



Consultation Draft – January 2020

**Food allergen labelling
and information
requirements under the
EU Food Information for
Consumers Regulation
No. 1169/2011:
Technical Guidance**

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Revision history

Revised	Purpose of revision and paragraph number	Revised by
[Day] [Month] 2020	Complete document has been updated into the latest FSA guidance format. Additional text and examples have been added on prepacked for direct sale specifically paragraphs 15 to 18, 92 to 106 and the Reference and Resources page, Paragraph 33 has also been updated in light of Commission Implementing Regulation (EU) No. 828/2014. References to Scotland have been removed throughout the document.	Food Allergy Branch
10 April 2015	Updated advice in paras 1, 10, 14 - 20, 31, 33, 34, 36, 39, 40, 48 – 50, 52, 55, 56, 58, 59, 65, 66 (example), 72, 73, 74 – 76, 78, 79, 82, 83, 90 – 93, 95 – 98 and References and Resources page	Food Allergy Branch

Summary

Intended audience:	<ul style="list-style-type: none">• Importers• Manufacturers and processors• Retailers, caterers and carers• Packers
Which UK nations does this cover?	England, Wales, and Northern Ireland
Purpose:	To support food businesses (including institutional caterers, such as workplace canteens, schools and hospitals, and carers), especially small and medium sized enterprises, in following allergen requirements on labelling and providing information. To also assist authorised food officers at local food authorities in enforcing these measures. Technical advice on the interpretation and application of the requirements is provided.
Legal status:	This is 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 Food Information Regulations 2014 (SI 2014/1855) and corresponding Regulations in Wales, and Northern Ireland.
Key words	<ul style="list-style-type: none">• Allergy and intolerance• Allergen Labelling• Prepacked food• Non-prepacked food• Prepacked for Direct Sale Food
Review date	[Day] [Month] [Year]

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Introduction

1. The legislative framework around the provision of food allergen information is largely contained in the European Regulation on the provision of food information to consumers (EU) No. 1169/2011 (EU FIC). The Food Information Regulations 2014 (FIR) and equivalent regulations in Northern Ireland, and Wales establish the enforcement measures in the UK. EU FIC imposes a duty on food businesses to ensure that all mandatory food allergen information (relating to 14 substances listed in EU FIC that are known to cause allergies) is accurate, available and easily accessible to the consumer. EU 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 EU 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 must be non-prepacked food. This includes but is not limited to: food not packed such as as loose fruit and vegetables, food packed on the sales premises at the consumer's request and food prepacked for direct sale (PPDS).
3. These guidance notes cover the interpretation and application of allergen provisions for prepacked, non-prepacked and prepacked for direct sale foods. Failure to comply with the allergen provisions may result in a business being served an improvement notice or 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. Precautionary allergen statements such as 'produced in a kitchen which uses...' or 'may contain' should only be used following a risk assessment which demonstrates a significant risk of cross contamination and must not be used as a substitute for good hygiene and safety practices. Any voluntary food information must comply with the requirements of Chapter V of EU FIC

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Intended audience

6. These guidance notes on EU FIC rules on 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 who are not food businesses and occasionally provide food at charity events or voluntary cake sales, for example, do not need to follow these requirements. If you are a charity or community food provider and unsure whether you should be registered as a food business, you can speak to your local authority's environmental health department. Further guidance is also available in the FSA's guidance document 'Community and charity food provision guidance on the application of EU food hygiene law' which is available on the FSA's website: www.food.gov.uk/safety-hygiene/providing-food-at-community-and-charity-events

Purpose of guidance

8. These guidance notes have been produced to:
- provide informal and non-binding technical guidance on the interpretation and practical application of EU FIC specific requirements on allergen labelling and information.
 - develop understanding by providing regulatory guidance and interpretation in this area.
 - be read alongside the EU Food Information for Consumers Regulation (No. 1169/2011) (EU FIC) and Food Information Regulation (FIR) 2014 (as amended) (SI 2014/1855) and corresponding Regulations in Wales, and Northern Ireland

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Legal status of guidance

~~These notes have been produced to provide practical guidance about allergen labelling of prepacked food, food prepacked for direct sale and allergen information provision for non-prepacked foods.~~

9. These notes have been produced to provide guidance on:
- the legal requirements of the EU Food Information for Consumers Regulation (No. 1169/2011) and

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- enforcement and penalties outlined in the Food Information Regulations 2014 (as amended) and corresponding Regulations in Wales, and Northern Ireland and

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- 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 enforcement agency, which will usually be the trading standards department/ environmental health department of the Local Authority.

