
There have been in excess of 30 foods placed on the EU market by the simplified procedure. Further details of these substantially equivalent foods and other information about novel foods can be found on the European Commission website: [http://www.foodsafetyauthorityireland.ie](http://www.foodsafetyauthorityireland.ie)
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 European Commission website that covers all aspects of food safety.

What is a novel food?

A novel food, 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 regulation (Regulation EC 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 because they 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.

The novel food Regulation initially included foods or ingredients produced from genetically modified organisms (GMOs) but these are now covered by the GM food and feed Regulation (EC 1829/2003). However, a GM food may also require authorisation under the novel food Regulation if it contains a new component that is unrelated to the genetic modification.

Simplified procedure / notification

A food that is very similar, or identical to, an existing food or food ingredient with regard to composition, nutritional value, metabolism, intended use and level of undesirable substances, is considered substantially equivalent and does not require a novel food authorisation prior to being placed on the EU market. In following the 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. The notification to the Commission should include any documentation or evidence used in establishing substantial equivalence.

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 labelling should not mislead consumers as to the production, composition, nutritional value or characteristics of a food.

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 within the EU

Authorisation to market a novel food in the EU is a multi-step process with defined time limits and is co-ordinated 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. This dossier and a summary of the application must be provided to the competent authority of the Member State where the product will be first marketed. 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.

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, then the application returns back to the Commission which may then adopt its own Decision.

Application Dossier & Summary

Summary to Member States

Member States opinions or objections by 60 days

Commission adopts draft Decision

EU or reject product

Further assessment required

Referred to Council of Ministers if no agreement reached

Standing Committee for Food Chain and Animal Health

European Food Safety Authority (Scientific advice)

Lead Member State

Assessment within 90 days

Application

Dossier & Summary

Member States

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