



Guidance on Allergen and Miscellaneous Labelling Provisions

March 2011

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Summary

Intended audience:	All food manufacturers, producers, retailers, caterers and enforcement authorities.
Regional coverage:	The UK.
Purpose:	To help all food manufacturers, producers, retailers, caterers and enforcement authorities understand the requirements of those Regulations which relate to the allergen and miscellaneous labelling provisions and to offer advice on relevant best practice.
Legal status:	The guidance gives both regulatory and best practice advice, so the latter is enclosed in shaded boxes labelled “best practice” .
Essential actions to comply with regulation(s):	Allergens, additives and irradiated ingredients used in compound ingredients must be declared on the label in accordance with food labelling and allergen labelling regulations.

REVISION HISTORY

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please contact us using the number on the front sheet. If you have any comments on the guidance, again please contact us on the number on the front sheet.

Revision No.	Revision date	Purpose of revision	Revised by
1	May 2008	Draft Guidance	Dionne Davey, FSA
2	July 2009	Draft Guidance	Dionne Davey, FSA
3	January 2010	Update Guidance	Dionne Davey, FSA
4	March 2011	Update Guidance	Sue Hattersley, FSA

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REGULATIONS REFERRED TO IN THIS GUIDANCE

These Guidance Notes cover separate but parallel Regulations in all four countries of the UK.

Details are below of how the regulations are referred to in the text, plus the full name and number of the respective regulation in each country. A summary of these regulations by country is in **Annex 1**.

The 2004 Regulations

The Food Labelling (Amendment) (England) (No. 2) Regulations 2004

The Food Labelling Amendment (No 2) (Scotland) Regulations 2004

The Food Labelling (Amendment) (No.2) (Wales) Regulations 2004

The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) 2004

The 2008 Regulations

The Food Labelling (Declaration of Allergens) (England) Regulations 2008

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2008

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2008

The 2009 Regulations

The Food Labelling (Declaration of Allergens) (England) Regulations 2009

– now revoked

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2009

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2009 –
now revoked

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2009

– now revoked

The 2011 Regulations

The Food Labelling (Declaration of Allergens) (England) Regulations 2011

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2011

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2011

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2011

INTRODUCTION

1. These guidance notes cover the interpretation of the legislation and are relevant across the UK.
2. **Annex 2** contains background on the legislative changes, **Annex 3** contains Schedule AA1, the list of ingredients that must be declared on labels and exemptions to the declaration, **Annex 4** contains other relevant legislation and guidance documents, **Annex 5** shows the key provisions organisation of the 2004 Regulations, and **Annex 6** lists relevant FSA contacts.

INTENDED AUDIENCE

3. These guidance notes are intended to help all food manufacturers, producers, retailers, caterers and enforcement authorities understand the requirements of those Regulations which relate to the allergen and miscellaneous labelling provisions.

PURPOSE AND LEGAL STATUS

4. These guidance notes have been produced to provide informal, non-binding advice on:

the legal requirements of the 2004, 2008, the 2009 Regulations (in Scotland only) and the 2011 Regulations which amend the Food Labelling Regulations 1996 (as amended); and best practice in this area.
5. These guidance notes should be read in conjunction with the legislation itself. The guidance on legal requirements should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. It is ultimately the responsibility of individual businesses to ensure their compliance with the law. Compliance with the advice on best practice is **not** required by law. **To distinguish between the two types of information, all advice on best practice is in shaded boxes, with a heading of Best Practice.**
6. Businesses with specific queries may wish to seek advice from the trading standards / environmental health department of their local authority/District Council.

LABELLING REQUIREMENTS IN THE 2004 REGULATIONS

7. Directive 2003/89/EC amended Directive 2000/13/EC, mainly in respect of Article 6 and the declaration of ingredients, including additives. It also introduced a list of 12 ingredients known to cause allergies or intolerances, as listed in the Annex to Directive 2003/89/EC which introduces Annex IIIa into Directive 2000/13/EC.

Ingredients listing

Regulations 5 & 15 to the 2004 Regulations

8. Regulation 5 of the 2004 Regulations:
 - removed “mixed nuts” and added in “mixed mushrooms” from the exemptions in existing regulation 13(5) of the Food Labelling Regulations 1996 (as amended):
 - allowed for individual ingredients that make up less than 2% of the finished product to be listed in a different order after other ingredients:
 - allowed for ingredients which are similar or mutually substitutable, that are not likely to alter the nature or perceived value of the finished product and which make up less than 2% of the finished product, to be listed using the phrase “contains...and/or”, where more than one and no more than two of such ingredients are present in the finished product. For example: for varieties of dried vine fruit; varieties of citrus peel; sources of vegetable oil; glucose syrup or dextrose. In the example of dried vine fruit the label could indicate “Dried vine fruit (Contains sultanas and/or raisins)”.