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.

General background on allergens

12. 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, an auto-immune condition which causes damage to the gut lining when gluten is consumed.

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13. An allergic reaction can be produced by a tiny amount of a food ingredient that a person is sensitive to (for example a teaspoon of milk powder, 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, wheezing and on occasion anaphylaxis (shock). In the UK, around ten people die from allergic reactions to food every year.

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14. There is no cure for food allergy. The only way to manage the condition is to avoid food that makes the person ill. 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.

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Main allergen labelling changes

15. Currently and until 1st October 2021 in England, food businesses can provide allergen information for prepacked for direct sale (PPDS) food by any means that they choose, including orally by 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.

16. Due to these reasons an amendment to the FIR¹ was introduced to improve the provision of information to consumers purchasing PPDS foods. The changes to FIR 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.

17. In recognition that food businesses will need time to adapt to this change, these changes will come into effect on the 1st October 2021 in England. This implementation period was considered necessary as a result of the information gathered from food businesses during the consultation on amending allergen information provision.

18. 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

¹ the FIR has been amended by [The Food Information \(Amendment\) \(England\) Regulations 2019](#) which apply in England.

other is packaged in front of the consumer at their request. The changes bring consistency of allergen information between PPDS and prepacked foods.

19. In specific circumstances where individuals are owed a duty of care by those providing them with food, such as in prisons, nurseries, schools and hospitals; a process should be put in place to safeguard those individuals, especially those unable to communicate their dietary needs (for example the very young or those with mental illness). The process needs to ensure that allergen information is recorded and reported in line with EU FIC and requirements in other legislation concerning the adult mental capacity and care for minors such as the Mental Capacity Act 2005 and the Children Act 1989 respectively, should also be considered. For example, where the individual cannot make a safe dietary choice, the caregiver should be able to identify that individual and provide them with food which is safe for their consumption.

Mandatory obligations for all FBOs

20. Under Article 9 (1) (c) of EU FIC, all FBOs should 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 EU FIC the mandatory information should be easily accessible, in a conspicuous place, easily visible and clearly legible. Information should be indelible (where appropriate for example on food labels where it needs to withstand handling). The information should 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, howsoever it is provided.

Deleted: EU FIC and the FIR allergen requirements makes clear when the food business has not complied with the allergen provisions (i.e. for non-prepacked food it is clear how the FBO should provide allergen information and, for prepacked foods, how information should be declared on the label). Failure to meet the allergen requirements is a criminal offence due to the impact of non-compliance on public health. Details on local authority responsibilities and penalties are covered on p34 of this guidance. ¶

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The fourteen allergens (Annex II allergens)

21. The 14 allergens listed in Annex II (as amended by Commission Delegated Regulation No. 78/2014) are recognised across Europe as the most common ingredients or processing aids causing food allergies and intolerances. If there is a food product which contains or uses an ingredient or processing aid (such as wheat flour used to roll out dough made from rye flour) derived from one of the

substances or products listed in the Annex II, information regarding the presence or use of the allergen must be provided to **the** consumer.

22. 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
 - b) 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

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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 whiskey) 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)

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 across Europe 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 EU 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 will not 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

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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.
26. In the case of wine and wine fining agents derived from egg and milk, EU Regulation No. 579/2012 will need to be considered. In determining whether egg and milk fining agents are still present in wine they should not be found at the limit of detection (<0.25 mg per litre) as indicated in EU Regulation No. 579/2012. Where egg or milk fining agents are not detected at these levels, they are exempt from the allergen labelling requirements.

