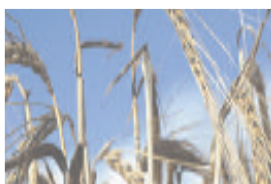


NOVEL FOOD



This leaflet is intended as an information source that includes the definition of a novel food in the European Union, the pertinent legislation and the process for obtaining authorisation to place a novel food on the market.



Novel Food

Food Safety Authority of Ireland (FSAI) - competent authority for novel foods

The Food Safety Authority of Ireland (FSAI) is a science based consumer protection agency operating under the aegis of the Department of Health and Children (DoHC). On January 1 2001, the FSAI assumed the role of competent authority for novel foods in place of the DoHC which retains the policy remit.

As competent authority for novel foods, the FSAI is involved with the safety assessment of all novel foods and is the point of contact for applicants wishing to market a novel food for the first time in Ireland.

Further information on novel foods is available on the FSAI website (www.fsai.ie); including links to the relevant European Commission website that covers all aspects of food safety.

What is a novel food?

A novel food in the EU, according to EU legislation, is a food or food ingredient that has not been available on the EU market to a significant degree prior to May 15, 1997 when the novel food legislation (Regulation EC No. 258/97) came into force. This definition includes new food processes that result in a product with significant nutritional or compositional differences or altered levels of undesirable substances. Food additives, flavourings and extraction solvents are not considered novel food and are governed by separate legislation.

Novel foods must not present a danger to the consumer, mislead the consumer or differ from foods or food ingredients that they are intended to replace to an extent that their normal consumption would be nutritionally disadvantageous for the consumer.

While foods or food ingredients containing, consisting of or produced from genetically modified organisms (GMOs) are governed by the GM food and feed Regulation (EC No. 1829/2003) since April 2004, they may still fall within the scope of the Novel Food Regulation in certain circumstances.



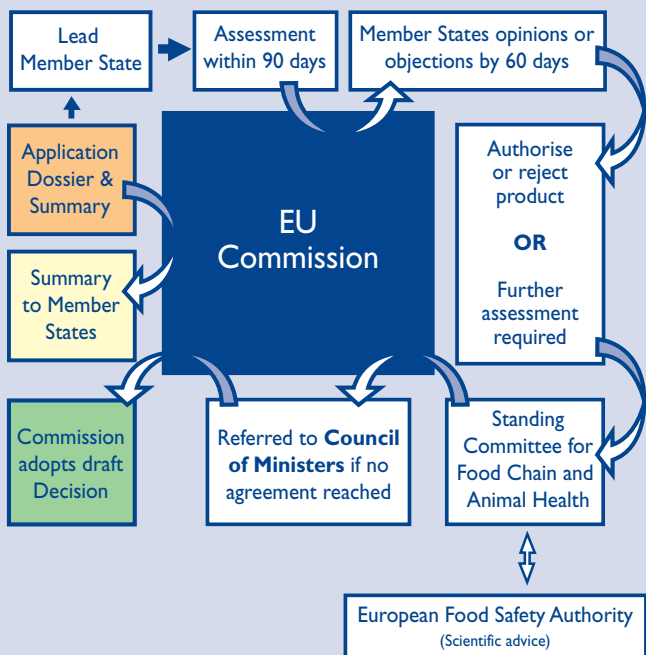
Novel food authorisation within the EU

Authorisation to market a novel food in the EU is a multi-step process with defined time limits and is coordinated by the Health and Consumer Protection Directorate (DG SANCO) of the EU Commission. An initial safety assessment is carried out by the competent authority of one Member State and is reviewed by all other Member States before they decide whether to authorise or reject an application.

A novel food applicant must assemble a dossier of scientific information based on the criteria set out in Commission Recommendation 97/618/EC. The dossier and a summary of the application must be provided to the competent authority of the Member State where the product is to be first marketed which then carries out an initial assessment. If there are no objections to the recommendation delivered with the initial assessment, the applicant is informed and the product is authorised or rejected accordingly. If there are any reasoned objections to the recommendation delivered with the initial assessment, the Commission refers the application to the European Food Safety Authority (EFSA) for independent scientific assessment. Based on the opinion of EFSA, the Commission then drafts a Decision on which Member States vote through the Standing Committee for the Food Chain and Animal Health (General Food Law section). If a qualified majority is not achieved in favour of the draft Decision, it is referred by the Commission to the Council of Ministers. If the Council does not act, or fails to achieve a majority vote in favour or against the draft Decision, the application reverts back to the Commission which may then adopt its own Decision.

