

Food allergen labelling and information requirements Technical Guidance

October 2020

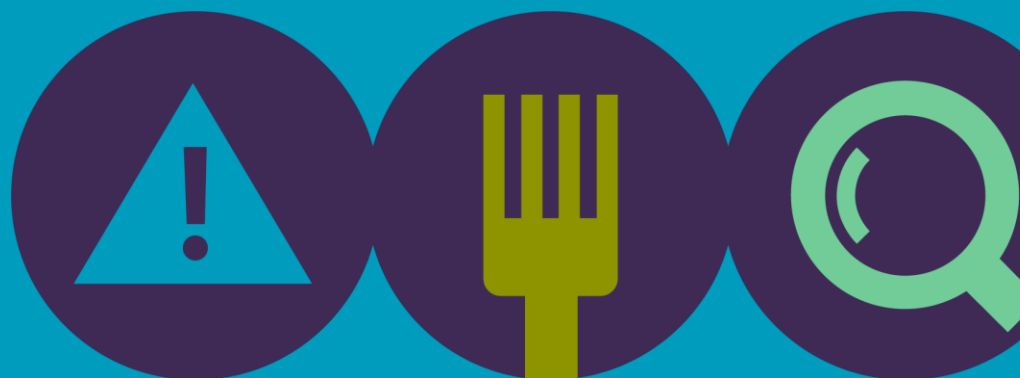


Table of Contents

- Summary 4
 - Purpose 4
 - Legal status..... 4
 - Intended Audience 4
 - Applicable to which UK Nations..... 4
 - Review date 4
 - Key words 4
- Introduction 5
 - Intended audience 6
 - Purpose of the guidance 6
 - Legal status of the guidance 6
 - Best Practice 7
 - Example 7
 - General background on allergens 7
 - Main allergen labelling changes 8
 - Mandatory obligations for all FBOs 9
- The fourteen allergens (Annex II allergens) 9
 - Ingredients and processing aids excluded from the 14 allergens in Annex II..... 10
 - Voluntary information (Article 36)..... 11
- Part 1: Guidance for businesses providing prepacked food 12
 - List of mandatory particulars (Article 9) 12
 - Cereals containing gluten 12
 - Best Practice 13
 - Crustaceans 13
 - Eggs..... 13
 - Fish 14
 - Peanuts..... 14
 - Soyabeans 14
 - Milk 14
 - Best Practice 15
 - Nuts..... 15
 - Celery..... 16
 - Mustard 16
 - Sulphur dioxide and / or sulphites at levels above 10 mg/Kg or 10 mg/litre 16
 - Example 17
 - Lupin 17

Molluscs	17
Presentation of mandatory particulars (Article 13).....	18
Omission of the list of ingredients (Article 19)	19
Labelling of certain substances or products causing allergies or intolerances (Article 21) .	19
Example	19
Example	20
Food products without ingredients lists	20
Example	21
Applicable requirements – voluntary information (Article 36).....	21
Distance selling – Prepacked foods (Article 14)	21
Example	21
Part 2: Guidance for businesses providing non- prepacked food	22
Responsibilities (Article 8).....	22
Best Practice	22
Presentation of mandatory allergen information (Articles 9, 12, 13 and 21).....	23
Example	23
Example	24
Best Practice	25
Best Practice	26
National Measures (Article 44).....	26
Best Practice	27
Distance selling – non-prepacked food (Article 14)	27
Best Practice	27
Example	28
Part 3: Guidance for businesses providing food prepacked for direct sale	29
Best Practice	29
Example	32
Example	33
List of mandatory particulars for PPDS food	33
Distance selling (Article 14).....	34
Enforcement of the measures.....	35
Local authority responsibilities	35
Penalties and offences.....	35
Glossary of terms used.....	36
References and Resources	39
Relevant Legislation	40
Review	40

Summary

Purpose

This publication aims to help food businesses follow allergen labelling requirements. It will also help authorised food officers enforce these measures.

Legal status

This is best practice and regulatory guidance intended to accompany the allergen provisions of the EU Regulation on the provision of food information to consumers (Regulation (EU) No. 1169/2011) and the Food Information (Scotland) Regulations 2014, SSI 2014/312 as amended.

Intended Audience

This guidance is for:

- all food manufacturers, importers and producers
- retailers, institutional caterers and other food businesses
- packers
- enforcement authorities

Applicable to which UK Nations

- Scotland

Review date

We will review this guidance before December 2021.

Key words

- Allergy and intolerance
- Allergen Labelling
- Prepacked food
- Non-prepacked food
- Prepacked for Direct Sale food

Introduction

1. The legislative framework around the provision of food allergen information is largely contained in the Regulation (EU) No. 1169/2011 on the provision of food information to consumers (FIC) which brings together European rules on the general and nutrition labelling into a single directly applicable regulation to simplify and consolidate labelling legislation. The Food Information (Scotland) Regulations 2014 (FIR) provides for the execution and enforcement in Scotland of the FIC. The FIC imposes a duty on food businesses to ensure that all mandatory food allergen information (relating to 14 substances listed in the FIC that are known to cause allergies) is accurate, available and easily accessible to the consumer. Under the FIC, food which is prepacked, for example a ready meal sold in a supermarket, must be labelled with full ingredients and any of the 14 specified food allergens present must be emphasised in an ingredients list. The FIC allows Member States to make a distinction between prepacked foods and non-prepacked foods in how mandatory allergen information is provided to consumers.
2. Under the FIC, food which is prepacked, for example a ready meal sold in a supermarket, must be labelled with full ingredients and any of the 14 specified food allergens present must be emphasised in an ingredients list. For non-prepacked food the allergen labelling requirements differ. Any food that does not fall within the FIC definition of prepacked food is non-prepacked food. This includes but is not limited to: food without packaging such as loose fruit and vegetables, bread sold without wrapping in bakery shops and food packed on the sales premises at the consumer's request.
3. These guidance notes cover the interpretation and application of allergen provisions for prepacked, non-prepacked and prepacked for direct sale (PPDS) foods. Failure to comply with the allergen provisions may result in a criminal prosecution being brought against a food business or food business operator (FBO).
4. This guidance does not cover other labelling requirements (such as other general labelling (e.g. country of origin, minced meat, quantities, additives, nutrition etc.)
5. 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.

Intended audience

6. These guidance notes on the FIC rules and the provision of allergen information are intended to help food businesses such as producers, manufacturers, packers, importers, distributors, wholesalers, retailers, caterers and also for enforcement officers responsible for enforcing relevant measures.

7. Individuals who¹ occasionally provide food at charity events or voluntary cake sales, for example, may also need to follow the legal requirements. If you are a charity or community food provider and are unsure whether you should be registered as a food business, you can speak to your local authority's environmental health department. Further information is also available in our [guidance on providing food at community and charity events](#) which can be downloaded from the FSS website:

Purpose of the guidance

8. These guidance notes have been produced to:
 - provide informal and non-binding technical guidance on the interpretation and practical application of FIC specific requirements on allergen labelling and information,
 - develop understanding by providing regulatory guidance and interpretation in this area, and
 - be read alongside the FIC and FIR.