However, allergens and additives **must** be declared on the label in accordance with food labelling and allergen labelling regulations

9. Regulation 15 no longer allows “crystalised fruit” and “vegetables” from the collective (generic) names to be used in a list of ingredients. These collective terms may only be used if followed by a list of the types of vegetables/fruit concerned and, if appropriate, the phrase “in varying

proportions” .

Removal of the 25% compound ingredients exemption

Regulation 7 of the 2004 Regulations

10. The 2004 Regulations removed the 25% compound ingredient exemption. With the exception of a very few cases (see paragraph 11), all ingredients now have to be listed on food labels.

Exceptions

11. The 2004 regulations exempted a small number of compound ingredients from the requirement to list their ingredients in cases where:
 - the compound ingredient is a foodstuff whose composition is defined in Community legislation (for example, spreadable fats, cocoa and chocolate products, fruit juices and similar products, fruit jams, jellies, marmalade and sweetened chestnut puree) **and** makes up less than 2% of the finished product;
 - the compound ingredient is made up entirely or almost entirely of a single basic ingredient (for example, carbonated water, fermentation vinegars, cheese, butter, fermented milk and cream in certain circumstances); or
 - the compound ingredient is made up of a mixture of spices or herbs or both **and** makes up less than 2% of the finished product.

However, allergens, additives and irradiated ingredients, used in compound ingredients **must** be declared on the label in accordance with food labelling and allergen labelling regulations.

Multi-pack foods

Section 35 of the Food Labelling Regulations 1996

12. Under the Food Labelling Regulations all mandatory labelling information must appear on either: the outermost packaging, a label attached to the outermost packaging, or be clearly visible through the outer packaging. For multi-packs not for individual sale the above applies. Where the products within the multi-pack are for individual sale, all the information should appear on each product.

ALLERGEN LABELLING

13. The scope of the 2004 Regulations, the 2008 Regulations, the 2009 Regulations (in Scotland only) and the 2011 Regulations includes all pre-packed food, as well as alcoholic drinks. A number of exemptions to these rules, and other allergen labelling that is not covered by these rules, are explained in paragraphs 41 - 46.

Ingredients covered by the allergen labelling requirements

14. All added ingredients and components of added ingredients are covered by the requirements, if they are present in the finished product, even in an altered form, including:

carry-over additives – additives allowed by the relevant Regulations in one of the ingredients of a compound food;

Additives used as processing aids – substances not consumed by themselves as food ingredients which are used for technological purposes during the treatment or processing of raw materials, foods or their ingredients where unavoidable residues remain in the final product (provided that these residues do not present a hazard to health and do not have any technological function in the final food); and

solvents and media for additives or flavourings – substances used to dissolve, dilute, disperse or otherwise physically modify a food additive or flavouring without altering its function (and without exerting

any technological effect themselves) in order to facilitate its handling, application or use.

Declaration of allergenic ingredients

Regulation 12 to the 2004 Regulations

Schedule AA1 to the Food Labelling Regulations 1996 (as amended)¹

15. Allergen information will only need to be given for the ingredients and their derivatives specified in Schedule AA1 to the Food Labelling Regulations 1996 (See Annex 3 of these Guidance Notes).
16. Where an allergenic ingredient or its derivative is not clearly identified in the name of the food (e.g. malt vinegar), the ingredient should always be identified on the labelling with a clear reference to the name of the allergenic ingredient concerned, for example “malt vinegar (from barley)”. In order to avoid ambiguity and confusion, this reference should be made in words.

BEST PRACTICE

The Government’s Clear Food Labelling Best Practice Advice recommends the use of simple language and also refers to examples of recommended ingredient names for consistent identification of the presence of food allergens and gluten. Three illustrative examples are “stock (from fish)”, “couscous (wheat)”, and “tahini (sesame)”.

See

<http://webarchive.nationalarchives.gov.uk/20100817075455/http://www.food.gov.uk/multimedia/pdfs/clearfoodlabelling.pdf>

Where the product has an ingredients list it would be best practice for the allergenic source of the ingredient to be indicated in this list.

¹ Also the Food labelling Regulations (NI) 1996 (as amended) in Northern Ireland

Allergen labelling of foods in small packaging and certain indelibly marked bottles

Regulation 4 of the 2004 Regulations as read with Regulation 26 of the Food Labelling Regulations 1996 (as amended)

17. These products need to indicate the presence of the specified allergens and their derivatives, although they do not need to provide a full ingredients list.