Part 1: Guidance for businesses providing prepacked food

27. For food manufacturers, packers, retailers and online or catalogue stores

Prepacked food

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

- Article 9 on the list of mandatory particulars
- Article 13 on the presentation of mandatory particulars
- Article 19 on the omission of the list of ingredients
- Article 21 on labelling of certain substances or products causing allergies or intolerances
- Article 36 on applicable requirements relating to the provision of voluntary food information

List of mandatory particulars (Article 9)

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

Cereals containing gluten

30. The Regulations (Annex II to EU Regulation No. 1169/2011 as amended by Commission Delegated Regulation (EU) No.78/2014) define these as: wheat such as spelt and Khorasan wheat), rye, barley and oats or their hybridised strains. Spelt and Khorasan are types of wheat, which are not suitable substitutes for people with coeliac disease and/or wheat allergy.
31. Cereals containing gluten will 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

Deleted: The voluntary use of signposting to direct consumers where allergen information is found and emphasised is permitted. Details on signposting can be found in British Retail Consortium (BRC) / Food and Drink Federation (FDF) guidance www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf ...

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reference to wheat would be required; for example 'spelt (**wheat**)' or 'Khorasan **wheat**' and 'Kamut (**wheat**)'.

32. The voluntary inclusion of gluten within the ingredients list following the mandatory declaration of a specific cereal (containing gluten) is possible. However, the regulation requires that it is the cereal that should be emphasised, rather than the gluten; for example '**barley**(gluten)'. ▾

33. Where foods have been voluntarily labelled as 'gluten-free' they must meet the requirements set in Commission **Implementing Regulation (EU) No. 828/2014²**. This legislation sets out the conditions under which foods may be labelled as "gluten-free" (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 Commission Implementing 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.

Deleted: When using a signpost to allergen information indicating the presence of cereals containing gluten is also permitted as outlined in the BRC/FDF guidance document.

Example

When gluten free oats are used in a gluten free product, the word "oats" would still need to be emphasised and declared as the product will still contain some gluten. In addition, any oats used in this product must comply with the specific requirements laid down in the Commission Implementing Regulation (EU) No. 828/2014.

Crustaceans

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

² Enforced in Wales by The Food Information (Wales) (Amendment) Regulations 2016

35. 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**)'.

Eggs

36. 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 unless exempt (see p 10-11 for exemptions).

Fish

37. The rules do not name any species of fish because 'fish' means all species of fish and fish products. 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.
38. 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).

Peanuts

39. 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 should be used for products or ingredients made from them for allergen labelling purposes, as this is the term specified in Annex II of EU FIC.
40. Both refined and unrefined peanut oil have to be labelled with reference to peanut.

Soyabeans

41. 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).

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Milk

42. 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. 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).
43. 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) 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, butter, cream and yoghurt can be emphasised within the ingredients to demonstrate the presence of a milk product.

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Best Practice

The British Retail Consortium (BRC) and Food and Drink Federation FDF guidance provides best practice advice on this area and a literal interpretation of the EU 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)')

44. However, the information should 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, should be declared with a clear reference to milk e.g. 'whey (milk)'.

Nuts

45. 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 should 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 and pine nuts are also known to cause allergy in some people but are not required to be **emphasised within the ingredients**.
46. Where ingredients or processing aids derived from nuts have been used, the ingredient should be indicated with a clear reference to the nut; for example 'flavourings (**almond**)' unless exempt (**see p 10-11** for exemptions).

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Celery

47. This term is used generically in EU 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).

Mustard

48. 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 should be used in labelling. The rules do not name any particular species of mustards and therefore should be applied to all types of mustard.

Sesame

49. This term refers to sesame seeds, ground sesame powder and sesame oil. Products derived from sesame seeds, such as tahini, should 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 should be applied to all.