Legal status of the guidance

9. These guidance notes have been produced to provide guidance on:
 - the legal requirements of the FIC and the FIR, and
 - best practice guidance. You are not required by law to follow best practice guidance

10. Businesses with specific queries may wish to seek the advice of their [local authority environmental health department](#).

¹ See 'food business' in Glossary, definition of 'food business' in Article 3(2) of Regulation 178/2002 (General Food Law), Recital (9) of the Introductory Text of Regulation 852/2004 (Food Hygiene including food business registration) and Recital (15) of the Introductory Text of Regulation (EU) No. 1169/2011 (Food labelling/Information).

11. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law. You are not required by law to follow best practice guidance. All guidance on best practice is identified in shaded boxes, with a heading of Best Practice:

Best Practice

All best practice guidance is clearly identified within this document by this style of format

12. This guidance also uses practical examples to help explain the requirements. All examples are identified in shaded boxes, with a heading of Example.

Example

All practical examples are clearly identified within this document by this style of format.

General background on allergens

13. 1-2% of the UK adult population and 5-8% of children in the UK 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, 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). 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. 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. Currently, FBOs who offer for sale PPDS food to the final consumer or to a mass caterer can provide mandatory allergen information for such food by any means that they choose, including orally. Where the FBO intends to provide that information orally, they must indicate that details of the mandatory allergen information used as an ingredient or processing aid in the manufacture or preparation of the food, or derived from such as substance can be obtained by asking a member of staff. Continuing fatalities and the effect on public health mean that allergen information provision is of significant interest to the public, with individual cases often receiving a significant amount of media attention. Anecdotal evidence indicates that it is often difficult for some consumers to distinguish between prepacked and PPDS foods, and that some consumers assume that the absence of allergen information on PPDS foods means food allergens are not contained in the product, whether or not this is the case.
17. Due to these reasons, legislation to amend the FIR has been proposed to improve the provision of information to consumers purchasing PPDS foods. These changes are intended to place a duty on food businesses to label PPDS food with a list of ingredients containing emphasised allergens bringing the provision of allergen information in line with labelling for prepacked food, reducing consumer confusion.
18. In recognition that food businesses will need time to adapt to this change, these changes are not proposed to come into effect until the 1st October 2021. This period was considered necessary as a result of the information gathered from food businesses during the consultation on amending allergen information provision.
19. The FIR requirements regarding allergen information in respect of other forms of non-prepacked foods, such as foods which are not packaged and those packed at the consumer's request, are unaffected by these changes. This is because unpackaged food does not have packaging in order to place a label on, and the other is packaged in front of the consumer at their request. The proposed changes are intended to bring a greater level of consistency of

allergen information between PPDS and prepacked foods.

Mandatory obligations for all FBOs

20. Under 9(1)(c) of the FIC, indication of any ingredient or processing aid listed in Annex II (the 14 major allergens) or derived from a substance or product listed in Annex II (i.e. major allergens) causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, is mandatory. Regulation 8 (7) of the FIC obligates FBOs, within the businesses under their control to ensure shall the mandatory particulars required under Articles appear on the prepackaging or on a label attached thereto, or on the commercial documents referring to the foods where it can be guaranteed that such documents either accompany the food to which they refer or were sent before or at the same time as delivery:(a)where prepacked food is intended for the final consumer but marketed at a stage prior to sale to the final consumer and where sale to a mass caterer is not involved at that stage;(b)where prepacked food is intended for supply to mass caterers for preparation, processing, splitting or cutting up.

The fourteen allergens (Annex II allergens)

22. The 14 allergens listed in Annex II to the FIC (substituted by Commission Delegated Regulation (EU) No. 78/2014 of 22 November 2013) are recognised as the most common ingredients or processing aids causing food allergies and intolerances. If a food contains or uses an ingredient or processing aid used in the manufacturer 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.

- a. The Annex II allergens are:
- b. Cereals containing gluten namely wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof, except:
 - i. wheat based glucose syrups including dextrose;
 - ii. wheat based maltodextrins;
 - iii. glucose syrups based on barley;
 - iv. cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- c. Crustaceans and products thereof (for example prawns, lobster, crabs and crayfish);
- d. Egg and products thereof;
- e. Fish and products thereof, except
 - i. fish gelatine used as carrier for vitamin or carotenoid preparations
 - ii. fish gelatine or Isinglass used as a fining agent in beer and wine

- f. Peanuts and products thereof
- g. Soybeans and products thereof, except:
 - i. fully refined soybean oil and fat;
 - ii. natural mixed tocopherols (E306), natural D-alpha tocopherols, natural D- alpha tocopherol acetate and natural D-alpha tocopherol succinate from soybean sources;
 - iii. vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - iv. plant stanol ester produced from vegetable oil sterols from soybean sources;
- h. Milk and products thereof (including lactose), except:
 - i. whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
 - ii. lactitol;
- i. Nuts, namely: almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis (Wangenh.) K. Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- j. Celery and products thereof;
- k. Mustard and products thereof;
- l. Sesame seeds and products thereof;
- m. 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;
- n. Lupin and products thereof;
- o. Molluscs and products thereof.

23. The use of icons or symbols to indicate the presence of allergens is permitted as long as it is accompanied 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

24. 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.

25. 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)

26. Any voluntary food information referred to in Articles 9 or 10 of the FIC must comply with the requirements of Sections 2 and 3 of Chapter V of the FIC which states that voluntary food information must not mislead the consumer, must not be ambiguous or confusing, and where appropriate be based upon scientific data. The use of precautionary allergen labelling when there is not a real risk could be considered to be misleading food information.

Best Practice

FBOs may voluntarily use labelling such as ‘produced in a kitchen which uses...’ or ‘may contain’ or ‘not suitable for...’ to communicate the risk of the unintentional presence of an allergen (e.g. milk, egg, peanuts, almonds) in a food product due to the allergen entering the product accidentally, or through cross contamination.

These statements should only be used after a meaningful risk assessment has been performed and there is considered to be a significant and real risk to the food allergic or food intolerant consumer and should not be used as a substitute for good hygiene and safety practices.

Food Drink Europe (FDE) has produced best practice guidance on voluntary application of precautionary allergen labelling:

www.fooddrinkeurope.eu/uploads/publications_documents/Guidance_on_Food_Allergen_Management.pdf

Part 1: Guidance for businesses providing prepacked food

27. The following section provides guidance and examples of compliance with the FIC provisions specific to allergen labelling for prepacked foods. This is based on the following articles:

- Article 9 (List of mandatory particulars);
- Article 13 (Presentation of mandatory particulars);
- Article 19 (Omission of the list of ingredients);
- Article 21 (Labelling of certain substances or products causing allergies or intolerances); and
- Article 36 (Applicable requirements). These relate to the provision of voluntary food information

List of mandatory particulars (Article 9)

28. Below, you will find guidance on the scope of each allergenic ingredient captured in Annex II of the FIC and how the allergens must be emphasised in the ingredients list.