BEST PRACTICE

As there are no provisions in the Regulations to avoid repetition of listing the same allergenic source for more than one ingredient in an ingredient list, it would seem reasonable to apply the following guidance:

Where an allergenic ingredient in Schedule AA1 is already clearly indicated on the label, it would be acceptable not to have to declare it again as the source of a derived allergenic ingredient.

Where several ingredients are derived from the same allergenic ingredient, it would be acceptable to asterisk them to a single source allergenic ingredient (for example, *from soya), provided that this would not be confused with other uses of asterisks (for example, with reference to GM ingredients). The referenced allergenic ingredient could be placed in a separate allergy information/alert box, if used.²

² Note that this will only work where there is one allergen source referenced using an asterisk. Where there are more than one, multiple asterisks could make the information confusing.

Allergen labelling on drinks with an alcoholic strength by volume (abv) of more than 1.2%

Regulation 12 of the 2004 Regulations

18. Alcoholic drinks are subject to special rules. Drinks with an alcoholic strength by volume (abv) of more than 1.2% are exempt from ingredient listing under general food labelling rules. In these cases, the label should declare the allergenic ingredient with the word “contains” followed by the Schedule AA1 name, unless already in the name of the drink or any list of ingredients provided. This information should be provided in a language that is easily understood by consumers in the country in which the product is to be sold. For drinks with an alcoholic strength by volume (abv) of 1.2% or less, where ingredient listing is required, the provisions for indication of allergenic ingredients and their derivatives is the same as for other foods.

Foods which fall within scope of the list in Schedule AA1 (ANNEX 3 of these Guidance Notes)

Regulation 12 to the 2004 Regulations

Schedule AA1 to the Food Labelling Regulations 1996

Regulation 2 of the 2008 Regulations

19. The following is meant to provide guidance and best practice advice on the scope of each allergenic ingredient in Schedule AA1 to the Food Labelling Regulations 1996. The terms used in listing allergenic ingredients should closely resemble those used in Schedule AA1 to avoid confusing the consumer. Whilst there is no official guidance regarding terms that should be used in every case, where species are identified (for example for cereals containing gluten and for nuts) the common names listed are those that should be used in labelling. In other cases, guidance

is provided here, which is based on the European Food Safety Authority (EFSA) opinion.³

Celery

20. This term is used generically in the Regulations to refer to both celery (stick celery) and celeriac (root celery). However, the term refers to any part of the celery plant and other forms that originate from it, such as celery leaf, celery seeds, celery oil, celery seed oil and celery seed oleoresin.

BEST PRACTICE

Use the words “celery” and/or “celeriac” to identify the nature of the ingredient to consumers.

Cereals containing gluten

21. The Regulations define these as: wheat, rye, barley, oats, spelt, kamut or their hybridised strains. Other types of cereals containing gluten would therefore not be included in the scope of these rules. Spelt is a type of wheat, which is not usually a suitable substitute for people with coeliac disease and/or wheat allergy.

³ The opinion of the Scientific Panel on Dietetics Products, Nutrition and Allergies, Request No.: EFSA-Q-2003-016 adopted 19 February 2004.

Website: <http://www.efsa.europa.eu/en/efsajournal/pub/32.htm>

BEST PRACTICE

There is no requirement for gluten itself to be indicated in the ingredient list but if manufacturers choose to use an allergy information/alert box it would be best practice to declare both gluten and the name of the cereal.

Crustaceans

22. The rules do not name any species of crustaceans. However, “crustaceans” includes all types of crustaceans (for example lobster, crab, prawns and langoustines – which are used to make scampi).

BEST PRACTICE

Use of the common species names should be sufficient to indicate the “crustacean” content of a product, but care should be taken to use the term “crustacean” where its inclusion might not be appreciated and to ensure that the use of any uncommon species of crustacean is made clear.

Any reference to crustacean should be in addition to labelling the ingredient specifically in accordance with the relevant legislation, including The Food Labelling Regulations 1996 (as amended) and The Fish Labelling Regulations 2010.

Eggs

23. The rules do not name any species of eggs, because “eggs” refers to eggs from laying hens as well as eggs from other birds, such as duck, turkey, quail, goose, gull, and guinea fowl.

Fish

24. The rules do not name any species of fish because “fish” includes fish from 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. A list of common names (i.e. “names prescribed by law”) to be used for different species of fish can be found in the schedule to the Fish Labelling Regulations 2010⁴.

BEST PRACTICE

Use of the common species names (e.g. cod, mackerel) should be sufficient to indicate the “fish” content of a product, but care should be taken to use the term “fish” where its presence might not be recognised and to ensure that the nature of any exotic fish is made clear.

