter, ii) the technical dossier iii) supporting documentation, and iv) an explanatory note clarifying the purpose and relevance of the submitted documentation. Instructions and templates for the cover letter and the technical dossier are included in Annexes I and II of the regulation 2018/456, respectively. The technical dossier should contain the following elements: i) **description of the food**, ii) further **characterization of the food or source of the food** (for example, taxonomic name of the organism, CAS number, chemical names and formulae of chemical substances etc), iii) **conditions of use**, iv) **production process**, and v) **history of human consumption in the Union** before 15 May 1997. Further information may be required in the case of extracts or when the food has been produced using a process that was not in use before May 15, 1997. It should be noted that the food or ingredient does not have to be tested for safety for the consultation request, but the information presented is mostly descriptive and based on the literature and other data/information already available about the food, ingredient and/or its source.

The Competent Authority should express its opinion within **four months** after receiving a valid consultation request. It may ask the applicant to provide more information, but this does not normally extend the evaluation time. The Competent authority can also consult the other Member States and the Commission.

After reaching its decision the Competent authority should immediately inform the applicant, the other Member States and the Commission. The resulting notification is published in the **Catalogue of Novel Foods** on the Commission website with the information defined in Article 7 of 2018/456. If the conclusion is that the product is considered novel food, an independent authorisation process should be started according to Regulation 2015/2283.

4. How are novel foods evaluated and what kind of data is requested

4.1 The required data in the novel food dossier

4.1.1 Identity of the novel food

Identity of the novel food should be established following the specific requirements for different **novel food categories** shown below:

- Chemical substances
- Polymers
- Foods consisting of, isolated from or produced from microorganisms, fungi or algae
- Food consisting of, isolated from or produced from material of mineral origin
- Food consisting of, isolated from or produced from plants or their parts

- Food consisting of, isolated from or produced from animals or their parts
- Foods consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, fungi or algae
- Foods consisting of engineered nanomaterials

Generally, chemical, molecular, or structural formula, different common and scientific names and synonyms, identification of the species and strain, and geographical origin should be provided where applicable. If the novel food belongs to more than one category, requirements for both categories must be followed.

4.1.2 Compositional data

Compositional information is essential for the evaluation of the product, and the product should be characterized as far as it is possible with reasonable efforts. **Simple compounds and simple mixtures of few components must be fully characterized whereas complex mixtures and whole foods, such as extracts, milk or seeds, have to be characterized for their main components.** Proximate analysis is one part of the basic data to be provided in the dossier. All analytical data should be derived from five independent batches. Thus, the same data set can be used to determine batch-to-batch variation, to propose and justify specification, and demonstrate repeatability of the process. Pilot scale batches are acceptable provided that the process and components essentially represent the full-scale process. The character of the food determines whether any additional analytics is needed, for example, for the analysis of specific metabolites or compound groups. Nutritional constituents and substances of possible concern to human health are of specific importance. Literature reviews can be used to support the analytical data and selection of analytes.

In addition to the composition, information on chemical and microbiological impurities and contaminants, possible by-products and residues must be provided. Heavy metals, mycotoxins, pesticides, dioxins and PCBs, and possible solvents used in the process are commonly analysed. Literature should be reviewed for the history of (safe) use of the food or its source, for occurrence of possibly harmful substances, and for toxicity or pathogenicity. Based on the literature findings, it may be necessary to analyse, for example, secondary metabolites which can be produced by the microbial strain or species.

Compositional data should be provided for a defined manufacturing process. If several parallel processes are used, like alternating different raw materials in the process, the final product resulting from each different process should be analysed.

Stability data is required to support the proposed shelf-life of the novel food. Parameters to be followed are selected based on the properties of the food and their probability to change during the storage. Typically, microbiological purity and concentration of main components are followed in five, representative batches of the food. If the novel food is used as an ingredient in other foods, the stability in the processed food should also be evaluated in real food matrix or by using a suitable model system (processing temperature, acidity, other components etc.). For example, for ingredients intended to be used in bakery products the stability could be tested in one representative product such as bread. If the ingredient is used in very different types of products, for example, stored at different temperatures, it might be reasonable to select one representative food matrix from each different category.