Cereals containing gluten

29. Annex II of the FIC as amended by Regulation (EU) No. 78/2014 defines these as: wheat such as spelt and Khorasan wheat), rye, barley and oats or their hybridised strains, and products thereof except wheat based glucose syrups including dextrose, wheat based maltodextrins, glucose syrups based on barley and cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin. Spelt and Khorasan are types of wheat, which are not suitable substitutes for people with coeliac disease and/or wheat allergy.

30. Cereals containing gluten must be declared in the ingredients list using the specific name of the cereal, i.e. wheat (such as spelt or Khorasan), rye, barley or oats. Where 'spelt', 'Khorasan' and 'Kamut' have been used; the inclusion of a specific reference to wheat would be required; for example 'spelt (**wheat**)' or 'Khorasan **wheat**' and 'Kamut (**wheat**)'.

31. Ingredients which are or have been derived from cereals containing gluten will need to be emphasised within the ingredients list. This will make clear for those with an allergy to specific cereals to avoid such food; for example: 'Codex **wheat** starch'; '**barley** malt extract'. The voluntary inclusion of the word 'gluten' within the ingredients list following the mandatory declaration of a specific cereal (containing gluten) is permitted however FIC requires the cereal to be emphasised, rather than the gluten; for example '**barley**(gluten)'.

Best Practice

The Food and Drink Federation has produced best practice guidance in this area: www.fdf.org.uk/corporate_pubs/FDF-gluten-labelling-guidance.pdf

32. Where foods have been labelled as 'gluten-free' they must meet the requirements set in Regulation (EU) No. 828/2014² which applies to the provision of information to consumers on the absence or reduced presence of gluten in food. It sets out the conditions under which a statement on the absence or reduced presence of gluten in food may be given. For example a statement "gluten-free" may only be made where the food sold contains no more than 20 mg/Kg in the food as sold to the final consumer, or "very-low gluten" (no more than 100 mg/Kg gluten in the food as sold to the final consumer). When a product containing one of the cereals mentioned in Annex II (e.g. oats) and meets the relevant requirements of Regulation (EU) No. 828/2014, then the statement 'gluten-free' or 'very low gluten' can be used on the product. However, the cereal mentioned in Annex II must still be indicated and emphasised in the list of ingredients. These rules surrounding use of the terms "gluten-free" and "very-low gluten" apply to all foods including non-prepacked foods such as those served in restaurants. No other statements to describe the absence or reduced presence of gluten are permitted. When gluten free oats are used in a gluten free product, the word "oats" would still need to be emphasised and declared in accordance with Article 21 and 9 (1) (c) of the FIC.

Crustaceans

33. The rules do not name any specific species of crustaceans which means all types of crustaceans are included (for example lobster, prawns and langoustines).

34. Labelling of crustaceans and products made from them need to have a clear reference to the Annex II food; for example 'prawns (crustaceans)', 'crayfish (crustaceans)', 'lobster (crustaceans)', 'shrimp paste (crustaceans)' and comply with all other requirements set out under Article 21 of the FIC.

Eggs

35. The rules do not name any species of eggs, because 'eggs' refers to eggs from all birds, for example from laying hens as well as eggs from ducks, quails, geese, gulls and guinea fowl. Therefore all eggs need to be declared when used as an ingredient or a processing aid and comply with all other requirements set out under Article 21 of the FIC.

² Commission Implementing Regulation (EU) No 828/2014

Fish

36. The rules do not name any species of fish because 'fish' means all species of fish and products except for fish gelatine used as carrier for vitamin or carotenoid preparations; and fish gelatine or Isinglass used as fining agent in beer and wine. The generic terms provisions allow the generic name fish to be used in an ingredient list only where there is no specific reference to a common fish species name on the label, for example fish stock
37. Labelling of fish ingredients or products need to have a clear reference to the Annex II food; for example, 'cod (**fish**)', 'salmon (fish)', 'tilapia (**fish**)' unless exempt (see p 10-11 for exemptions) and comply with all other requirements set out under Article 21 of the FIC.

Peanuts

38. While peanuts may also be commonly referred to as groundnuts (which can be confused with ground/powdered nuts such as almonds or a mix of nuts and peanuts) or monkey nuts, the term peanuts must be used for products or ingredients made from them for allergen labelling purposes, as this is the term specified in Annex II of the FIC
39. Both refined and unrefined peanut oil must be labelled with reference to peanut and comply with all other requirements set out under Article 21 of the FIC.

Soyabeans

40. Terms such as 'soya' or 'soy' are sufficient to indicate the soybean origin. However less common terms such as tofu or edamame may not be recognised as originating from soya and its clear presence need to be indicated for soya products or derivatives. e.g. tofu (soya) or edamame (soya) unless exempt (see p 10-11 for exemptions) and comply with all other requirements set out under Article 21 of the FIC. Notably Soybeans and products do not include fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources, vegetable oils derived phytosterols and phytosterol esters from soybean sources and plant stanol ester produced from vegetable oil sterols from soybean sources.

Milk

41. The rules do not name the animal origin of milk because the word 'milk' includes milk from mammals such as cow, sheep, goat, and buffalo etc. They do not apply to whey used for making alcoholic distillates including ethyl alcohol of agricultural origin or lactitol. It should be noted that all mammalian milk proteins have a similar structure and if someone has an allergy or intolerance to cows' milk, they are likely to be allergic or intolerant to other

mammalian milk. Therefore all milk and milk products (including lactose) need to be declared when used as an ingredient or a processing aid unless exempt (see p 10-11 for exemptions) and comply with all other requirements set out under Article 21 of the FIC.

42. Milk products such as cheese, butter, fermented milk and cream do not have to have an ingredients list where no other ingredients have been added other than lactic acid, food enzymes and microbiological cultures and (in the case of cheese) salt. In order to ensure that consumers still receive the information they need to clearly identify the presence of milk in such cases, the following advice may be applied. [The use of sales names such as 'cheese', 'butter' 'cream' and 'yoghurt' is considered to refer clearly to the milk because legally these products can only be made from mammalian milk (Regulation (EU) No. 1308/2013 on common organisation of the markets in agricultural products including dairy designations). In such cases, further reference to milk is not necessary because the Dairy designations protect such products. Therefore, cheese, and cream³ can be emphasised within the ingredients to demonstrate the presence of a milk product.