Simplified procedure / notification

A food or food ingredient that is very similar to a product already on the EU market with regard to composition, nutritional value, metabolism, intended use and level of undesirable substances may be considered substantially equivalent and thereby not require a novel food authorisation prior to being placed on the EU market. According to simplified procedure, an applicant may claim substantial equivalence on the basis of an opinion received from a Member State competent authority or by presenting generally recognised scientific evidence to the Commission directly. Once substantial equivalence is established, an applicant may notify the Commission of their intention to market the product and provide any relevant documentation or evidence.



Labelling of novel foods

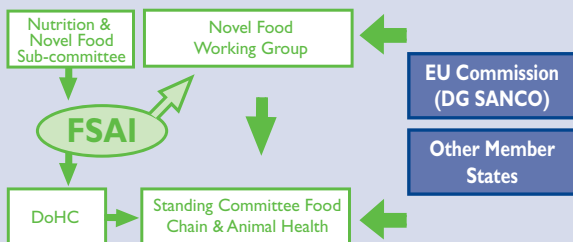
All novel food labelling requirements are developed, without prejudice, to the general food labelling Directive 2000/13/EC, which is based on the principle that labelling and methods of labeling should not mislead consumers as to the production, composition, nutritional value or characteristics of a food.

Claims relating to additional or health benefits of a novel food must take into account the requirements of the Nutrition and Health Claims Regulation EC No. 1924/2006. Additional labelling requirements for specific novel foods are considered on a case by case basis and are intended to inform the consumer of any new characteristics that the novel food or food ingredient possesses.



Novel food authorisation process in Ireland

Any company wishing to apply for a novel food authorisation through Ireland must contact the FSAI, which is the competent authority for novel foods in Ireland. The FSAI utilises the best scientific advice available in assessing the safety of novel foods which is provided through its Scientific Committee and associated Sub-committees.



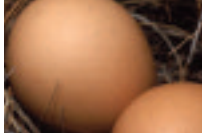
The FSAI represents Ireland at the Novel Food Working Group in Brussels which is the forum where initial discussions take place with regard to novel food applications and related issues. The FSAI provides expert advice to the Department of Health and Children which represents Ireland on food safety matters at the Standing Committee for the Food Chain and Animal Health.

The FSAI has carried out the initial assessment of a number of novel food applications while routinely reviewing initial assessments carried out by other Member States and delivering opinions on substantial equivalence to Irish food companies.

Novel food applications to date

A total of 93 novel food applications have been submitted up to September 2008.

Of these applications, 33 were authorised, 6 were refused, 14 were withdrawn, 6 were transferred to more appropriate authorisation processes and the remainder are pending.



Some of the authorised novel foods:

- Phospholipids from egg yolk
- Yellow fat spreads with added phytosterol-esters
- Pasteurised fruit-based preparations produced using high pressure pasteurisation
- Bacterial Dextran preparation for bakery products
- Trehalose
- Coagulated potato proteins and hydrolysates thereof
- Noni
- Oil rich in DHA
- Salatrim as a novel food ingredient
- Yellow fat spreads, salad dressings, milk type products, milk based fruit drinks, milk based beverages, fermented milk type products, yoghurt type products, soya drinks, spicy sauces, cheese type products and rye bread with added phytosterols/phytosteranols
- Isomaltulose
- Maize-germ oil and rapeseed oil high in unsaponifiable matter
- Lycopene from *Blakeslea trispora*
- Diacylglycerol oil of plant origin
- D-Tagatose
- GM maize lines.

Up to June 2008, a total of 110 foods had been placed on the EU market by the simplified procedure.

Further information about novel foods and processes can be found on the European Commission website:

http://www.europa.eu.int/comm/food/food/biotechnology/novelfood/index_en.htm.



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