4.1.3 Proposed use, anticipated intake and nutritional information

Nutritional significance of the food is evaluated based on the **anticipated intake of the food in Europe**. Intake estimate is based on the analytical data, the proposed use and use level, and data on consumption of the food/food category in the European target population. Similarly, potential health hazards are evaluated based on the anticipated intake of the food.

Applicants need to specify the target population (adults, children, etc.), use of the food, the food categories (for ingredients), and whether the food is intended for replacing another food or ingredient. Maximum daily intake as well as any precautions or restrictions of use should be proposed if relevant.

Specific instructions are available in the EFSA guidance (EFSA NDA Panel, 2021a) for establishing the anticipated daily intake using **EFSA Comprehensive European Food Consumption Database and EFSA Food Additive Intake Model (FAIM) tool**. Combined intake of the food from other sources must also be considered.

Nutritional information refers to the role of the novel food in the diet in comparison with other foods or ingredients. Evaluation is based on the anticipated intake and use levels, bioavailability, interaction with other nutrients, and possible further processing of the food. Intake of both nutritional and antinutritional compounds should be evaluated and compared to the available dietary reference values and possible upper intake levels. *In vitro* or *in vivo* experimental studies are not usually required.

4.1.4 Safety related data

Adsorption-Distribution-Metabolism (ADME) studies and especially toxicological investigations have a prominent role in the safety assessment. Data on **genetic toxicology, subchronic oral toxicity**, and - depending on the case - long-term toxicological studies may be required. All relevant knowledge on the novel food such as composition of the food, previous human consumption, and available human or animal studies, should be considered to decide whether and which toxicity studies are necessary.

In vitro genotoxicity studies and an *in vivo* 90-day subchronic toxicity study are the basic tests to start, and further testing may be necessary only if toxicity is observed in these first tests. ADME studies follow the same principles as those applied to food additives, concerning pure compounds or simple mixtures. Whole foods and complex mixtures are usually not analysed for ADME unless they contain compounds of known biological or toxicological activity.

The **allergenic potential** of the novel food should be evaluated based on its composition, the protein content, the source, the manufacturing process and components, and available experimental and human data. Literature reviews, allergen databases, bioinformatic tools, immunological testing, and – if necessary – human testing can be exploited for assessing the allergenicity. Potential allergenicity does not prevent authorisation but must be taken into consideration in labeling. For known allergens, labelling is mandatory.

4.2 Special cases

The establishment of safety is the central part of novel food authorisation and assessment. This assessment is done using the compositional data, studies on the adsorption, metabolism and excretion (ADME) of the relevant food components, and toxicological tests on specific compounds or whole foods as discussed above. However, there are cases, in which this general approach must be modified or

complemented by other types of studies. Foods consisting of or derived from microorganisms or containing engineered nanomaterials are the most notable examples.

4.2.1 Food consisting of or produced with microorganisms

In contrast to chemicals there is no established and validated safety assessment framework for microorganisms. Consequently, their safety evaluation in the EU is based on the division of microorganisms into two categories: Microorganisms with the **Qualified Presumption of Safety (QPS)** status subject to a generic safety assessment, and non-QPS microorganisms assessed on a case-by-case basis.

The QPS microorganisms have an established history of safe use in food or feed applications, and thus are exempted from a detailed safety assessment. EFSA regularly reviews the QPS status of notified microorganisms (automatically for microorganisms subject to applications) and publishes the outcomes of the assessments and the list of QPS microorganisms on its web page.

Once in the QPS list, no toxicological safety assessment is required for the microorganism. The QPS status is generic, applying to the microbial species, and not to any particular strain, although the taxonomic identity and the absence of transmissible resistances to antibiotics with medical or veterinary relevance has still to be confirmed for each strain. In the case of bacteria and yeasts these studies are currently based on the **bioinformatic analysis of the whole genome sequence (WGS)** of the strain.

It should be noted that the food produced by or consisting of QPS microorganisms might still be novel, and the other aspects of the novel food assessment still apply, except for the safety studies on the production microorganism.

