

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

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April 2015

**For all queries about this guidance — including if you require the information in an alternative format such as audio, large print or Braille — please get in touch using the information below.**

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## Summary

<b>Intended audience:</b>	<ul style="list-style-type: none"> <li>• All food manufacturers and producers</li> <li>• Retailers, institutional caterers and other food businesses</li> <li>• Enforcement authorities</li> <li>• Packers</li> <li>• Importers</li> </ul>
<b>Which UK nations does this cover?</b>	England, Wales, Scotland and Northern Ireland
<b>Purpose:</b>	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.
<b>Legal status:</b>	This guidance is intended to accompany the allergen provisions of the EU Food Information for Consumers Regulation (No. 1169/2011) and Food Information Regulations 2014 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.
<b>Key words</b>	<ul style="list-style-type: none"> <li>• Food allergy and intolerance</li> <li>• Allergen labelling</li> <li>• Prepacked foods</li> <li>• Non-prepacked foods</li> <li>• Distance selling</li> </ul>
<b>Review date</b>	1 July 2016
<b>Sunset date</b>	Not applicable

## Revision history

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please let us know by emailing [betterregulation@foodstandards.gsi.gov.uk](mailto:betterregulation@foodstandards.gsi.gov.uk). If you have any comments on the guidance itself, please call us using the contact number on page 2 or complete our ongoing [Guidance survey](#): <https://www.surveymonkey.com/s/55QQDCG>

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
1	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

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## Introduction

1. These guidance notes cover the interpretation and application of allergen provisions for prepacked, prepacked for direct sale and non-prepacked foods, which can be found in the EU Food Information for Consumers Regulation (No. 1169/2011) (EU FIC) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF> and Commission Delegated Regulation (EU) No. 78/2014 amending Annex II of 1169/2011. The allergen rules came into effect in the UK and the EU on 13 December 2014. The allergen labelling rules for prepacked products apply to products placed on the market or labelled on or after this date. For non-prepacked foods, the allergen information rules apply to foods placed on the market on or after 13 December 2014. Failure to comply with the allergen provisions may result in criminal prosecution being brought against a food business operator (FBO) (see p 34 for details on enforcement of measures).
2. This guidance does not cover other labelling requirements (such as other general labelling (e.g. country of origin, minced meat, quantities, additives, nutrition etc.).
3. The EU FIC does not affect the legal basis for the application of voluntary precautionary allergen statements to indicate the unintentional presence of allergens due to cross contamination such as “*may contain x, y, z*”. Precautionary allergen statements should only be used after a thorough risk assessment and where there is considered to be a real risk to the consumer.

## Intended audience

4. These guidance notes on EU FIC’s rules on allergen labelling and 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.
5. 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.

## Purpose of guidance

6. These guidance notes have been produced to:
  - provide informal and non-binding technical guidance on the interpretation and practical application of EU FIC's 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 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.

## Legal status of guidance

7. These notes have been produced to provide practical guidance about allergen labelling of prepacked food and allergen information provision for non-prepacked foods.
8. These notes have been produced to provide guidance on:
  - the legal requirements of the EU Food Information for Consumers Regulation (No. 1169/2011)
  - enforcement and penalties outlined in the Food Information Regulations 2014 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.
  - examples of how to comply with the legal provisions.

These guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself and other parallel legislation to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law.

Examples of ways in which businesses can provide allergen information to comply with the legal provisions are also given. **To separate the legal provisions from**

**examples of what compliance could look like, they are provided in shaded boxes with the heading of 'Examples'.** You are not required by law to use these particular examples as other approaches may also be compliant.

9. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/ environmental health department of the Local Authority.

## **General background on allergens**

10. EU FIC changes how allergen information is provided and presented for all foods.
11. In the UK, it is estimated that 1-2% of adults and 5-8% of children have a food allergy. This equates to around 2 million people living in the UK with a food allergy, this figure does not include those with food intolerances. This means the actual number of affected people living with food allergy and/or food intolerance is considerably more.
12. 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). Around ten people in the UK die from allergic reactions to food every year.
13. There is no cure for food allergy. The only way to manage the condition is to avoid food that makes the person ill. This can be achieved by checking ingredients details on labels of prepacked foods and being provided allergen ingredients information for non-prepacked foods. Therefore, it is very important that food businesses provide clear and accurate information about allergenic ingredients in their products. EU FIC introduces new rules for food businesses relating to the labelling and provision of allergen information.