Best Practice

The British Retail Consortium (BRC) guidance provides best practice advice on this area and a literal interpretation of the FIC where all milk products have a clear reference to milk regardless of whether it is a protected term or not (e.g. 'butter (**milk**)')

43. However, the information must make a clear reference to milk in the case of less familiar milk products used as ingredients (e.g. fromage frais, Mascarpone, Cantal, Quark) or products being sold under a name which does not clearly refer to milk. Components derived from milk, such as lactose, casein and whey, must be declared with a clear reference to milk e.g. 'whey (milk)'.

Nuts

44. The rules list these as: almond, hazelnut, walnut, cashew nut, pecan nut, Brazil nut, pistachio nut, macadamia nut or Queensland nut and products made from these nuts. The type of nut must be listed and emphasised in the ingredients panel. Other types of nuts, and other foods which are not nuts (even though they are called nuts i.e. chestnuts, pine nuts and coconut), are not named in the rules. Chestnuts pine nuts and coconut are also known to cause allergy in some people but must not be emphasised within the ingredients.

45. Where ingredients or processing aids derived from nuts have been used, the

³ [Commission Notice on substances or products causing allergies or intolerances \(2017/C 428/01\)](#)

ingredient must be indicated with a clear reference to the nut; for example 'flavourings (almond)' unless exempt (see p 10-11 for exemptions) and comply with all other requirements set out under Article 21 of the FIC.

Celery

46. This term is used generically in the FIC to refer to stick celery and celery root/tuber (also often known as celeriac). However, the term refers to any part of the celery plant and other forms that originate from it, such as celery leaf, celery root, celery seeds, celery oil, celery salt, celery spice, celery seed oil and celery seed oleoresin (an oil / resin extract from celery) All requirements set out under Article 21 of the FIC must be complied with.

Mustard

47. This term refers to the mustard plant and other products which originate from it, such as leaves, sprouted seeds, mustard flour, table mustard, mustard oils, mustard seed oils and mustard oleoresins. The appropriate terms must be used in labelling as well as all other Article 21 of the FIC requirements must be complied with.

48. The rules do not name any particular species of mustards and therefore must be applied to all types of mustard. All other requirements set out under Article 21 of the FIC.

49. This term refers to sesame seeds, ground sesame powder and sesame oil. Products derived from sesame seeds, such as tahini, must be clearly labelled with a reference to sesame e.g. 'tahini (sesame)'. The rules do not name any particular species of sesame seeds and therefore must be applied to all. All other requirements set out under Article 21 of the FIC.

Sulphur dioxide and / or sulphites at levels above 10 mg/Kg or 10 mg/litre

50. The labelling rules apply to sulphur dioxide and/or sulphites that have been deliberately added for example when it has been used as a preservative or have been added to an ingredient used in a preparation of the food. The rules require sulphur dioxide and/or sulphites to be labelled when present above 10 mg/Kg or 10 mg/litre (calculated in terms of the total sulphur dioxide (SO₂)) in the finished product as consumed, i.e. prepared according to the manufacturer's instructions. The method of analysis for sulphur dioxide sulphites cannot differentiate between those naturally present in the food or added as a preservative. Where sulphur dioxide and/ or sulphite based preservatives (even as carryover in an ingredient) have been used and the levels in the finished product are above 10 mg/Kg or 10 mg/litre, it will need to be declared on the label. . All other requirements set out under Article 21 of the FIC must be complied with.

51. Under general food additives legislation, where sulphur dioxide and/or sulphites have been added and have a technological function in the finished product, the function and the name and/or e number of the additive must be

included - for example: 'Dried Apple, (Preservative: sulphur dioxide)' – however if only the E number is provided a clear reference to the allergen must be provided so it is easily understood by the consumer. Under allergen labelling legislation, when sulphites are present at above 10 mg/Kg/litre in the finished product, whether or not they have a technological function, a clear declaration of sulphites and/or sulphur dioxide is always required. All other requirements set out under Article 21 of the FIC must be complied with.

Example

The term 'sulphites' (or 'sulfites') may also be used as a generic term for this ingredient. Furthermore, depending on the particular sulphite present, the chemical name may be used with the sulphite element emphasised, for example, 'sodium metabisulphite'

52. References to sulphur dioxide and/ or sulphites, which are used and found present in the finished product (ready for consumption or reconstituted according to manufacturers' instructions) at less than 10 mg/Kg or 10 mg/litre is not required.

Lupin

53. The term lupin is used generically in the FIC to refer to both lupin seed and products from it such as lupin flour. The appropriate terms must be used in labelling. The rules do not name any particular species of lupin and therefore must be applied to all. All other requirements set out under Article 21 of the FIC must be complied with.

Molluscs

54. The rules do not name any species because molluscs includes all types of mollusc (for example oyster, squid, cockles, mussels, winkles and scallops as well as land molluscs like snails). All other requirements set out under Article 21 of the FIC must be complied with.

55. Labelling of mollusc ingredients and products derived from molluscs need to have a clear reference to the Annex II food; for example, 'mussels (mollusc)', 'octopus (mollusc)', 'oyster (mollusc)'. All other requirements set out under Article 21 of the FIC must be complied with.

Presentation of mandatory particulars (Article 13)

56. Mandatory particulars listed in Article 9 (1) must be presented in accordance with Article 13. Mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material (for example under a flap or across a fold or crease, detracted from or interrupted by any other written or pictorial matter or any other intervening material). When appearing on the package or on the label attached thereto, mandatory particulars listed in Article 9(1) shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height, as defined in Annex IV, is equal to or greater than 1,2 mm. In case of packaging or containers the largest surface of which has an area of less than 80 cm², the x-height of the font size referred to in paragraph 2 shall be equal to or greater than 0,9 mm.

57. Consider whether the mode of emphasis:

- is sufficiently visible,
- is readable for those with visual impairments? For example consider individuals with colour blindness when using contrasting colours,
- a minimum font size where the x-height (as illustrated in Annex IV of the FIC) is 1.2 mm or more must be used where labelling surface is 80 cm² or more, and
- a minimum font size where the x-height is 0.9 mm or more must be used where the labelling surface is less than 80 cm². Figure 1 below illustrates how the x-height of the font used is measured.

Figure 1: How to measure x-Height 1 (of your font)

x-HEIGHT



Legend

1	Ascender line
2	Cap line
3	Mean line
4	Baseline
5	Descender line
6	x-height
7	Font size

58. Where the food packaging or container's largest surface area is less than 10 cm² (e.g. a single portion sachet of sauce), the ingredients list can be omitted, provided that the ingredients information is provided by other means or made available at the consumer's request. In such cases, the presence of Annex II ingredients in the food must be indicated by the word 'contains...' followed by the name of substance or product (e.g. Contains: celery, fish). The minimum font size rules also apply to other mandatory information as listed in Article 9 (1) of the FIC. Please refer to Article 13 of the FIC for further details.