⁴ The relevant Regulations are:-

The Fish Labelling (England) Regulations 2010 (SI No. 420)

The Fish Labelling (Scotland) Regulations 2010 (SSI No. 90),

The Fish Labelling (Wales) Regulations 2010 (SI No. 797 (W.78),

The Fish Labelling Regulations (Northern Ireland) 2010 (SI No. No.54)

Lupin

25. The term is used generically in the Regulations to refer to both lupin seed and lupin flour, which was introduced into the UK in 1996. 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. There is cross reactivity to lupin in a significant number of people allergic to peanuts.

Milk (including lactose)

26. The rules do not name any species of milk, because “milk” includes milk from sheep, goats, 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.

BEST PRACTICE

Under general food labelling rules, dairy products (cheese, butter, fermented milk and cream) do not have to have an ingredients list in certain circumstances. 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 base of these products. In such cases, further reference to “milk” may not be necessary. However, the labelling should make a clear reference to milk in the case of unfamiliar dairy 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, in non-transparent packaging on a non-dairy shelf.

In addition, components derived from milk, such as casein and whey, should be declared with reference to milk.

Molluscs

27. The rules do not name any species of mollusc because “molluscs” includes all types of mollusc (for example oyster, squid, cockles, mussels, winkle and scallops as well as land molluscs like snails).

BEST PRACTICE

Use of the common species names should be sufficient to indicate the “mollusc” content of a product but care should be taken to use the term “molluscs” where its presence might not be appreciated and to ensure that the nature of any exotic mollusc is made clear.

Any reference to molluscs should be in addition to labelling the ingredient specifically in accordance with the relevant legislation, which included The Food Labelling Regulations 1996 (as amended) and The Fish Labelling Regulations 2010.

Mustard

28. This term refers to the mustard plant and other forms 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 mustard and therefore should be applied to all.

Nuts

29. The rules list these as: almond, hazelnut, walnut, cashew nut, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut. The type of nut should be listed in the ingredients panel. Other types of nuts, and other foods which although, strictly speaking, are not nuts (even though they are called nuts i.e. 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 listed in these rules.

Peanuts

30. Whilst these may also be commonly referred to as groundnuts or monkey nuts, the term “peanuts” should be used for allergen labelling purposes, as this is the term specified in Directive 2000/13/EC as amended.
31. Both refined and unrefined peanut oil has to be labelled with reference to peanut. However, there is no requirement to indicate whether the oil has been refined or is cold-pressed (unrefined).

Sesame seeds

32. Sesame seeds and products deriving from it such as tahini, humous and sesame oil have to be labelled under the allergen derivative requirement.

Soybeans

33. Terms such as “soya” or “soy” are sufficient to indicate the soybean origin.

Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO₂

(This requirement relates only to products that have had sulphur dioxide and sulphites intentionally added.)

34. Certain foods may naturally contain sulphur dioxide and sulphites (for example garlic, onion and certain dried fruits like apricots), but food-

labelling rules apply only to ingredients that have been deliberately added in the preparation of the food. The rules require this ingredient to be labelled when present above the level indicated (calculated in terms of the total SO₂) in the finished product as consumed, i.e. prepared according to the manufacturer's instructions. This additive must be declared by reference to the terms 'sulphur dioxide and sulphites', 'sulphur dioxide' or 'sulphites', depending on the form of the ingredient added. 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, for example, sodium metabisulphite. The use of the category name (such as preservative in the case of sulphur dioxide) followed by the E-number (E-220 series), which is permitted under the additives Directive (95/2/EC) alone, is not sufficient, nor is the use of the chemical symbol "SO₂".

Ingredients that were temporarily exempted by Directive 2005/26/EC but did not gain permanent exemption

35. Certain derived ingredients originating from the listed allergens were given temporary exemption before the permanent exemption list was published. Whilst the exemption list maintained many of the temporary exemptions, the following ingredients used in certain processes are no longer exempt and, subject to transitional arrangements explained below, must be declared on labels:

- almonds/walnuts to flavour spirits
- celery leaf oil and seed oil
- celery seed oleoresin
- egg albumin fining agent for cider
- fish gelatine as a carrier for flavours
- isinglass fining agent for cider
- milk (casein) fining agent for cider
- mustard oil
- mustard seed oil
- mustard seed oleoresin.

Products containing these were exempt from labelling until 31 May 2009 but since that date, must be labelled. Any products that have been labelled under the old rules and are still on the market after that date may continue to be sold until stocks are exhausted.

