

Nutrition and health claims

Once a characteristic feature of "health foods", labelling claims promising a variety of nutritional or health benefits for those who consume them are now commonplace on certain foodstuffs marketed in the EU. The proliferation of such claims on general foodstuffs reflects the extent of innovation and competitiveness within the food market, but also poses a challenge for regulators to ensure their legitimacy so that consumers are not misled. Regulation (EC) No. 1924/2006 on nutrition and health claims came into force on 19th January 2007 and applies from 1 July 2007. This Regulation harmonises the rules governing nutrition and health claims across all Member States while providing assurance to consumers that only standardised nutritional claims or specifically authorised health claims may be carried on food. However, medicinal claims relating to cure, prevention or treatment of disease remain the remit of medicines legislation.

Food fortification

Regulation (EC) No. 1925/2006 on fortification of foods with vitamins and minerals, and certain other substances came into force on 19th January 2007 and applies from 1 July 2007. This Regulation defines the criteria by which food fortification is allowed and includes a positive list of permitted vitamins and minerals, and their sources, along with a negative list of other substances that may not be added to food. The maximum and minimum levels of vitamins and minerals that can be added to a food will be scientifically allocated on a case by case basis, while certain labelling and presentation rules are also set out.



Classification as a Food or a Medicinal Product

Food

The FSAI is responsible for the enforcement of all aspects of food legislation, in Ireland, including food labelling. In this capacity, the FSAI decides when a labelling claim is in breach of Article 2.1(b) of the General Food Labelling Directive (2000/13/EC) which stipulates that food labelling must not "attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties".

Medicinal product

The manufacture, importation, distribution and supply of medicinal products for human use in Ireland is regulated by the Irish Medicines Board (IMB) pursuant to the Irish Medicines Board Act of 1995 and the Medicines Bill of 2005. Medicinal products are defined in the Medicinal Product Directives, specifically Article 1(2) of Directive 2001/83/EC, as amended by Directive 2004/27/EC as "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings" or, "any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis". As a general rule, the composition of a product, or the claims made in regard to it form the basis upon which classification is determined.

Composition

- Any food or food ingredient that is considered by the IMB to have an effect on the physiology of humans through pharmacological, immunological or metabolic action may be classed as a medicinal product. Even an established food may be reclassified by the IMB as a medicinal product where new scientific evidence becomes available that demonstrates a specific physiological effect.

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Health claims

- Any food, whether new or established, may be classified as a medicinal product by the IMB if it is presented as having properties that can help treat or prevent a disease.

  The IMB has produced an information document that defines medicinal products, while also providing guidance on the classification of borderline food or medicinal products (http://www.imb.ie/uploads/publications/6342926_guidelines.pdf).

  The FSAI and the IMB cooperate to ensure that all products on the market are properly classified as food or medicinal products with respect to composition and labelling claims.

This information leaflet is intended to be used as a guide only and does not necessarily represent a legal opinion or definitive interpretation of any legislation. As food legislation is in a constant state of flux, certain aspects of the information provided here may change in due course. While this document will be updated periodically, the FSAI will provide direct information where there are any ambiguities or where changes in the legislation have occurred.

Food Safety AUTHORITY OF IRELAND

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FUNCTIONAL FOOD

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FUNCTIONAL FOOD

A balanced and varied diet should provide sufficient nutrition for the average person and food, in all its forms, has traditionally been produced and marketed primarily for this purpose. However, an emerging category of food, termed "functional food" is routinely presented as possessing characteristics that can help achieve or maintain good health, in addition to providing basic nutrition. The delivery of health benefits through general foodstuffs is a relatively new concept within the EU, and though functional food is gaining in popularity with both the food industry and consumers alike, the legal status with respect to food law is not well documented.

The information provided here is intended as a broad guide to functional food along with the relevant legislation regulating such food.

Food and Food Categories

Food is defined in Article 2 of Regulation (EC) No. 178/2002 as any substance or product, whether processed or not, that is ingested by humans. In this definition, food includes beverages and water incorporated into food as well as products such as chewing gum. However, though many medicines are ingested by humans, they are not considered food and instead are covered by medicines legislation.

Most food and food ingredients fall into a number of categories defined by criteria such as: source, e.g. food of animal or non-animal origin, method of pre-harvest production, e.g. organic food, history of use, e.g. novel food, intended use, e.g. food supplements or food additives, or a production or processing treatment, e.g. irradiated or pasteurised food. The majority of these food categories are supported by specific legislation that controls authorisation, labelling and in some cases, production and processing.