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

~~This requirement relates to products or ingredients that have had sulphur dioxide and/or sulphites intentionally added for example when it has been used as a preservative.~~

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.
51. Under general EU food labelling 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 should 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.

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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.

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Lupin

53. The term lupin is used generically in EU FIC to refer to both lupin seed and products from it such as lupin flour. The appropriate terms should be used in labelling. The rules do not name any particular species of lupin and therefore should be applied to all.

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).
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**)'.

Presentation of mandatory particulars (Article 13)

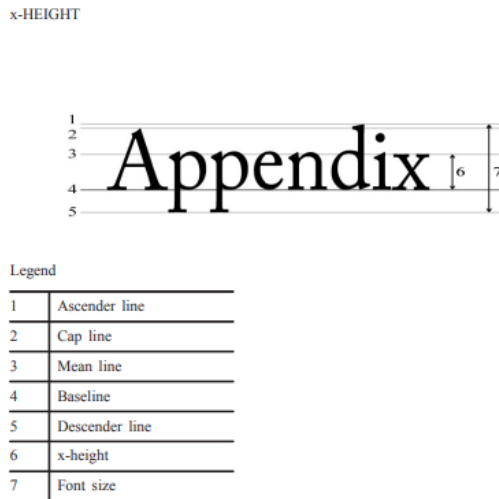
56. Mandatory **particulars** is the information **that must be provided**. All written mandatory **allergen** information should be easily visible, clearly legible and not obscured in any way. Mandatory information should be not hidden for example under a flap or across a fold or crease, detracted from or interrupted by any other written or pictorial matter or any other intervening material.
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.
58. A minimum font size where the x-height (as illustrated in Annex IV of EU FIC) is 1.2 mm or more should be used where labelling surface is 80 cm² or more.
59. A minimum font size where the x-height is 0.9 mm or more should 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.

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



60. 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 EU FIC. Please refer to Article 13 of EU FIC for further details.

Omission of the list of ingredients (Article 19)

61. 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**

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example gingelly is sesame oil and should therefore be labelled 'contains: sesame'.

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

62. This 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**)'
63. The FBO has flexibility in deciding which mode of emphasis to use to declare the presence of allergens.

Example

Use an allergy advice statement 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**.'

64. The source of allergens for each ingredient needs to be declared even if there are several ingredients from the same allergenic food. For 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).
65. 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 is **wheatflour**' or to emphasise the entire name '**wheatflour**').
66. Where an ingredient comprises of several words (such as 'skimmed milk powder' and 'egg white') then only the Annex II food should be emphasised (in these examples, 'skimmed **milk** powder' and '**egg** white').

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

Example

Where ingredients used in a food product contain added sulphur dioxide and/ or sulphites, carry over presence will need to be considered. Where the level of added sulphur dioxide /sulphite in the finished product is >10 mg/Kg, the presence will need to be declared in ingredients containing added sulphur dioxide and/ or sulphites and contributing to the end level.

67. 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. 'gingelly oil (**sesame**)', 'ghee (**milk**)', 'edamame beans (**soya**)'). **In such cases there should always be a clear reference to the name of the substance as listed in Annex II.**

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Food products without ingredients lists

68. 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 EU 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 should have a statement such as: 'Contains: sulphites' if the finished product contains sulphites at more than 10 mg/litre. The presence of egg and milk fining agents will also need to be declared if found present at 0.25 mg/litre and above.

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Example

Allergen(s) with in a 'contains' statement on products without 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)

69. Where an ingredients list is provided, the EU 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.

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Voluntary use of precautionary allergen labelling to indicate the unintentional presence of allergen

70. FBOs **may** voluntarily use precautionary allergen 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 during production, **or** through cross contamination. The voluntary use of such precautionary allergen labelling is **permitted** the basis for this is contained within Article 14 of EU Regulation No. 178/2002 (General Food Law).

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The use of the generic term 'may contain nuts' to cover both nuts and peanuts is permitted if the risk of contamination is from both foods. There is no need to provide details of specific nuts under this type of voluntary labelling.