Derived ingredients

36. The scope of the allergen labelling extends to ingredients originating from ingredients listed in Schedule AA1 and any derivatives of those derivatives, and assumes that, unless otherwise demonstrated, the allergenic potential remains.
37. Based on the European Food Safety Authority's (EFSA's) opinion, the Commission has agreed which derived ingredients should be permanently exempt from the allergen labelling provisions. A list of the permanently exempt ingredients is set out in Directive 2007/68/EC and implemented into national legislation by the Food Labelling (Declaration of Allergens) Regulations 2008 which is in force from 31 May 2008. See paragraph 43 for further information.
38. Micro-organisms that have been fed on allergenic substrates are not considered to be derived from the allergenic substrates for the purposes of labelling.

BEST PRACTICE

In cases where an ingredient such as a food additive is produced using micro-organisms (which have been fed on the specified allergens or their derivatives), manufacturers will have to consider the likelihood of any carryover of the allergenic growing medium into the food ingredient and whether any precautionary labelling (such as "may contain") is required. Such a situation is outside the scope of these Regulations, which apply only to ingredients added to foodstuffs and not contamination.

Listing of additives and flavourings

Regulation 12 to the 2004 Regulations Schedule AA1 to the Food Labelling Regulations 1996 as read with Regulation 14 of the Food Labelling Regulations 1996

39. Where a flavouring or other additive contains an allergenic ingredient or its derivative and this is not clearly identified in the name under which the flavouring or additive is listed, the ingredient should always be identified with a clear reference to the name of the allergenic ingredient concerned.

EXEMPTIONS TO THE RULES ON ALLERGEN LABELLING

Allergen labelling of non-prepacked foods and foods sold at catering establishments

Regulation 11 of the 2004 Regulations

40. The rules do not apply to foods sold loose or foods sold pre-packed for direct sale (non-prepacked) (see paragraph 4). However, in many cases foods being supplied to businesses are accompanied by full labelling information, including ingredients information. This could be on the packaging itself or on the documentation delivered alongside the goods. The Agency has provided voluntary guidance on the provision of allergen information on food sold loose or pre-packed for direct sale. See <http://www.food.gov.uk/allergy>.

Seasonal Selection Packs

Regulation 28 of the Food Labelling Regulations 1996

41. There is an exemption for ingredient listing on seasonal selection packs that states that outer packaging does not need to be marked or labelled with any of the particulars specified in those Regulations, provided that the individual items contained in the pack are labelled.

Ingredients on the 2007/68/EC Permanent Exemptions List

Schedule in the 2008 Regulations

42. Directive 2005/26/EC, as amended, made provision for a temporary exemption from allergen labelling rules for certain allergenic derivatives that are no longer allergenic (based on the opinions of the European Food Safety Authority (EFSA)). These exemptions expired on 25 November 2007.

43. Following an assessment by EFSA of the dossiers provided by the food industry to the Commission many of those ingredients which had been temporarily exempt from food labelling rules were granted permanent exemption status by the European Commission. These are listed in Schedule AA1 under the allergenic substance they are made from.⁶

See paragraph 35 for a list of ingredients that were on the temporary list but from 31 May 2009 are no longer exempt.

44. Under the permanent exemption rules, the exempt ingredients do not have to be indicated on the labelling with a reference to the parent allergen. However, they still have to be indicated according to the general food labelling rules in the Food Labelling Regulations 1996. For example, glucose syrup would have to be listed in the ingredient list but it would not have to declare that it was “from wheat” or “from barley”.

Labelling a source allergen that is no longer present in the final product

45. Although the 2008 Regulations exempt ingredients listed in Schedule AA1 from the requirement to make reference to the source allergen on the

⁶ There are temporary exemptions from labelling for both egg albumin and milk (casein) used as a fining agent for wine, and lysozyme (produced from egg) used in wine, until June 2012.

labelling, there is no legal requirement preventing reference being made to it on the label.

BEST PRACTICE

If an allergic consumer were to eat something which was labelled as containing an allergen, that in reality was no longer allergenic, this could lead to confusion, and a potentially dangerous situation, where the allergic consumer might incorrectly assume that they can safely eat that allergen. In order to avoid this confusion, it would be best practice, not to make reference to the source allergen on the label.

Other similar derived ingredients manufactured by methods other than that specified in the dossiers submitted to the European Food Safety Authority (EFSA)

46. We understand the exemptions to be linked to the specific methods of manufacture and uses specified in the individual dossiers submitted to EFSA. It will be up to manufacturers who want to benefit from exemptions already granted to ensure that the sourcing of their particular ingredient is consistent (in terms of method of manufacture and use) with those for which exemptions have been granted, as set out in the relevant dossier. Website links to the EFSA opinions, including descriptions and intended applications, on the ingredients for which exemptions have been granted are included in these Guidance Notes and can be found in Annex 3.