The safety assessment of a non-QPS microorganisms includes WGS-based confirmation of I) the taxonomic identification, ii) the absence of virulence factors and iii) acquired antibiotic resistances, and iv) of genetic modifications. Additionally, the production of antimicrobial metabolites should be tested. Viable cells and, in case of genetically modified strains, DNA of the production strain should not be present in the product. Although the EFSA guidance on the assessment of novel foods does not mention toxicological safety assessment even in the case of non-QPS microorganisms, the EFSA guidance on the characterisation of microorganisms (EFSA FEEDAP Panel, 2018) indicates that toxicological tests might be required.

4.2.2 Food containing nanomaterials

Engineered nanomaterials contain or consist of **particles with at least one dimension of 100 nm or less**. Because of their high surface-to-volume ratio, these particles have high surface activity and generally have physicochemical and biological properties different from those displayed by larger particles of the same material. Nanoparticles can be inorganic or organic, and they can find uses in different composite materials as well as in food applications.

Because of their unique properties and its impact on the safety assessment, specific guidance documents related to the nanoparticles have been published by EFSA (**Table 4**). Guidelines are given in the guidance to help the applicants to decide whether specific safety assessment of nanoparticles is required, or whether the safety can be evaluated on the basis of the chemical identity of the material(s).

The decisive criterion in the preliminary assessment includes the determination, whether the small particles (dimensions 500 nm or less) are fully soluble in water or in the food matrix. If the particles are completely soluble, no specific safety assessment for nanoparticles is required. If the product contains non-soluble small particles, the fraction of particles of less than 250 nm should be determined. If more than 10% of the small particles fall to the potential nanoscale (below 100 nm), then the existing safety studies should be reviewed to determine, whether they cover the types of nanoparticles present in the product. If not, then specific assessment of nanoparticle safety should be performed according to the guidance.

The risk assessment of nanomaterials/nanoparticles starts with the determination of their fate in the digestive system. For particles fully dissolved or digested, no nanoparticle-specific safety studies are required. If this is not the case (and the existing safety data are not sufficient,) then the nanoparticle toxicity needs to be assessed first *in vitro* (genotoxicity, cytotoxicity etc). Also, exposure estimations based on the expected oral consumption should be made.

If there are indications of toxicity in the *in vitro* tests, *in vivo* ADME and toxicity studies (such as *in vivo* genotoxicity or 90-day subchronic oral toxicity) are required. It is understood that the methodologies designed for chemicals and not optimized for nanomaterials or –particles can lead to uncertainties regarding the relevance of the results obtained. These uncertainties should be characterized, quantified and reported.

5. Possible bottlenecks and pitfalls

5.1 Genetic modifications

Genetically modified (GM) material can be used in the production of novel foods or as a production organism, for example, for fermentation products. Genetically modified feedstock or ingredients used in the manufacturing are not affecting the GMO status of the final product.

Genetically modified microbial strains are also commonly used to produce various fermentation products, such as proteins. EFSA guidance provides detailed instructions how to describe and analyse the modifications using WGS data (**Table 3**). However, the situation will become more complicated when the **final product contains DNA or biomass of the GM production strain**. According to the current interpretation of Regulation (EC) 1829/2003 on genetically modified food and feed, this kind of products are falling under the Regulation and, thus, needs to be separately **authorised as genetically modified food/feed**.

5.2 Nutrition claims and health claims

In case the novel food (or food traditionally consumed in third countries) is associated with nutrition and health claims, the procedures outlined in Regulation (EC) No 1924/2006 should be followed. In article 2 of the Regulation **nutrition claims** are defined as “any claim which states, suggests or implies that a food has particular beneficial nutritional properties ", and **health claims** as “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health”. A special category of health claims, reduction of disease risk claim is further defined as “any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease”. It