## **Main allergen labelling changes**

14. Food businesses who supply prepacked foods already follow specific requirements. The EU FIC however, introduced a new requirement to emphasise any of the 14 specific allergens in the ingredients list of prepacked food.
15. Prepacked products with old style allergen labelling that were placed on the market or labelled before 13 December 2014 can be sold through until stocks have been exhausted. Products such as frozen, tinned or dried food have a long shelf life. It will be possible therefore to see both types of labelling being used on these types of products for a few years after the application date.
16. For food businesses which provide non-prepacked food, such as retailers, restaurants, takeaways, bakeries and institutional caterers (prisons, nurseries, schools, hospitals, workplace canteens etc.), the EU FIC introduced a new requirement to provide information on allergenic ingredients. This information can be provided in writing and/or orally.
17. 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.
18. 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.

## **Mandatory obligations for all FBOs**

19. 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 and non-prepacked food is explained later in this guidance. However, in both 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 (permanent) 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.

## **The fourteen allergens (Annex II allergens)**

20. 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, it must be declared, by the FBO to the consumer.

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:
  - 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 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 10mg/kg or 10mg/L (litre) in terms of the total SO<sub>2</sub> 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)

21. 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 and non-prepacked foods.

## **Exemptions from allergens declaration**

22. The EU FIC requires the presence of allergens in the final foodstuff to be declared. 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 assessed by the European Food Safety Authority (EFSA) as not possessing an allergenic risk to the consumer.
23. 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.
24. 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 (<0.25mg 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**

- For food manufacturers, packers, retailers and online or catalogue stores

## **Prepacked food**

25. 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

26. Individuals who are not food businesses and occasionally provide food, for example at charity events or voluntary cake sales, do not need to follow these requirements.

## **List of mandatory particulars (Article 9)**

27. 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. 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](http://www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf)

## **Cereals containing gluten**

28. 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.

29. 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 reference to wheat would be required; for example 'spelt (**wheat**)' or 'Khorasan **wheat**' and 'Kamut (**wheat**)'.
30. The voluntary inclusion of gluten within the ingredients list following the mandatory declaration of a 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)'. 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.  
[www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf](http://www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf)
31. Where foods have been voluntarily labelled as 'gluten free', they must meet the requirements set in Commission Regulation No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. Guidance on the specific requirements for 'gluten free' labelling can be found on [www.food.gov.uk/business-industry/allergy-guide/gluten](http://www.food.gov.uk/business-industry/allergy-guide/gluten). 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'.

## **Crustaceans**

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

34. 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 p11-12 for exemptions).

## **Fish**

35. 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.
36. 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 p11-12 for exemptions).

## **Peanuts**

37. 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.
38. Both refined and unrefined peanut oil have to be labelled with reference to peanut.

## **Soybeans**

39. 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 p11-12 for exemptions).

## **Milk**

40. 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 p11-12 for exemptions).
41. 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 (EU Council Regulation No. 1308/2013 on 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. 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.

[www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf](http://www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf)

42. 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

43. 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 listed under these rules.
44. 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 p11-12 for exemptions).

## Celery

45. 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

46. 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

47. 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 10mg/kg or 10 mg/litre

48. 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.
49. The labelling rules apply to sulphur dioxide and/ or sulphites that have been deliberately added in the preparation of the food 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 10mg/kg or 10mg/litre (calculated in terms of the total sulphur dioxide (SO<sub>2</sub>)) 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 10mg/kg or 10mg/litre, it will need to be declared on the label.
50. 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.

#### **EXAMPLE**

51. 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 10mg/kg or 10mg/litre is not required.

#### **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**)'.

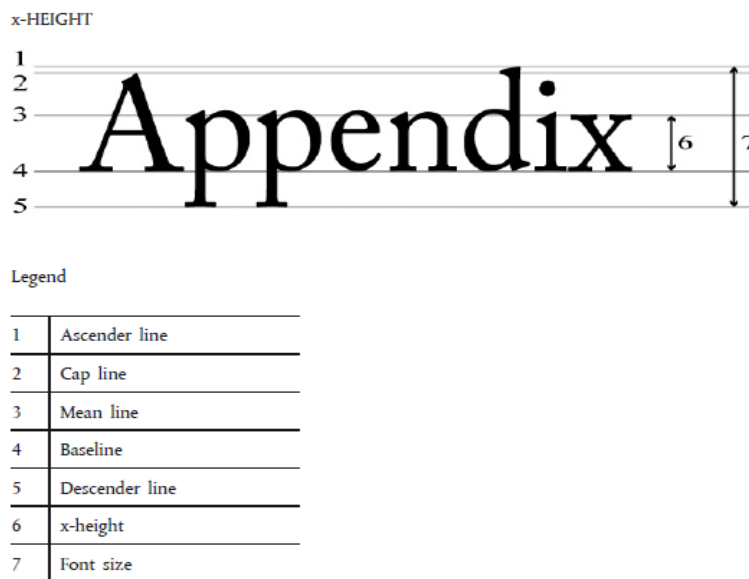
#### **Presentation of mandatory particulars (Article 13)**