71. **P**recautionary allergen labelling should only be **used**, after a thorough risk assessment has been performed and there is considered to be a real risk to the food allergic or food intolerant consumer. The use of precautionary allergen labelling when there is not a real risk, could be considered to be misleading **food information**. For detailed best practice guidance on voluntary application of precautionary allergen labelling, please see:

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Food Standards Agency best practice guidance on:

www.food.gov.uk/sites/default/files/multimedia/pdfs/maycontainguide.pdf

or

Food Drink Europe (FDE) guidance:

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

Distance selling (Article 14)

72. FBOs selling prepacked foods through distance selling need to make the same level of information on allergens available for example on their website or in their

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

catalogue, as when the food is bought from a retail environment³. This is to ensure that the mandatory allergen information is available before the purchase is concluded and at the point 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. Where multiple items are contained within a gift box or hamper of food, mandatory food information such as allergen ingredients information should be provided on materials that support this sale.

Example

When selling prepacked food via the internet allergen information must be made available at the point of sale. A business could for example list the ingredients (with allergens emphasised in some way) on the website where the customer views the product prior to purchasing it. This information must also be given to the customer at the point of delivery for example displayed on the packaging of the food.

³ For distance sales of prepacked food, you are also required to provide other mandatory information as listed in Article 9 with exception of Article 9 (1) (f)

PART 2: Guidance for businesses providing non-prepacked food

Deleted: and prepacked for direct sale foods

73. For restaurants, cafés, fast food outlets, delicatessens, butchers, bakeries, institutional and other types of caterers

Non-prepacked food

74. 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. 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. The requirements are based on the following articles:

Deleted: includes prepacked for direct sale foods such as meals prepared in a canteen for consumption on or off the premises, cheese or meat sold loose from a delicatessen counter, bread or pies sold at bakeries or meat and meat products at butchers and...

Deleted:). All mandatory allergen ingredients information (Article 9 (1) (c)) should be available and

Deleted: The rules for non-prepacked food came into effect on 13 December 2014.

- 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

~~Individuals who are not food businesses, for example those who occasionally provide food at charity events or voluntary cake sales, do not need to follow these requirements. Further guidance is also available in the FSA's guidance document 'Community and charity food provision guidance on the application of EU food hygiene law' which is available on the FSA's web site.~~

~~www.food.gov.uk/enforcement/enforcework/food-law/guidance-enforcement/community-hall-guidance~~

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For detailed best practice guidance on allergen management for non-prepacked food, please see Food Standards Agency Scotland's Cooksafe Food Safety Assurance Scheme: www.foodstandards.gov.scot/cooksafes

(Please note responsibility for CookSafe will be transferred to Food Standards Scotland after 1 April 2015)

Responsibilities (Article 8)

75. Every FBO in the food supply chain has to take responsibility 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**.
76. 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.

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

77. 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 food businesses to provide a full ingredients list. Where food business choose for this information to not be provided upfront in a written format (for example allergen information on the menu), the food business should 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 Food Information Regulations 2014)

Deleted: or foods sold by a butcher or delicatessen

Deleted: or webpages

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

- 78. 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.
- 79. All mandatory allergen information on menus or signpost statements to where it could be found should 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: Before you order your food and drinks please speak to our staff if want to know about our ingredients'

- 80. Allergen information for cereals containing gluten and nuts **must specify** the cereal or the nut as listed Annex II. This is because there are people who have an allergy to a specific cereal such as wheat allergy as well as those with gluten intolerance. This is also the case for those with nut allergies.
- 81. 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.
- 82. Allergen ingredients information should be made available for the entire dish as served, **however it** can be provided in a variety of ways.
- 83. Where food is provided through a buffet format, the allergen information should be provided for each food item separately.