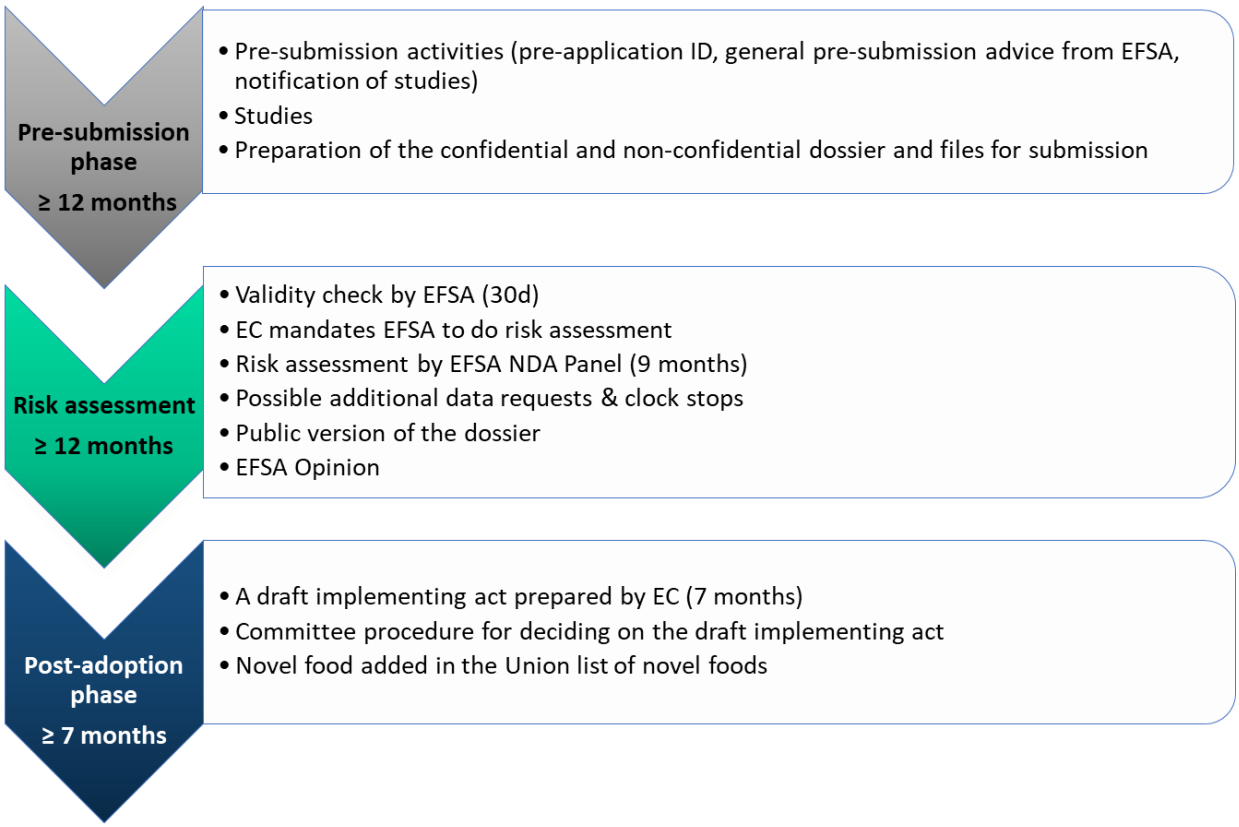
should be noted that **no food-associated claim referring to curing, preventing or alleviating the symptoms of any disease is allowed** in the EU.

The allowed nutrition claims are generic in nature such as “Low fat” or “Low energy”. They, together with the required qualifications that the food must fulfill, are listed in Annex 1 of Regulation No 1924/2006 and complementary Regulation (EU) 1047/2012.