56. Mandatory information is the information you have to provide for the food you sell. All written mandatory allergenic 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 1.2mm or more should be used where labelling surface is 80cm<sup>2</sup> or more.
59. A minimum font size where the x-height is 0.9mm or more should be used where the labelling surface is less than 80cm<sup>2</sup>. Figure 1 below illustrates how the x-height of the font used is measured.

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



60. Where the food packaging or container's largest surface area is less than 10cm<sup>2</sup> (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 is less familiar you may wish to include a contains statement; for example gingelly oil (contains sesame)

### **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').

#### 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 >10mg/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, further qualification is required.

#### 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). However, they will need to declare 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. For example, a bottle of wine should have a statement such as: 'Contains: sulphites' if the finished product contains sulphites at more than 10mg/litre. The presence of egg and milk fining agents will also need to be declared if found present at 0.25mg/litre and above.

## **EXAMPLE**

Allergen(s) within 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.

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

70. FBOs voluntarily use precautionary allergen labelling such as 'may contain' or 'not suitable for...' to communicate the risk of the unintentional presence of an allergen (e.g. milk, egg, nuts) in a food product due to the allergen entering the product accidentally during production, through cross-contamination. The voluntary use of such precautionary allergen labelling is still permitted; the basis for this is contained within Article 14 of EU Regulation No.178/2002 (General Food Law).
71. 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.
72. The application of precautionary allergen labelling should only be made 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. For detailed best practice guidance on allergen management and the voluntary application of precautionary allergen labelling, please see:

Food Standards Agency best practice guidance on:

[www.food.gov.uk/sites/default/files/multimedia/pdfs/maycontaininguide.pdf](http://www.food.gov.uk/sites/default/files/multimedia/pdfs/maycontaininguide.pdf)

or

Food Drink Europe (FDE) guidance on:

[www.fooddrinkeurope.eu/uploads/press-releases\\_documents/temp\\_file\\_FINAL\\_Allergen\\_A4\\_web1.pdf](http://www.fooddrinkeurope.eu/uploads/press-releases_documents/temp_file_FINAL_Allergen_A4_web1.pdf)

### **Distance selling (Article 14)**

73. 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 catalogue, as when the food is bought from a retail environment<sup>1</sup>. 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.

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<sup>1</sup> 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 and prepacked for direct sale foods**

- 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 (such as meals served in a restaurant or café) and includes prepacked for direct sale foods (such as meals prepacked 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 packed at the consumer's request). All mandatory allergen ingredients information (Article 9 (1) (c)) should be available and easily accessible for the consumer. The rules for non-prepacked food came into effect on 13 December 2014. 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:

- Article 8 on responsibilities
- Article 9 on the list of mandatory particulars (see p11-12 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

75. 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. 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 web site:

[www.food.gov.uk/enforcement/enforcework/food-law/guidance-enforcement/community-hall-guidance](http://www.food.gov.uk/enforcement/enforcework/food-law/guidance-enforcement/community-hall-guidance)

76. 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/cooksafe](http://www.foodstandards.gov.scot/cooksafe)

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

### **Responsibilities (Article 8)**

77. 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 the law.
78. 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 (prepacked and non-prepacked) are accompanied with sufficient information to enable subsequent food businesses to meet their responsibilities. FBOs who do not affect food information must not supply food which they know or presume to be non-compliant. FBOs are responsible for ensuring compliance with the provisions relevant to their activities and verify that those requirements are met. This applies to manufacturers, suppliers and the caterers.

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

79. 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 or foods sold by a butcher or delicatessen), 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 or webpages (see Regulation 5 (4) of the Food Information Regulations 2014).