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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:

Dish	Cereals containing gluten	Crustaceans	Eggs	Fish	Peanuts	Soyabeans	Milk	Nuts	Celery	Mustard	Sesame	Sulphites	Lupin	Molluscs
Chicken korma							✓	Almond						
Seafood risotto		✓		✓			✓		✓					✓
Lincolnshire Sausage and mustard mash	✓ Wheat						✓		✓	✓				
Special fried rice	✓ Wheat		✓			✓					✓			
Lemon cheesecake	✓ Wheat, oats		✓				✓	Almond						

84. 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 allergenic ingredients must be provided. This should 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.

Deleted: hotels, airline meals, meals

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Best Practice

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

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.

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

National Measures (Article 44)

85. **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, 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.
86. 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.
87. **FBOs who elect to provide allergen information orally must therefore ensure that the information provided orally by staff members is accurate.**
88. 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.

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Best Practice

FBOs are recommended to have a system in place to ensure that when allergen information is provided orally to consumers, it is supported by that information being available to staff and others in a recorded form (in writing for example) to provide consistency, accuracy and verifiable safety procedures. To ensure that **accurate** allergen information is provided, the FBO should consider using a system where staff direct queries to a nominated person(s).

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Distance selling (Article 14)

89. FBOs selling non prepacked food through distance selling (e.g. such as food takeaway businesses which offer purchase through telephone/ internet) will need to ensure that mandatory allergen information is available to the consumer:
- before the purchase is concluded; and
 - at the point of delivery.

Best Practice

Regulation No. 1169/2011: Technical Guidance

The allergen information should be 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.

90. Whatever the chosen method of presentation, the FBO must always ensure that the allergen information is current and accurate.
91. The allergen information should be provided without any supplementary costs being charged to the customer by the FBO (e.g. premium line numbers).

Example

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

- the customer is signposted to where the 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

92. For food manufacturers, packers, retailers, cafés, fast food outlets, delicatessens, butchers, bakeries, institutional and other types of caterers.

Prepacked for direct sale food (PPDS)

93. Whether a food is PPDS depends on whether, where and when it is packed in relation to the point at which it is offered for sale. Food businesses should consider the type of foods they package before the process of a sale begins, in order to check if these requirements apply.

94. The specific requirements are based on the following articles:

- Article 8 on responsibilities
- Article 9 on mandatory particulars (see p10-11 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 14 on distance selling

95. The information below provides guidance and best practice examples on the provision of allergen information for prepacked for direct sale food. The new rules for prepacked for direct sale food come into effect on 1 October 2021 in England.

96. Prepacked for direct sale food is a 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 site⁴; 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) if the food is offered for sale by the same food business who packed it.

97. Prepacked is defined as (EU FIC) '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'

Example

Prepacked for direct sale 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 buys wholesale cuts of meat to make burgers or sausages which are prepacked to be sold on the same premises.
- Foods produced and 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.

⁴ 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.

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;
- 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

98. Food is considered prepacked when it is put into packaging prior to 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.

Example

Food on a non-disposable plate covered by cling film – Non-disposable tableware or crockery which remains the property of the food business is not considered to be packaging (e.g. a ceramic or china bowl, plate or cup). Foods served on non-disposable tableware will generally not be 'prepacked' therefore the rules applicable to PPDS will not apply.

99. 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 prepacked for direct sale 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.

100. Prepacked for direct sale food does not cover 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.) 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.

101. Prepacked for direct sale 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.)

Example

A whole cake, sliced and presented in a box to be sold by the slice, is not presented as a single item and is therefore not prepacked. The requirements applicable to PPDS do not apply.

Whereas, an individual slice of cake presented in a box is presented as a single item so is prepacked and may be PPDS if sold directly to the consumer from the same premises it was packed.

102. Prepacked for direct sale food does not cover food packed by one business and supplied to another business for sale (for example a packaged pork pie made by business "A" and sold by business "B" at a farmer's market.) This is prepacked food.

List of mandatory particulars for PPDS

103. All foods that are prepacked for direct sale must have on the package⁵ or on a label attached to the package:

- the name of the food and;

⁵ See Article 16(2) of Regulation (EU) No. 1169/2011 for the requirements applicable to packaging or containers with a surface area less than 10 cm², so far as it relates to the particulars required by Article 9(1)(b).