Labelling of ingredients made from soya oil

47. Ingredients derived from those ingredients in the Schedule to the 2008 Regulations, which are marked with footnote, are also exempt from the allergen labelling requirements, provided that the process they have undergone is not likely to have increased the level of allergenicity above that of the original product evaluated by EFSA. So, products made from fully refined soya oil do not have to be labelled with reference to soya; however products made from unrefined or partially refined soya bean oil or fat would have to be labelled with reference to soya.

ALLERGEN LABELLING THAT IS NOT COVERED BY THESE REGULATIONS

Allergy information boxes and statements

48. Allergy information/alert boxes are not covered by the legislation and their use is entirely voluntary.

BEST PRACTICE

If a separate allergy information/alert box is used on the label, best practice would be for all specified allergens present in the food to be included and for the box to be in the same field of vision as the ingredient list. If an allergy information/alert box is used on the label of a product containing several species of crustacean or molluscs then it may be sufficient to use the term “shellfish” in the box. However, if the generic term “nuts” is used to represent more than one species of tree nut, it is important not to include peanuts in the generic term and to list this separately.

The use of 'may contain' (nut trace) warnings to indicate possible allergen cross-contamination

50. The allergen rules apply to the labelling of Schedule AA1 ingredients and their derivatives that have been intentionally added in the course of preparing the food. There is no legal requirement in the Regulations to use 'may contain' or nut trace warnings to indicate possible allergen cross-contamination. However, many manufacturers and retailers provide this information voluntarily in order to indicate the possible presence of unintentional ingredients that people may be allergic to in pre-packed food.
51. Consumers have raised concerns that inappropriate use of nut trace warnings could unnecessarily restrict consumer choice and undermine valid warnings. In response to these concerns, and requests from the food industry for guidance on this matter, the Food Standards Agency has published voluntary best practice guidance on the appropriate and proportionate use of label statements to warn allergic consumers of the risk of cross-contamination with any allergen.

See: www.food.gov.uk/multimedia/pdfs/maycontaininguide.pdf

Claims that products are 'free from a particular allergen'

52. Currently the only free from claims which are covered by specific regulations are relating to gluten. Commission Regulation (EC) No 41/2009 established rules for the use of terms concerning the absence of gluten, as defined in Article 4(a) of the Foods for Particular Nutritional Uses Directive 89/398/EC. It aims to set out the compositional criteria and labelling rules that may be used for those products which are specially produced to be gluten free and also to make provision for ordinary foods that naturally do not contain gluten to be able to make a claim to this effect. In addition to specifying the conditions under which a free from claim can be made, the Regulation also allows for a claim of very low gluten. However, manufacturers have until 1 January 2012 before they

have to comply with these new provisions. Separate guidance on compliance with these new provisions can be found at:

<http://www.food.gov.uk/multimedia/pdfs/publication/guidancelabellinggluten2010.pdf>

53. There are no specific regulations covering such claims for any of the other listed allergens, but under the provisions of the General Food Law Regulations 2004 (as amended)⁷, labelling, advertising and presentation of food, including the information made available, should not mislead consumers. In addition, under the general provisions of the Food Safety Act 1990 claims must not be false or mislead as to the nature, substance or quality of the food. Manufacturers should ensure that they have adequate Quality Assurance and Good Manufacturing Practice systems to back up any such claims that are made.

⁷ The General Food Law Regulations (NI) 2004 (as amended) in Northern Ireland
Allergen and Miscellaneous Labelling Provisions

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ANNEX 1 – SUMMARY OF REGULATIONS BY UK COUNTRY

These Guidance Notes cover separate but parallel Regulations in all four countries of the UK.

A summary of the Regulations referred to for each country is below. A list of the Regulations showing how they are referred to in this guidance is at the front of the document.

England

The Food Labelling (Amendment) (England) (No. 2) Regulations 2004

The Food Labelling (Declaration of Allergens) (England) Regulations 2008

The Food Labelling (Declaration of Allergens) (England) Regulations 2009 (now revoked by the 2011 Regulations)

The Food Labelling (Declaration of Allergens) (England) Regulations 2011

Wales

The Food Labelling (Amendment) (No.2) (Wales) Regulations 2004

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2008

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2009 (now revoked by the 2011 Regulations)

The Food Labelling (Declaration of Allergens) (Wales) Regulations 2011

Scotland

The Food Labelling Amendment (No 2) (Scotland) Regulations 2004

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2009

The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2011

Northern Ireland

The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) 2004

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2008

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2009 (now revoked by the 2011 Regulations)

The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2011

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ANNEX 2 – BACKGROUND ON LEGISLATIVE CHANGES

The 2004 Regulations implemented Directive 2003/89/EC, which is an amendment to Directive 2000/13/EC. These came into force across the UK on 25 November 2004. These Regulations established a list of allergens that have to be indicated on the label whenever they or their derivatives are used as deliberate ingredients in pre-packed food, including alcoholic drinks, (Annex IIIa of Directive 2000/13/EC or Schedule AA1 of the Food Labelling Regulations 1996 (as amended)).