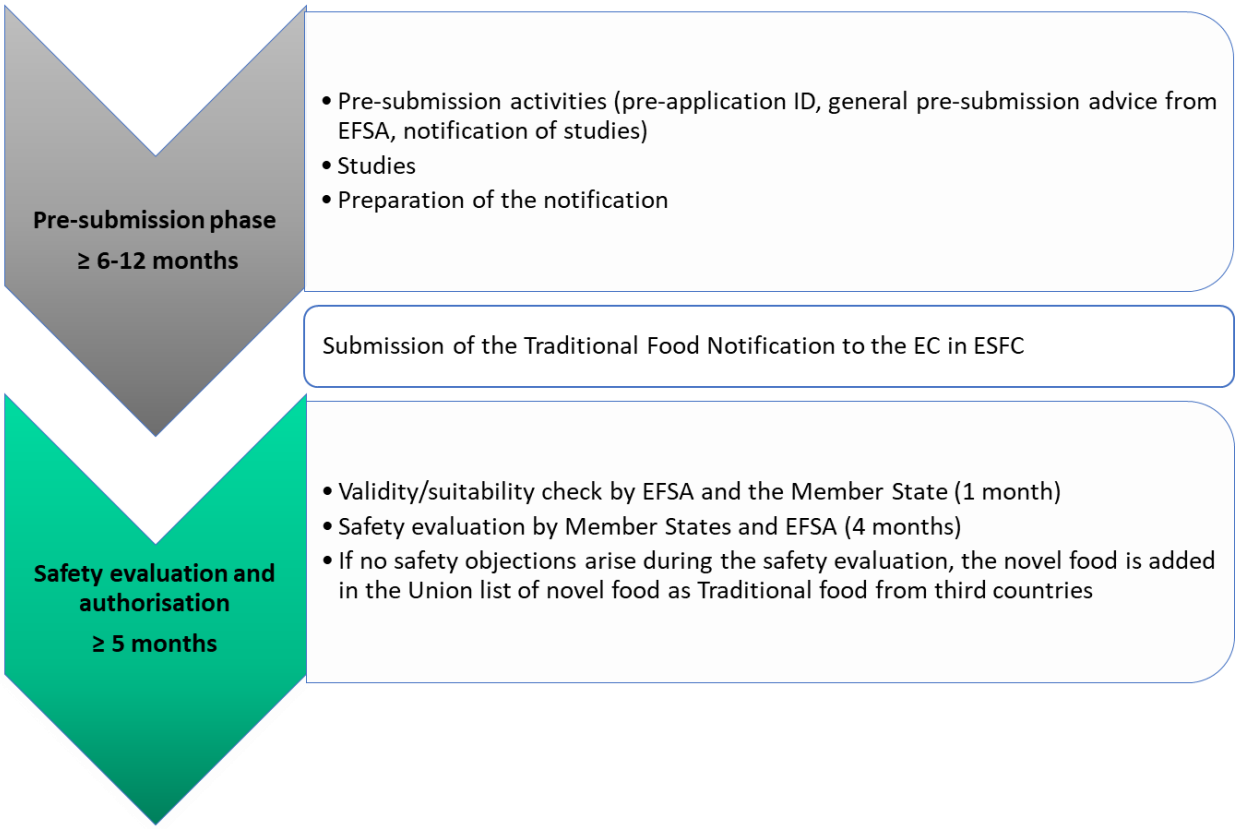
Health claims are divided into general function health claims and claims related to disease risk reduction and child development and health. The general function claims refer to the role of a nutrient or substance in growth, development and body functions; psychological and behavioral functions; slimming and weight control, satiety or reduction of available energy from the diet. General function health claims can be generic claims based on established scientific knowledge (“Calcium contributes to normal muscle function”) or they may be based on newly developed scientific research and be of a proprietary nature. EFSA is currently conducting a review of generic claims and also assessing novel claims. The list of permitted generic health claims under the scope of article 13(3) is published as Annex 1 of Regulation (EU) No 432/2012.

The disease reduction claims and claims related to child development and health always require assessment by EFSA. The outline of the assessment procedure is very similar to that of novel foods or other regulated products. The approved health claims are published on the Commission web page. Specific guidance documents related to various health claims can be found on EFSA web site (Applications/Nutrition).

Appendix 1 Authorisation process of novel foods



Appendix 2 Notification process of traditional foods from third countries



If safety objections for the notification are found by Member States or EFSA, the applicant can prepare an application to the EC. There are specific instructions for preparing an application for traditional foods from third countries in Regulation 2015/2283. The application is evaluated by EFSA (6 months) after which EC prepares a draft implementing act (3 months). The process follows similar pathway as the process of other novel foods, but the legal deadlines are shorter.