Omission of the list of ingredients (Article 19)

59. Where the name of the product consists of a single ingredient (e.g. bag of peanuts or a box of eggs) and clearly refers to the presence of a substance or product causing allergies, further indication of the presence of the Annex II substance or product is not required. Therefore, in these examples, a bag of peanuts and a box of eggs would not need to declare the presence of peanut and egg respectively. However, where the name of the food does not clearly refer to the substance as named in Annex II, information regarding the presence in the food of an Annex II substance must be provided in the manner required for those substances. For example gingelly oil is sesame oil and must therefore be labelled 'contains: sesame'.

Labelling of certain substances or products causing allergies or intolerances (Article 21)

60. Article 21 specifies that mandatory information about the presence of the Annex II ingredients which cause allergies will need to be emphasised from the other ingredients within the ingredients lists by means of contrasting font, size, style or background colour. For example 'INGREDIENTS: Oatmeal, sunflower oil, prawn (crustacean)'

61. The FBO has flexibility in deciding which mode of emphasis to use to declare the presence of allergens.

Example

An allergy advice statement could be used on the product label to explain how allergens are emphasised within the ingredients list. For example: 'Allergy advice: for allergens, see ingredients in **bold**' or 'Allergy advice: for allergens, including cereals containing gluten, see ingredients highlighted in **blue**.'

62. The source of allergens for each ingredient needs to be declared even if there are several ingredients from the same allergenic food.

Example

Partially Reconstituted Skimmed **Milk** Concentrate, Sugar, Sunflower Oil, Whey Powder (**milk**), Dextrose, Emulsifier (Mono- and Di-Glycerides of Fatty Acids), Flavouring, Stabilisers (Guar Gum, Sodium Alginate), Colours (Beetroot Red, Beta-Carotene).

63. If the name of an ingredient partly includes the Annex II allergen in a single word, then the name of the ingredient corresponding to the Annex II food can be emphasised. (For example: 'wheatflour' can be emphasized as '**wheat**flour' or '**wheat**flour').
64. Where an ingredient comprises of several words (such as 'skimmed milk powder' and 'egg white') then only the Annex II food must be emphasised (in these examples, 'skimmed **milk** powder' and '**egg** white').
65. If individual ingredients used to make a food contain added sulphur dioxide and/or sulphites, their presence must be emphasised for those ingredients separately if, when added together, the level in the overall food is >10 mg/Kg. Where foods are sold under a less common name, due to appellation, trade name, foreign cuisine etc., it could be difficult to tell whether they contain any of the Annex II products/ substances (e.g. 'monkey nuts (peanuts)', 'gingelly oil (**sesame**)', 'ghee (**milk**)', 'edamame beans (**soya**)'). In such cases there must always be a clear reference to the name of the substance as listed in Annex II.

Food products without ingredients lists

66. Some foods do not require an ingredients list such as alcoholic drinks with more than 1.2% by volume of alcohol (see Article 16 (4) of the FIC). In this case the presence of any substances or products derived from the Annex II list which is present and not clear from the name of the food needs to be indicated. For example, a bottle of wine must have a statement such as: 'Contains: sulphites, milk and egg' if the finished product contains sulphites at more than 10 mg/litre and if milk or egg residues are detectable in the wine.

Example

Allergen(s) within a 'contains' statement on products without an ingredients lists do not need to be emphasised however, you can voluntarily choose to emphasise the allergens to make clear their presence in a product (e.g. 'Contains: **sulphites**').

Applicable requirements – voluntary information (Article 36)

67. Where an ingredients list is provided, the FIC does not permit the voluntary use of allergen advisory statements such as 'Contains: wheat, egg and milk' to repeat mandatory allergen ingredients information. Information about allergens as ingredients can only be presented in the mandatory format (i.e. emphasised within the ingredients list). This is to ensure that information is presented in a single and consistent format across food products.

Distance selling – Prepacked foods (Article 14)

68. FBOs selling prepacked foods through distance selling need to make the same level of information on allergens available to consumers, for example on their website or in their catalogue, as when the food is bought from a retail environment⁴. This is to ensure that the mandatory allergen information is available before the purchase is concluded and at the moment of delivery. Telephone numbers provided by FBOs which enable consumers to obtain oral allergen information over the telephone, must not be at an additional cost (in other words the calls must be free or non-chargeable within standard rate call plans). The distance selling rule to provide information before the purchase is concluded does not apply to prepacked foods sold through vending machines.

Example

One method a business could use is to list the ingredients (with allergens emphasised in some way) on the website where the customer views the product prior to purchasing it. To make this information available to the customer at the moment of delivery it could appear on the packaging of the food.

⁴ For distance sales of prepacked food, other mandatory information must be provided as listed in Article 9 with exception of Article 9 (1)(f)

Part 2: Guidance for businesses providing non-prepacked food

69. The information below provides guidance and best practice examples on the provision of allergen ingredients information for non-prepacked food (such as meals served in a restaurant or café) and also food packed at the consumer's request which is covered by the same rules. Information on the presence or use of allergens in food must be provided in a manner that is easily accessible for the consumer. The requirements are based on the following articles:

- Article 8 on responsibilities
- Article 9 on the list of mandatory particulars (see p 10-11 for list of 14 allergens)
- Articles 12 and 13 on availability and presentation of mandatory particulars
- Article 21 on labelling of certain substances or products causing allergies or intolerances
- Article 44 on national measures for non-prepacked food
- Article 14 on distance selling

Responsibilities (Article 8)

70. Every FBO in the food supply chain is responsible for ensuring that the allergen information they provide is accurate. They must not supply food which they know or presume to be non-compliant with food information requirements.

Best Practice

Businesses should review ingredients information for foods provided by them and ensure that their suppliers provide them with the necessary information to meet their obligations.

71. Food businesses supplying food to other food businesses that is not intended for the final consumer and / or not intended for mass caterers must ensure that business to business sales of food are accompanied with sufficient information to enable subsequent food businesses to meet their responsibilities. FBOs whose activities do not affect food information must not supply food which they know or presume to be non-compliant with food information requirements. FBOs are responsible for ensuring compliance with the provisions relevant to their activities and verifying that those requirements are met. This applies to all operators including: manufacturers, suppliers and caterers.

Presentation of mandatory allergen information (Articles 9, 12, 13 and 21)

72. Allergen information for non-prepacked food can be communicated through a variety of means to suit the business format of the FBO. The requirement is to provide information about the use of allergenic ingredients in a food. The provision does not require a food business to provide a full ingredients list. Where a food business chooses for this information to not be provided upfront in a written format (for example allergen information on the menu), the food business must use clear signposting to direct the customer to where this information can be found such as asking members of staff. In such situations there must be a statement that can be found on food menus, chalkboards, food order tickets, food labels (see Regulation 5(4) of the FIR).
73. In the drive-through (or drive-thru) scenario signage that indicates that oral information is available through a member of staff elsewhere on the premises is permitted.
74. All mandatory allergen information on menus or signpost statements to where it could be found must be easily accessible and visible, and clearly legible to the final consumer regardless of whether they have a food allergy or not.