The Food Labelling (Amendment) (England) (No. 2) Regulations 2005 and parallel legislation elsewhere in the UK⁸ implemented Commission Directive 2005/26/EC and established a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council. These Regulations expired on 25 November 2007.

The Food Labelling (Amendment) (England) (No.2) (Amendment) Regulations 2005 and parallel legislation elsewhere in the UK⁹ implemented Directive 2005/63/EC,

⁸ The relevant Regulations elsewhere in the UK are:-

The Food Labelling (Amendment) (No. 2) (Scotland) Regulations 2005 (SI No 456)

The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2005 (SI No. 2835 (W.200))

The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) 2005 (SR. No. 396)

⁹ The relevant Regulation elsewhere in the UK are:

The Food Labelling Amendment (No. 3) (Scotland) Regulations 2005 (SI No. 542.)

The Food Labelling (Amendment) (Wales) (No. 2) (Amendment) Regulations 2005 (SI No. 3236 (W.241))

The Food Labelling (Amendment No.2) (Amendment) Regulations (Northern Ireland) 2005 (SR No.475)

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which amended the list of ingredients provisionally exempt from the allergen labelling rules to include fish gelatine used as a carrier for vitamin or carotenoid preparations and flavours. These Regulations also expired on 25 November 2007.

The 2007 Regulations implemented Commission Directive 2006/142/EC, of 22 December 2006, amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council by adding two more allergens to the list of ingredients which must under all circumstances appear on the labelling of foodstuffs. These Regulations were rescinded by the 2008 Regulations, which included a revised list of ingredients which must under all circumstances appear on the labelling of foodstuffs.

The 2007 Regulations came into force on 23 December 2007, from which date products complying with the new rules may be sold and manufacturers had 12 months to make the necessary label changes. It was not permitted as from 23 December 2008 to produce products with labels that do not comply with these provisions. However, products that were labelled before this date could be sold while the stocks lasted.

The 2008 Regulations came into force on 31 May 2008 and implemented Commission Directive 2007/68/EC which further amended Annex IIIa to Directive 2000/13/EC. These Regulations set out a list of permanent exemptions from the allergen labelling rules in the case of ingredients derived from specified allergens in Schedule AA1 of the Food Labelling Regulations 1996 (as amended) that are no longer allergenic. This legislation confirms the exemption status of many of the ingredients originally set out in the Food Labelling (Amendment) (England) (No.2)

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Regulations 2005 and parallel legislation elsewhere in the UK¹⁰.

The 2009 Regulations came into force on 20 November 2009 and implement the enforcement requirements for Commission Regulation (EC) 415/2009 amending Directive 2007/68/EC amending Annex IIIA to Directive 2000/13/EC. These Regulations provided a temporary exemption from labelling for egg albumin as a fining agent for wine and lysozyme (produced from egg) used in wine and for milk (casein) used as a fining agent for wine until December 2010. These Regulations have been revoked in England, Wales and Northern Ireland.

The 2011 Regulations came into force in March 2011 and implement enforcement requirements for Commission Regulation (EC) 1266/2010 amending Directive 2007/68/EC amending Annex IIIA to Directive 2000/13/EC. The Regulations provide a further temporary exemption from labelling for egg albumin as a fining agent for wine and lysozyme (produced from egg) used in wine and for milk (casein) used as a fining agent in wine until 30 June 2012.

¹⁰ The relevant Regulations elsewhere in the UK are:-

The Food Labelling (Amendment) (No. 2) (Scotland) Regulations 2005 (SSI No 456)

The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2005 (SI No. 2835 (W.200))

The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) 2005 (SR. No. 396)

ANNEX 3 – SCHEDULE AA1: THE LIST OF ALL INGREDIENTS THAT MUST BE DECLARED ON LABELS AND EXEMPTIONS TO THOSE DECLARATIONS

The ingredients listed in Schedule AA1 (as amended by the 2008 Regulations, the 2009 Regulations in Scotland and the 2011 Regulations) are as follows:

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains), except:

- (a) wheat-based glucose syrups including dextrose*;
- (b) wheat-based maltodextrins*;
- (c) glucose syrups based on barley;
- (d) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

Crustaceans.

Eggs¹¹.

Fish, except:

- (a) fish gelatine used as a carrier for vitamin or carotenoid preparations;
- (b) fish gelatine or isinglass used as a fining agent in beer and wine.

Peanuts.

