

Food allergen labelling and information requirements technical guidance: General background on allergens

Information on the 14 allergens and data and statistics relevant to this guidance

13. Around 6% of the UK adult population have a food allergy; this figure does not include those with food intolerances. In addition, it is estimated that 1 in 100 people have coeliac disease, a genetic and autoimmune disease triggered by eating gluten. This is a protein found in wheat, rye, and barley. Eating gluten triggers an abnormal immune response which results in damage to the lining of the gut and malabsorption causing nutritional deficiencies and associated complications.

14. An allergic reaction can be produced by a tiny amount of a food ingredient that a person is sensitive to (a drop of milk, a fragment of peanut or just one or two sesame seeds). Symptoms of an allergic reaction can range from mild symptoms such as itching around the mouth and rashes, and can progress to more severe symptoms such as vomiting, diarrhoea, difficulty breathing, and, on occasion, anaphylaxis (shock) and death. When people with coeliac disease consume even the smallest amount of gluten, the reaction is not the same as an allergic reaction, and they will not go into anaphylactic shock, but it will result in symptoms some of which can be serious and can result in hospital admission. These symptoms usually start a few hours after eating it and symptoms can last from a few hours to several days. Ongoing ingestion of gluten results in symptoms such as diarrhoea, constipation, nutritional deficiencies including iron, folic acid and B12 anaemias and associated complications such as osteoporosis.

15. There is no cure for food allergy or coeliac disease. The only way to manage food allergy and coeliac disease is to avoid food that triggers the abnormal immune response. Therefore, it is very important that food businesses provide consumers with clear and accurate information about allergenic ingredients in products to allow them to make safe food choices.

Main allergen labelling changes

16. From 1 October 2021, legislation to amend the FIR ([footnote 1](#)) came into force to improve the provision of information to consumers purchasing PPDS foods. These changes place a duty on food businesses to label PPDS food with the name of the food and a full list of ingredients containing emphasised allergens. These changes bring the provision of allergen information in line with labelling for prepacked food, reducing consumer confusion.

Mandatory obligations for all FBOs

17. Under Article 9(1)(c) of the FIC, all FBOs must declare the presence, whether for use as an ingredient or a processing aid, of any of the 14 major allergens listed in Annex II to the Regulation. The ways in which this mandatory information can be presented for prepacked food, non-prepacked food and prepacked for direct sale food is explained later in this guidance. However, in all cases it should be noted that in accordance with Articles 12 and 13 of the FIC the mandatory information must be easily accessible, in a conspicuous place, easily visible and clearly legible.

Information must be indelible (for example on food labels where it needs to withstand handling). The information must not be hidden, obscured, detracted from or interrupted by other written or

pictorial matter or any other intervening material. All information provided about allergens must be accurate, however it is provided.

The fourteen allergens (Annex II allergens)

18. The 14 allergens listed in Annex II of the FIC are recognised as the most common ingredients or processing aids that cause food allergies and intolerances. If a food contains or uses an ingredient or processing aid in the manufacture or preparation of the food derived from one of the substances or products listed in Annex II, and it is still present in the finished product, information regarding the presence or use of the allergen must be provided to the consumer.

19. The Annex II allergens are:

- Cereals containing gluten namely wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof, except:
 - a) wheat based glucose syrups including dextrose
 - b) wheat based maltodextrins
 - c) glucose syrups based on barley
 - d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin
- Crustaceans and products thereof (for example prawns, lobster, crabs and crayfish) Egg and products thereof
- Fish and products thereof, except
 - a) fish gelatine used as carrier for vitamin or carotenoid preparations of fish gelatine or Isinglass used as a fining agent in beer and wine
 - Peanuts and products thereof
 - Soybeans and products thereof, except
 - a) fully refined soybean oil and fat
 - b) natural mixed tocopherols (E306), natural D-alpha tocopherols, natural D-alpha tocopherol acetate and natural D-alpha tocopherol succinate from soybean sources
 - c) vegetable oils derived phytosterols and phytosterol esters from soybean sources
 - d) plant stanol ester produced from vegetable oil sterols from soybean sources
 - Milk and products thereof (including lactose), except
 - a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin
 - b) lactitol
 - Nuts (namely almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut and Macadamia nut (Queensland nut)) and products thereof except for nuts used for making alcoholic distillates (e.g., spirits such as vodka or whisky) including ethyl alcohol of agricultural origin
 - Celery and products thereof
 - Mustard and products thereof
 - Sesame seeds and products thereof
 - Sulphur dioxide and/ or sulphites at concentrations of more than 10 mg/kg or 10 mg/ (litre) in terms of the total SO₂ which are to be calculated for products as proposed ready for

consumption or as reconstituted according to the instructions of the manufacturers.

- Lupin and products thereof
- Molluscs and products thereof (for example mussels, clams, oysters, scallops, snails, and squid)

20. The use of icons or symbols to indicate the presence of allergens is permitted as long as it is accompanied by words and numbers to ensure uniform consumer understanding and to avoid misleading the consumer. Currently there is no single agreed set of icons or symbols for indicating the presence of allergens in prepacked, non-prepacked, and prepacked for direct sale food.

Ingredients and processing aids excluded from the 14 allergens in Annex II

21. The FIC requires information on the presence of allergens in the final foodstuff to be provided in the manner specified by the Regulation. Some ingredients made from the Annex II foods are unlikely to cause an allergic reaction because they have been highly processed (for example fully refined soya oil or wheat glucose syrups). This is because the allergen/protein has been removed and the product has been assessed by the European Food Safety Authority (EFSA) as not possessing an allergenic risk to the consumer.

22. Substances derived from an allergenic ingredient, which have been specifically exempted from declaration under Annex II (e.g., wheat glucose syrup), do not need to be declared as allergens for example - fully refined soya oil.

Voluntary information (Article 36)

23. Any voluntary food information must comply with the requirements of Chapter V of the FIC. In particular, voluntary statements must not mislead consumers, or be ambiguous or confusing.

24. A Precautionary Allergen Label (PAL) is a statement that food businesses can choose to apply to food products where there is an unavoidable risk of allergen cross-contamination. It is commonly seen as “may contain allergen x” or “not suitable for someone with x allergy” on food products.

25. Although PAL is voluntary food information under the FIC, to avoid providing food that could be deemed unsafe, FBOs should provide consumers with accurate information about the risk of the unintended presence of allergens.

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A Precautionary Allergen Labelling statement or information [such as ‘may contain’] should only be provided with prepacked or non-prepacked foods if an unavoidable risk of allergen cross-contamination has been identified following a risk assessment that cannot be sufficiently controlled through controls, such as segregation and cleaning.

Its use is not a substitute for good food hygiene and safety practices, and it could be considered misleading food information if it does not convey a real risk to the consumer. [A checklist to understand when and how to apply precautionary allergen labelling to food product](#) is provided in this FSA guidance.

1. The Food Information Regulations and equivalent legislation in Wales and Northern Ireland have been amended by The Food Information (Amendment) (England) Regulations 2022,

The Food Information (Wales) (Amendment) (No. 2) Regulations 2020 and The Food Information (Amendment No. 2) Regulations (Northern Ireland) 2020.