Example

Upfront signposting to where allergen information will be found could be presented as a statement such as:

'Food Allergies and Intolerances: Please speak to our staff about the ingredients in your meal, when making your order.'

75. Allergen information for those cereals containing gluten which are named in Annex II and for the nuts listed in Annex II must specify the cereal (e.g. Wheat) or the nut (e.g. Almond) listed in Annex II. This is because there are people who may be allergic or sensitive to only one cereal or one nut and not all cereals or all nuts.
76. No specification needs to be provided for fish, molluscs or crustaceans when used as ingredients in a dish as there is no designated list for this group within the Annex II list.

77. Allergen ingredients information must be made available for the entire dish as served, however, it can be provided in a variety of ways.
78. Where food is provided through a buffet format, the allergen information should be provided for each food item separately.

Example

Allergen information could be provided as a 'contains' statement, for example 'Chicken Tikka Masala (contains: milk, nuts (almond))'. Another method could be the use of a chart such as the example below:

Best Practice

Figure 2: Allergen matrix example 1

Dishes / Allergens contained	Cereals containing Gluten	Crustaceans	Eggs	Fish	Peanuts	Soyabeans	Milk	Nuts	Celery	Mustard	Sesame	Sulphites	Lupin	Molluscs
Chicken Korma							Yes	Yes Almond						
Seafood Risotto		Yes		Yes			Yes		Yes					Yes
Lincolnshire Sausage and mustard mash	Yes Wheat						Yes		Yes	Yes				
Special fried rice	Yes Wheat		Yes			Yes								
Lemon cheesecake	Yes Wheat		Yes				Yes	Yes Almond			Yes			

79. Where food is placed on the market by a food business free of charge (such as testers and samples, canapés served at events) or as complimentary snacks or meals (such as a plate of biscuits, pastries or unwrapped chocolates at a hotel, or a meal served at an event), information about ingredients containing allergens must be provided. This must be provided in writing or signposted to where it could be obtained for example through a member of staff on a label, menu or ticket.

Best Practice

Allergen information for the components within a dish could voluntarily be provided to give a better service and choice for the consumer.

For example BBQ Chicken Burger and coleslaw (Chicken: **wheat, fish, celery**; BBQ sauce: **celery, fish**; Bap: **wheat, eggs** and **sesame**; Coleslaw; **egg, celery, mustard**)

If a customer had an allergy to mustard for example, the dish could be served without the coleslaw.

National Measures (Article 44)

80. Under Article 44 of the FIC where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer's request or prepacked for direct sale, Member States may adopt national measures concerning the means through which the particulars or elements of those specified particulars are to be made available and, where appropriate, their form of expression and presentation.

81. To allow for practical difficulties, such as ensuring that written menus are kept up to date and displaying accurate information regarding allergenic ingredients used in products, the FIR was adopted. Under these national measures, FBOs have flexibility to provide allergen information for non-prepacked food orally. In such cases customers must be able to obtain information from member(s) of staff.

82. However, businesses adopting this approach will need to ensure that there is a written notice, menu, ticket or label that is clearly visible at the point that the customer chooses their food to indicate that allergen information is available from a member of staff.

83. FBOs who elect to provide allergen information orally must therefore ensure that the information provided orally by staff members is accurate.

84. To ensure that oral information is verifiable, ingredients information can be

contained on a chart, in a recipe book or on ingredients information sheets, which staff can easily refer to.

Best Practice

Members of staff have allergen training, know where to find allergen information and know how to communicate this to customers.

Distance selling – non-prepacked food (Article 14)

85. FBOs selling non prepacked food through distance selling⁵ (e.g. such as food businesses which offer purchase through telephone/ internet) must ensure that mandatory allergen information is available to the consumer (for free):

- before the purchase is concluded; and
- at the moment of delivery.

Best Practice

Allergen information is held in written form by the business and available in written form at some point between a consumer placing the order and taking delivery of it.

86. Whatever the chosen method of presentation, the FBO must always ensure that the allergen information is current and accurate.

87. The allergen information must be provided without any supplementary costs being charged to the customer by the FBO (e.g. premium line numbers).

⁵ Electronic order screens in store and drive through order screens are not 'means of distance communication' because of the simultaneous physical presence of the supplier and the consumer.

Example

Ways of providing allergen information at the time of order include:

- the customer is signposted to where the accurate information can be obtained in writing (e.g. an online menu); or
- staff provide the allergen information orally by telephone whilst referring to the written information.

To ensure that current and accurate allergen information is provided, the food business could ask the customer if allergen information is required before the order is taken on the telephone or online.

Ways of providing written allergen information at the time of delivery include:

- placing stickers on food containers to clearly identify food and allergenic ingredients used in that food (e.g. Chicken satay: 'Contains: wheat, soy, fish, peanut'); or
- a menu is provided with the order which allows the customer to clearly identify allergenic ingredients in the food, along with clear names, or other appropriate cross references on food containers;

written allergen information is presented to the customer, by the member of staff from the business delivering the food together with a means to clearly link the written information to each food item.

Part 3: Guidance for businesses providing food prepacked for direct sale

88. Whether a food is prepacked for direct sale (PPDS) depends on whether, where and when it is packed in relation to the point at which it is offered for sale.

The specific requirements are based on the following Articles of the FIC:

- Article 8 (Responsibilities);
- Article 9 (List of mandatory particulars) on mandatory particulars (see p 10-11 for list of 14 allergens);
- Articles 12 (Availability and placement of mandatory food information) and 13 (Presentation of mandatory particulars) on availability and presentation of mandatory particulars;
- Article 21 (Labelling of certain substances or products causing allergies or intolerances);
- Article 14 (Distance Selling)

89. The information below provides guidance and best practice examples on the provision of allergen information for PPDS food. New requirements for PDDS are in development and proposed for 1 October 2021.

Best Practice

Food businesses should consider the foods they package before the process of a sale begins, in order to check if these requirements apply.

90. PPDS food is any single food item for presentation (to final consumers and to mass caterers) which consists of the food item and packaging which may enclose the food item completely or partially (but in such a way that the contents of the food item cannot be altered) and where the food item is put into packaging before being offered for sale by the same food business (presenting or offering to sell) the food item to the final consumer and to mass caterers-

- i. on the same premises; or
- ii. on the same site⁶; or
- iii. on other premises if the food is offered for sale from a moveable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles) and the food is offered for sale by the same food business who packed it.

⁶ In this instance 'site' refers to a building complex such as a shopping centre or airport terminal in which the same food business operates from more than one unit within the building complex.

91. PPDS food does not cover foods packed on the sales premises at the consumer's request.
92. Regulation 2 of the FIR sets out that Prepacked food is defined in Article 2(2)(e) of the FIC as 'any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; 'prepacked food' does not cover foods packed on the sales premises at the consumer's request or prepacked for direct sale'

Figure 3 - What is prepacked for direct sale (PPDS) food?

For a prepacked food to be PPDS, it must meet all of the following three criteria:

(1) Is the food presented to the consumer in packaging*?