Soybeans, except:

- (a) fully refined soybean oil and fat*;

* The exception only applies to products derived from these products in so far as the process they have undergone is not likely to increase the level of allergenicity assessed by the European Food Safety Authority for the relevant product from which they originated.

¹¹ There is a temporary exemption from labelling for egg albumin used as a fining agent for wine and lysozyme (produced from egg) used in wine until June 2012.

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(b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;

(c) vegetable oils derived from phytosterols and phytosterol esters from soybean sources;

(d) plant stanol ester produced from vegetable oil sterols from soybean sources.

Milk (including lactose)¹², except:

(a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(b) lactitol.

Nuts, i.e. almonds (*Amygdalus communis L.*), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis (Wangenh.) K.Koch*), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia nuts and Queensland nuts (*Macadamia ternifolia*), except:

(a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

Celery.

Mustard.

Sesame seeds.

Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂.

Lupin.

Molluscs.

¹² There is a temporary exemption from labelling for milk (casein) used as a fining agent for wine until June 2012.

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This list may continue to be revised or amended by the European Commission as and when appropriate scientifically validated data (based on the opinion of the European Food Safety Authority - EFSA) becomes available, and may involve the addition or deletion of certain ingredients or products. EFSA opinions can be found at <http://www.efsa.europa.eu/en/nda/ndascdocs.htm>

The Commission has also indicated that it may issue technical guidelines for the interpretation of the list, where this is deemed to be necessary.

ANNEX 4

ANNEX 4 – OTHER RELEVANT LEGISLATION AND GUIDANCE

These guidance notes are intended to be read in conjunction with the legislation and guidance listed below:

- The Regulations listed at the start of this document;
- Directive 2000/13/EC (as amended) of the European Parliament and the Council of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs; <http://eur-lex.europa.eu/LexUriServ/site/en/consleg/2000/L/02000L0013-20070112-en.pdf>
- The Food Labelling Regulations 1996 (as amended), which implement (among other EC legislation) Directive 2000/13/EC as amended;
- The Food Standards Agency's Clear Food Labelling Guidance, published in 2008
- Other relevant guidance documents that are available on the Food Standards Agency's website (www.food.gov.uk);
- The Food Safety Act 1990¹³ ; and
- It should be noted that Commission Directive 2005/26/EC, which established a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council, as corrected by Commission Directive 2005/63/EC, expired on 25 November 2007.

¹³ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991 applies.

ANNEX 5 – KEY PROVISIONS IN THE 2004 REGULATIONS

Interpretation (regulation 3)

Includes a definition of “allergenic ingredient” by reference to Schedule AA1.

Exemptions (regulation 4)

Small packages and certain indelibly marked glass bottles brought into this country from other Member States of the EU or European Economic Area are not exempt from the allergen labelling requirements.

Order of ingredients (regulation 5)

Sets out new provisions for the order in which ingredients may be listed under certain circumstances.

Names of ingredients (regulation 6)

Ensures allergen labelling requirements override the rules on indicating generic names, flavourings and additives.

Compound ingredients (regulation 7)

Sets out new provisions exempting specified compound ingredients from ingredients listing in certain circumstances and abolishes the 25% compound ingredient listing exemption.

Ingredients that need not be named (regulation 8)

Adds a further ingredient to those that do not need to be named.

Foods that need not bear a list of ingredients (regulation 9)

Ensures the allergen labelling requirements override the exemption for foods which need not bear a list of ingredients.

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Foods sold non-prepacked or pre-packed for direct sale and fancy confectionery products (regulation 10)

Exempts food sold otherwise than at a catering establishment (namely food that is not pre-packed, similar food and certain fancy confectionery products) from the allergen labelling requirements.

Certain foods sold at catering establishments (regulation 11)

Exempts food sold at catering establishments which is not pre-packed or which is pre-packed for direct sale, from the allergen labelling requirement.

Foods containing allergenic ingredients or their derivatives (regulation 12)

Sets out new provisions for indicating Schedule AA1 ingredients in the case of foods containing such ingredients and their derivatives in pre-packed food.

Insertion of Schedule AA1 in the Food Labelling Regulations 1996 (regulation 14)

Indicates insertion point of new Schedule AA1 in the Food Labelling Regulations 1996. It should be noted that this has now been superseded by the 2008 Regulations.

Amendment of Schedule 3 to the Food Labelling Regulations 1996 (regulation 15)

Deletes entries relating to "crystallised fruit" and "vegetables" from Schedule 3 (generic names in list of ingredients) in the Food Labelling Regulations 1996.

ANNEX 6

ANNEX 6 – CONTACT DETAILS FOR FURTHER INFORMATION

The address for all correspondence relating to the issues set out in this advice is:

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