- an ingredients list⁶ including allergenic ingredients. The allergenic 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 contrasting colours or underlined.

104. Detailed guidance on how each allergenic ingredient captured in Annex II of EU FIC should be emphasised and named in the ingredients list on prepacked for direct sale food has been outlined in this guidance in paragraphs 33 to 73.

Distance selling (Article 14)

105. FBOs selling prepacked for direct sale food through distance means (e.g. such as food businesses which offer purchase through telephone/ internet) will need to ensure that mandatory allergen information is available to the consumer (for free) before they buy the product and also when it is delivered to them.

106. The requirement for a list of ingredients does not apply to prepacked for direct sale food sold online, via telephone or provided to the consumer by mail order only. 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 therefore those contained within Article 14 of the EU FIC. 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 when it is delivered to them. Whatever the chosen method of presentation, the FBO must always ensure that the allergen information is current and accurate.

⁶ See FIR for more rules on the required format of the ingredients list. Article 19 of Regulation (EU) No. 1169/2011 for foods which are not required to bear a list of ingredients.

Enforcement of the measures

Local authority responsibilities

107. In the UK, authorised food officers at Local Authorities have responsibility for official controls relating to allergen rules. ~~As allergen rules did not previously cover non-prepacked food (prior to EU FIC), some changes to food enforcement responsibilities at local level have been made.~~

~~In practice, the new allergen requirements for non-prepacked foods mostly impact on the food service/catering sector and retail businesses selling non-prepacked foods such as butchers, bakers, market stall holders and delicatessens.~~

108. In England, where there is a dual enforcement responsibility in some areas, the first tier (County Councils) are under a duty to enforce (Regulation 9 (1) Food Information Regulations 2014 (FIR) SI 2014/1855) and second tier councils have the power to enforce (Regulation 9 (2) Food Information Regulations 2014). Although there is no need for arrangements to be made to give powers to food hygiene enforcement officers in second tier councils, authorised food officers are encouraged to discuss and reach an understanding on how to enforce allergen requirements at a local level.

Penalties and offences

109. Failure to comply with the requirements of the provisions of the EU FIC set out in Regulation 10(2) of the FIR (SI 2014/1855 and SI 2019/1218) and corresponding Regulations in Wales, and Northern Ireland on the labelling of allergenic ingredients is a criminal offence and may result in a criminal prosecution being brought against a FBO. This position is the same in relation to a failure to comply with Regulation 5(5) ~~or Regulation 5A(1)(a)~~ of the FIR relating to the provision of allergen information for non-prepacked foods ~~and PPDS~~ etc. in a manner other than one provided for in EU FIC.

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110. A person ~~convicted~~ of an allergens offence under ~~the~~ FIR 2014 will be liable to an unlimited fine. The amount of the fine would be up to the Magistrates to decide on a case by case basis.

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Glossary of terms used

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 EU states 14 specific foods which are of public health importance (most potent and prevalent food allergens in Europe) which are listed in Annex II to the EU FIC.

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 direct face to face contact; for example selling food by internet (internet shopping, online takeaway aggregators etc.), mail order, telephone or television.

Deleted: prepacked for direct sale

Final consumer: This is defined in Article 3 (18) of EU Regulation 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 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 EU Regulation 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 EU Regulation No. 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 EU FIC as 'any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and

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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 presented to the final consumer or mass caterer that does not fall within the scope of ‘prepacked food’ for any reason including food not within any packaging, packaged at the consumers request and PPDS.

- 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 sold **without wrapping** in bakery shops, meat from butchers, pick and mix confectionery (including individually wrapped sweets and chocolates), 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 EU Regulation No. 1169/2011 (Article 2) 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.’

Food is considered prepacked when it is put into packaging prior to 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 or to a mass caterer

Prepacked foods for direct sale: is food that is packed before being offered for sale by the same food business to the final consumer:

- iv) on the same premises; or

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Deleted: a can of soup. All the following must apply: ¶ the food is either fully or partly enclosed by the packaging; ¶

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v) on the same site⁷; or

vi) 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) if the food is offered for sale by the same food business who packed it.