No → this is non-prepacked food

↓ **Yes**

The food is "packed"

(2) Is it packaged before the consumer selects or orders it?

No → this is non-prepacked food

↓ **Yes**

The food is "pre-packed"

(3) Is it packaged at the same place it is sold?**

No → this is prepacked food

↓ **Yes**

The food is "pre-packed for direct sale"

If the answers to all three questions above are "Yes",
the food is PPDS.

Notes

* A single item (the food and its packaging) presented to the consumer. The food is completely or partially enclosed and cannot be altered without opening or changing the packaging. Food in such packaging sold to other businesses (consumer and to mass caterers) is Prepacked food and already requires allergen labelling. (See Article 2(2)(e) of the FIC)

** Food (a) packaged by the same food business on the same site from which it is sold or (b) sold from temporary or moveable premises (such as a food truck or market stall) by the same food business that packaged it.

Example

PPDS food includes:

- Sandwiches placed into packaging by the food business and sold from the same premises.
- A café giving away packaged samples of a new range of cakes they have made on the same premises.
- Foods packaged and then taken by the same operator to their market stall to sell.
- A butcher who makes burgers or sausages which are prepacked to be sold on the same premises.
- Foods packed by a food business to be sold in its retail units located within the same building complex as the premises where the food was packed such as a train station, hospital, university or holiday park.
- In a retail environment such as a supermarket, the following examples would also be considered to be prepacked for direct sale food, **provided they are packed on the premises from which they are being sold before they are offered for sale:**
 - Fresh pizzas from the deli counter e.g. on a cardboard tray and wrapped in plastic;
 - Boxed salads;
 - Hot foods such as rotisserie chicken; and
 - Foods that are pre-weighed and packed such as cheese or meats from a delicatessen counter or baked goods from an in-store bakery

93. Food is considered prepacked when it is put into packaging before being offered for sale and:

- is either fully or partly enclosed by the packaging; and
- cannot be altered without opening or changing the packaging; and
- is ready for sale to the final consumer.

94. Any food that is packed on the premises by the same food business in anticipation of an order, before being offered for sale, would be considered to be PPDS food.

This can include food the consumer self-selects from a chiller cabinet or has to obtain from a member of staff.

Example

Some fast food may be prepacked for direct sale if it has been packed by the same business before being offered for sale in anticipation of an order, for example, a wrapped burger or boxed fried chicken placed under a hot lamp and the contents cannot be altered without opening the packaging.

95. Food placed into packaging after a consumer orders it (for example a freshly prepared sandwich or burger that is made and wrapped after taking an order) is not PPDS food. Although these items are packed, they are not packed before being offered for sale and therefore cannot be prepacked for direct sale. The same rules apply to these foods as apply to other forms of non-prepacked foods such as meals served in a restaurant.

96. PPDS food does not cover food which does not have packaging, or it is packaged in a way that the food can be altered without opening or changing the packaging (for example a hot dog served on a cardboard tray.)

97. PPDS food does not cover food packed by one business and supplied to another business for sale (for example a pork pie packed by business “A” and sold by business “B” at a farmer’s market.) This is prepacked food.

List of mandatory particulars for PPDS food

98. It is proposed that all PPDS food must have on the package⁷ or on a label attached to the package:

- the name of the food and;
- an ingredients list⁸ or processing aid listed in [Annex II/allergenic ingredients] or derived from a substance or products listed in Annex II/allergenic ingredients] causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form including allergenic ingredients. The [Annex II/ allergenic

⁷ See Article 16(2) of Regulation (EU) No. 1169/2011 for the requirements applicable to packaging or containers the larger of which has an area of less than 10 cm², so far as it relates to the particulars required by Article 9(1)(b).

⁸ See Article 18 of Article 19 of Regulation (EU) No. 1169/2011 for more rules on the required format of the ingredients list. See Article 19 of Regulation (EU) No. 1169/2011 for foods which are not required to bear a list of ingredients.

ingredients] within the food must be emphasised every time they appear in the ingredients list.

For example, the allergens in the food can be listed in bold, in capital letters, in contrasting colours or underlined.

99. Detailed guidance on how each allergenic ingredient captured in Annex II of the FIC must be emphasised and named in the ingredients list on PPDS food has been outlined in this guidance in paragraphs 29 to 66.

Distance selling (Article 14)

100. FBOs offering for sale PPDS by means of distance communication (other than foods offered for sale by means of automatic vending machines or automated commercial premises) (e.g. such as food businesses which offer purchase through telephone/ internet) will need to ensure that mandatory food (including allergen information) is available at the moment of delivery. Additionally this information is required before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. When other appropriate means are used, mandatory food information shall be provided for free.

101. The requirement for a list of ingredients does not apply to PPDS food sold online, via telephone or provided to the consumer by mail order. This is because the national rules applicable to the provision of food information for non-prepacked food including PPDS do not apply to food sold via distance means. The applicable rules for all food sold through distance means are = those contained within Article 14 of the FIC which extends to mandatory information set out in Article 9 the date of minimum durability or the 'use by' date).

102. However, prepacked for direct sale food sold in this way, must continue to have allergen information available for free to the customer before they buy the product and also available at the moment of delivery. Whatever the chosen method of presentation, the FBO must always ensure that the allergen information is current and accurate.

Enforcement of the measures

Local authority responsibilities

103. In Scotland, local authority environmental health departments have responsibility for official controls relating to allergen rules and wider food information requirements.

Penalties and offences

104. Failure to comply with the requirements of the provisions of the FIC set out in Regulation 10(a) of the FIR, on the labelling of allergenic ingredients is an offence and may result in a summary conviction. This position is the same in relation to a failure to comply with Regulation 5 of the FIR relating to the provision of allergen information for non-prepacked foods, including PPDS etc., in a manner other than one provided for in the FIC. Proposed amendments regarding PPDS food are subject to consultation.

105. A person convicted of an allergens offence under the FIR 2014 will be liable to a fine not exceeding level 5 on the standards scale, currently £5,000. However, higher penalties are available under the General Food Regulations 2004 where a person is convicted of an offence involving a breach of Article 14 (1) of Regulation (EC) No 178/2002 on food safety matter.

Glossary of terms used

Coeliac Disease: This is an autoimmune disease caused by an adverse reaction to eating gluten, a protein in cereals namely wheat, rye, oats, spelt, kamut or their hybridised strains. Adherence to the gluten free diet is the complete medical treatment and having coeliac disease therefore requires significant dietary modification.

Distance selling: This refers to the selling and buying of goods or services (for purposes of these guidance notes [prepacked, and non-prepacked foods] without the simultaneous physical presence of the consumer and supplier to complete the contract for sale; for example selling food by internet (internet shopping, online takeaway aggregators etc.), mail order, telephone or television.