80. 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.
81. 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'***

82. Allergen ingredients information for cereals containing gluten and nuts need to declare the specific 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.
83. 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.
84. Allergen ingredients information should be made available for the entire dish as served. Allergen information can be provided in a variety of ways.
85. 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:

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						

86. 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 or chocolates at hotels, airline meals, meals served at events), 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.

#### **EXAMPLE**

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.

#### **National measures (Article 44)**

87. Given the practical difficulties some businesses may face, 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 members of staff.
88. 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.
89. 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.

#### **EXAMPLE**

To ensure that consistent allergen information is provided, the FBO should consider using a system where staff direct queries to a nominated person(s).

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.

## Distance selling (Article 14)

90. 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.

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.

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

92. 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.

93. In distance sales involving a third party 'broker' (such as online aggregators for take away businesses) the third party and the FBO supplying the food to the consumer must work together to ensure that the required allergen information is provided to the consumer, and that the consumer is clear on how to obtain the allergen information. The FBO preparing and providing the food will be best placed to know the allergen content and provide the information to consumers and is therefore ultimately responsible for the allergen information given to the consumer.



## **Enforcement of the measures**

### **Local authority responsibilities**

94. 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.
95. 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.
96. 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**

97. 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 corresponding Regulations in Wales, Scotland and Northern Ireland on the labelling of allergenic ingredients is a criminal offence and may result in a criminal prosecution being brought against an FBO. This position is the same in relation to a failure to comply with Regulation 5(5) of the FIR relating to the provision of allergen information for non-prepacked foods etc. in a manner other than one provided for in EU FIC.
98. A person found guilty of an allergens offence under FIR 2014 will be liable to a fine. Section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 has come into effect meaning that fines in the legislation that had a £5,000 limit have changed the maximum fine into a fine of any amount. The amount of the fine would be up to the Magistrates to decide on a case by case basis. Please note that Section 85 of the 2012 Act only extends to England and Wales.

## **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, prepacked for direct sale 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.

**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'. A food business (as referred to in Article 3(2)) is also defined in the same regulation, 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 catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer'.

### **Non-prepacked foods:**

- 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 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 foods:** This refers to any food put into packaging before being offered for sale for example a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup. All the following must apply:

- the food is either fully or partly enclosed by the packaging;
- the food cannot be altered without opening or changing the packaging;
- the product is ready for sale to the final customer or to a mass caterer.  
(Adapted from the definition in Article 2 (2)(e) of EU FIC).

**Prepacked foods for direct sale:** This applies to foods that have been packed on the same premises from which they are being sold. Foods prepacked for direct sale are treated in the same way as non-prepacked foods in EU FIC's labelling provisions. For a product to be considered 'prepacked for direct sale' one or more of the following can apply:

- 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.

## References and Resources

- Further advice on food allergen labelling is available on the Agency's website: [www.food.gov.uk/policy-advice/allergyintol/label/](http://www.food.gov.uk/policy-advice/allergyintol/label/)
- FSA allergen resources at: [www.food.gov.uk/allergen-resources](http://www.food.gov.uk/allergen-resources)
- Advice for SMEs on prepacked food can be found here: [www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/allergy-labelling-prepacked.pdf](http://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/loosefoodsleaflet.pdf](http://www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/loosefoodsleaflet.pdf) and [www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/thinkallergy.pdf](http://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](http://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](http://www.food.gov.uk/sites/default/files/allergy-chef-cards.pdf)
- 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/>  
Free online training about the Food Information Regulation as a whole can be found here: <http://labellingtraining.food.gov.uk/>
- 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 2015. Cooksafe can be found on: [www.foodstandards.gov.scot/cooksafe](http://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](http://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>
- EU Regulation No. 579/2012 labelling and presentation of wine sector products [www.fsai.ie/uploadedFiles/Legislation/Food\\_Legislation\\_Links/Alcohol/Reg579\\_2012.pdf](http://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>
- Food Safety Act 1990 and subsequent amendments: [www.legislation.gov.uk/ukpga/1990/16/contents](http://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](http://www.legislation.gov.uk/nisi/1991/762/contents/made)
- Regulation (EU) 1308/2013 establishing common organisation of the markets in agricultural products ('Dairy Designations') <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0671:0854:EN:PDF>

## **Review**

This guidance will be reviewed on 1 July 2016. We welcome any comments/ feedback on this guidance. Please complete and return this [feedback questionnaire](#) .

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