Food prepacked for direct sale does not include food packed at a consumer's request, food not in packaging or food in packaging that can be altered without opening or changing the packaging.

Deleted: sale' one or more of the following can apply:

Deleted: It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients.[†]
Foods that could fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made.[†]
[†]

⁷ 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.

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References and Resources

111. Further advice on food allergen labelling is available on the Agency's website: www.food.gov.uk/business-guidance/allergen-labelling-for-food-manufacturers
112. FSA allergen resources at www.food.gov.uk/allergen-resources
113. Think allergy posters and chef cards can be found here: www.food.gov.uk/business-guidance/allergen-guidance-for-food-businesses#allergen-information-resources
114. Free online training about the Food Information Regulation as a whole can be found here: <http://labellingtraining.food.gov.uk/>
- ~~Advice for SMEs on prepacked food can be found here:~~
- ~~www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/allergy_labelling_prepacked.pdf~~
- ~~Advice for SME's on non prepacked food and the Think allergy poster can be found here:~~
- ~~www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/loosefoodleaflet.pdf and~~
- ~~www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/thinkallergy.pdf~~
- ~~Advice for consumers on the new allergen labelling allergen information when eating out and the chef cards can be found here:~~
- ~~www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/allergy_leaflet.pdf and~~
- ~~www.food.gov.uk/sites/default/files/allergy_chef_cards.pdf~~
115. FSA has produced free online training modules to help enforcement officers and businesses understand food allergen labelling and labelling in general under the EU FIC. Free online allergy training can be found here: <http://allergytraining.food.gov.uk/>

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Food Standards Agency Scotland produced an online resource called Cooksafe which contains detailed steps on managing allergen risks and communicating allergen information to staff and customers. Please note responsibility for CookSafe will be transferred to Food Standards Scotland after 1 April 2016. Cooksafe can be found on www.foodstandards.gov.scot/cooksafe

British Retail Consortium (BRC) and Food and Drink Federation (FDF) have produced best practice guidance to help those labelling prepacked foods and can be found on www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf

Relevant Legislation

Commission Delegated Regulation (EU) No. 78/2014 amending Annex II and III to Regulation (EU) No. 1169/2011 (EU FIC) - <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:027:0007:0008:EN:PDF>

Commission Regulation (EU) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:016:0003:0005:EN:PDF>

EC Regulation 178/2002 (General Food Law Regulation): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>

116. Regulation (EU) No. 1169/2011 on the provision of food information to consumers (EU FIC): <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R1169-20180101&qid=1570435977999&from=EN>
117. Commission Implementing 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: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0828&from=EN>
118. Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law (General Food Law): <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02002R0178-20190726&qid=1570436248892&from=EN>

Deleted: EU Regulation No.

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119. Commission Implementing Regulation (EU) No. 579/2012 labelling and presentation of wine sector products
www.fsai.ie/uploadedFiles/Legislation/Food_Legislation_Links/Alcohol/Reg579_2012.pdf
EU Regulation No. 1169/2011 on the provision of food information to consumers (EU FIC): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018-0063:EN:PDF>
120. Food Safety Act 1990 and subsequent amendments:
www.legislation.gov.uk/ukpga/1990/16/contents; Food Safety (NI) Order 1991 in Northern Ireland and subsequent amendments
www.legislation.gov.uk/nisi/1991/762/contents/made
121. Regulation (EU) 1308/2013 establishing a common organisation of the markets in agricultural products: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02013R1308-20190101&qid=1570436523923&from=EN>

Review

122. The FSA aims to keep all guidance material up to date and undertakes regular reviews of guidance material to ensure that material is still relevant. The next scheduled review date for this guidance is [day] [month] [year].
123. The FSA welcomes user feedback on guidance, including reports of any broken links to reference material or other content that may require updating. Please use the contact details below.

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