Final consumer: This is defined in Article 3 (18) of Regulation (EC) No.178/2002 as ‘the ultimate consumer of a foodstuff who will not use the food as part of any business operation or activity’. The final consumer will generally be the individual who will be eating or drinking the food or drink provided by the food business.

Food Allergen: This is the substance in a food that can cause an allergic reaction. Allergens are normally proteins and in some people, the immune system thinks allergens are foreign or dangerous. The immune response to these allergenic proteins is what leads to allergic reactions. The FIC sets out 14 (substances or products causing allergies or intolerances) specific foods of public health importance (most potent and prevalent food allergens in Europe) which are listed in Annex II (Substances or Products Causing Allergies or Intolerances) to the FIC.

Food Allergy: An adverse reaction to a food that involves the immune system and can be a potentially life-threatening condition. Symptoms can appear within minutes, or up to several hours after a person has eaten a food they are allergic to. There is no cure for food allergy. An allergic individual must avoid the food which makes them ill.

Food business operator (FBO): This is defined in Regulation (EC) No. 178/2002 (Article 3(3)) (General Food Law) as ‘the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control’.

Food business: This is defined in Regulation (EC) 178/2002 (Article 3(2)) [(General Food Law)] as ‘any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food’.

Food intolerance: Most food intolerances do not involve the immune system and are generally not life-threatening. However, they can make someone feel very ill or affect their long-term health. Examples of food intolerance include lactose and gluten intolerance.

Mass caterer: This is defined in Article 2(2)(d) of FIC as ‘any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer’.

Non-prepacked food: Any food item presented to the final consumer and to mass caterers and which does not fall within the definition of ‘prepacked food’; PDDS; or foods packaged at the consumers request; for any reason. including where food not is not enclosed completely or partially in packaging.

- In a physical retail environment this is likely to apply to foods which are sold loose from a delicatessen counter (e.g. cold meats, cheeses, quiches, pies and dips), fresh pizza, salad bars, bread or pastries sold without wrapping in bakery shops or via bakery counters, meat from butchers, etc.
- In a catering environment, this is likely to apply to foods which are not sold prepacked, for example food from a takeaway, or meals served in a canteen or a restaurant.

Prepacked food: This is defined in Article 2(2)(e) of the FIC as ‘any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; ‘prepacked food’ does not cover foods packed on the sales premises at the consumer’s request or prepacked for direct sale.’

Prepacked food has the following elements -

- any single item for presentation (to final consumers and to mass caterers);
- which consists of food item and packaging;
- where the food item was put into packaging before being offered for sale (to final consumers and to mass caterers);
- the packaging may enclose the food item completely or partially (but in such a way that the contents of the food item cannot be altered);

- and which is not Pre-packed for direct sale (PPDS) food or foods packed on the sale premises at the Consumer's request.

Prepacked for direct sale (PPDS): PPDS food is not prepacked food or food packed on the sales premises at the consumer's request. It is food that is packed **before** being offered for sale by the same food business to the final consumer:

- i) on the same premises; or
- ii) on the same site⁹; or
- iii) on other premises if the food is offered for sale from a moveable and/or temporary premises (such as marquees, market stalls, mobile sales vehicles) and the food is offered for sale by the same food business who packed it.

PPDS foods may include:

- Sandwiches placed into packaging by the food business and sold from the same premises;
- Foods that are pre-weighed and packed such as cheese or meats from a delicatessen counter or baked goods from an in-store baker;
- Fresh pizzas from a delicatessen counter e.g. on a cardboard tray and wrapped in plastic; or
- Boxed salads

Abbreviations

FBO	Food Business Operator
FSS	Food Standards Scotland
LA	Local Authority
RA	Risk Assessment
PPDS	Prepacked for Direct Sale

⁹ In this instance 'site' refers to a building complex such as a shopping centre or airport terminal in which the same food business operates from more than one unit within the building complex.

References and Resources

Further advice on [food allergen labelling is available on the FSS website](#):

www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/food-allergies-1

Free [online training about the Food Information Regulation](#) as a whole can be found here: <http://labellingtraining.food.gov.uk/>

FSS has produced [free online training modules to help enforcement officers and businesses understand food allergen labelling](#) and labelling in general under the FIC. Free online allergy training can be found here: www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/food-allergies-2/allergen-training-tool

FSS has produced [MenuCal](#) which is a free, secure, online tool that supports food businesses to manage allergen information and calculate calories in the food they serve: www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/menucal

The British Retail Consortium (BRC) and Food and Drink Federation (FDF) guidance on Allergen Labelling: <http://www.reading.ac.uk/foodlaw/pdf/uk-12024-BRC-FDF-Allergen-Labelling.pdf>

Food and Drink Federation Guidance on 'Allergen'-Free and Vegan Claims (February 2020): www.fdf.org.uk/corporate_pubs/dfd-guidance-allergen-free-and-vegan-claims.pdf

Food and Drink Federation Gluten Labelling Guidance: Best Practice for Prepacked Foods which Include or Exclude Cereals Containing Gluten (June 2019) : www.fdf.org.uk/corporate_pubs/FDF-gluten-labelling-guidance.pdf

British Retail Consortium & Food and Drink Federation Guidance on “Free-From” Allergen Claims (November 2015): www.fdf.org.uk/corporate_pubs/brc-free-from-guidance.pdf

Relevant Legislation

Regulation (EU) No. 1169/2011 on the provision of food information to consumers (“FIC”): www.legislation.gov.uk/eur/2011/1169/contents

Regulation (EU) No. 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food:
www.legislation.gov.uk/eur/2014/828/contents

Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law (General Food Law): www.legislation.gov.uk/eur/2002/178/contents

Food Safety Act 1990 and subsequent amendments:
www.legislation.gov.uk/ukpga/1990/16/contents

The Food Information (Scotland) Regulations 2014 (“FIR”):
<https://www.legislation.gov.uk/ssi/2014/312/made>

The Food (Scotland) Act 2015 gives the legal basis for Food Standards Scotland and related matters: <https://www.legislation.gov.uk/asp/2015/1/contents>

Regulation (EU) No. 1308/2013 establishing a common organisation of the markets in agricultural products: www.legislation.gov.uk/eur/2013/1308/contents

Review

We aim to keep all guidance up to date and regularly review it to ensure it is still relevant. The next scheduled review date for this guidance is December 2021. We welcome your feedback on this guidance, including reports of any broken links or out-of-date content.

Contact details

For further information please contact Food Standards Scotland:

- E-mail: enquiries@fss.scot
- Tel: 01224 285100

© Crown copyright 2020

This publication (not including logos) is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

For more information and to view this licence:

- visit [the National Archives website](#)
- email psi@nationalarchives.gov.uk
- write to: Information Policy Team, The National Archives, Kew, London, TW9 4DU

For enquiries about this publication contact [Food Standards Scotland](#)



Version Control

Version	Date	Last review carried out	Next review due	Comments
1.0	30/09/2020	N/A	Dec 2021	
2.0				