Functional Food

The concept of "functional food" was developed in Japan in the mid 1980s. At that time, the Government of Japan decided that greater consumption of certain food types could help to limit or reduce the impact of a number of disease risk factors, and thereby assist in controlling the rising health costs associated with an ageing population. While a globally accepted definition has yet to be agreed, functional food is broadly regarded as generally consumed foodstuffs that may provide added health benefits following the addition/concentration of a beneficial ingredient, or the removal/substitution of an ineffective or harmful ingredient.

Functional foods already available on the EU market include those with added cholesterol lowering plant sterols and stanols, as well as those containing live bacteria (probiotics) that allegedly enhance the quality of the human gut microflora.

Positive Health Properties of Existing Food

Scientific research has identified potential health benefits present in many of the food ingredients that are common to modern diets. For example, constituents of cranberries, wholegrain cereals, tomatoes, soya beans, flaxseed, oily fish, garlic and broccoli can have a positive effect on human health when they form part of a balanced and varied diet. Cranberry juice is not only a good source of fibre and vitamin C, but is frequently recommended by general medical practitioners to help eliminate or prevent urinary tract infections. Cranberries contain plant chemicals known as proanthocyanidins that are partly responsible for their colour, but which have also been shown to interfere with the ability of certain *E. coli* strains to infect human cells.

Relevant EU Food Legislation

While functional food is rapidly emerging as a distinct food category, it is still a "virtual category" in terms of food law. Functional food is not defined in EU or Irish food legislation and is regulated through existing food legislation which is outlined next.

Authorisation to market new food

Prior to placing a new food on the EU market, specific authorisation must be obtained through the process set out in the Novel Food Regulation (EC No. 258/97). This Regulation came into force on May 15, 1997 and defines novel food as "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community". Therefore, any food or ingredient not on the market in any of the 25 EU Member States prior to May 15, 1997 requires authorisation.

A new food may require a full novel food authorisation or alternatively, may be substantially equivalent to a food already on the EU market, whereby a notification to the European Commission accompanied by relevant evidence will suffice. The Food Safety Authority of Ireland (FSAI) has produced an information leaflet outlining the Novel Food Regulation and how it is implemented in Ireland (www.fsai.ie/publications/leaflets/Novel_Food.pdf).

A food or food ingredient that has a significant history of consumption in any Member State prior to May 15, 1997 does not fall within the scope of the Novel Food Regulation. However, a history of consumption as or in a food supplement or a food additive is not sufficient, on its own, to enable a food or food ingredient to be placed on the market in a general foodstuff without novel food authorisation.

Full novel food authorisation

- A full novel food authorisation involves an initial assessment of a dossier of scientific safety data submitted by the applicant company to a Member State competent authority. Where unanimous agreement by all Member States on the initial assessment is not achieved, the dossier is forwarded to the European Food Safety Authority (EFSA) for an independent safety assessment. The European Commission then drafts a proposal based on the EFSA safety assessment, and where sufficient Member State support is not achieved, the decision to authorise or reject the application reverts to the Commission.

Substantial equivalence

- Novel food legislation allows a new food to be placed on the market where it is shown to be substantially equivalent to a food already present on the EU market. Substantial equivalence may be established on the basis of generally recognised and available scientific evidence acceptable to the EU Commission, or by an opinion from a national competent authority, such as the FSAI.

Food Supplements

Food supplements are concentrated sources of nutrients or other substances presented in dose form, e.g. pills, capsules etc. to the consumer and are used to augment a regular balanced diet. In the EU, food supplements are governed by Directive 2002/46/EC (transposed into Irish law by S.I. No. 539 of 2003). This legislation stipulates that only those vitamins and minerals on the positive list may be marketed as of August 1st, 2005 while new supplements must undergo a full safety assessment. However, existing food supplements on the market prior to July 12th, 2002 may remain on the market until December 31, 2009 pending a positive safety assessment. In addition, a dossier supporting their safety must have been submitted to EFSA by July 12th, 2005 and a derogation granted by the FSAI. Further information on food supplements legislation can be viewed on the FSAI website (www.fsai.ie/legislation/food_supp/index.asp).

Food Labelling

The General Food Labelling Directive (2000/13/EC), implemented in Ireland by S.I. No. 483 of 2002, stipulates the labelling and advertising criteria for general foodstuffs. Additional labelling rules may also apply to certain food or food categories such as GM food, irradiated food, certain novel food and food for particular nutritional uses (PARNUTS).
The rules of general food labelling in Ireland are outlined in a report produced by the FSAI (http://www.fsai.ie/publications/index.asp#reports).