



Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2004

IMPORTANT NOTE

1. These guidance notes have been produced with the aim of providing informal, non-statutory guidance on the following Regulations:

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

2. The notes are intended to be read in conjunction with

- The Regulations listed above;
- Directive 2003/89/EC amending Directive 2000/13/EC of the European Parliament and of 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;
- The Food Labelling Regulations 1996 (as amended), which implement Directive 2000/13/EC of the European Parliament and of the Council on the indication of ingredients in foodstuffs;
- The Food Standards Agency's Clear Labelling Advice, published in 2002;
- Other relevant guidance notes that are available on the Food Standards Agency's website (www.food.gov.uk); and
- The Food Safety Act 1990.

3. The examples that these notes contain are provided for illustration only. The reader is advised to seek further advice from their home authority on any specific queries.
4. The guidance notes, including advice and best practice, and the examples should not be taken as an authoritative statement or interpretation of the law, as only the Courts have this power and will ultimately decide whether, in particular circumstances, an offence has been committed.
5. Our aims in producing this advice are to help:
 - manufacturers, producers, retailers and caterers to adopt consistent, transparent, labelling practices.
 - enforcement authorities to identify and clamp down on misleading labelling.
 - consumers by encouraging industry to adopt consistent and transparent labelling practices to provide more information.

Guidance Notes

Introduction

The Food Labelling (Amendment) (No. 2) (England) Regulations 2004, in these notes referred to as 'the Regulations', implement Directive 2003/89/EC of the European Parliament and the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of ingredients present in foodstuffs. This will come into force on 25 November 2004 (from which date products that comply may be sold). Products that do not comply with the new rules will be prohibited from 25 November 2005, but products that have been labelled or marketed before 25 November 2005 may be sold while stocks last.

The Regulations set out new labelling rules on the indication of ingredients, particularly allergenic ingredients in pre-packed foods, including alcoholic drinks.

Purpose

These guidance notes have been produced with the aim of providing informal, non-statutory guidance on the Regulations and should be read in conjunction with them. These guidance notes are not exhaustive.

Status

These notes are advisory only. Any legal queries should be resolved by reference to the Regulations or Directive 2003/89/EC. Enforcement officers should be approached for advice on any point about the legislation, although ultimately only the Courts can interpret the law with any authority.

Interpretation of the Regulations

In these notes we have indicated the practices that we believe are acceptable. However, our advice is not authoritative. We strongly urge those planning to follow practices in respect of which more than one interpretation of the Regulations is possible, to seek the agreement of their Home Authority (i.e. the local authority designated as the relevant decision-making base for their enterprise) before taking any definite action.

In the case of small businesses or individuals that do not have a Home Authority, queries should be forwarded to the enforcement authority, that is, the Trading Standards or Environmental Health Department within their own local authority. For companies wishing to import into the UK, the Port Health Authority should be contacted, or their importing agents in the UK should contact the enforcement authority within their own local authority.

Brief overview of the new rules

1. Directive 2003/89/EC is an amendment of Directive 2000/13/EC, mainly of Article 6 of this directive on the definition and declaration of ingredients including additives. It deletes two entries from Annex 1 to Directive 2000/13/EC ('crystallised fruit' and 'vegetables'), so that that these category names may no longer be used in future. It also introduces a list of 12 ingredients known to cause allergies or intolerances (Annex to Directive 2003/89/EC and Schedule AA1 to the Regulations)¹.
2. The new rules require foods containing ingredients on the list in Schedule AA1¹ or their derivatives to make a clear reference to the Schedule AA1 name whenever they are used in pre-packed foods, including alcoholic drinks. There are exemptions for foods sold loose, food that is pre-packed for direct sale and certain fancy confectionery products.
3. The new rules remove the so-called '25% rule', under which individual components of a compound ingredient making up less than 25% of the finished product do not have to be listed.
4. In order to take account of technical constraints in the manufacture of foodstuffs, the new rules allow the following derogations for ingredients used at less than 2% of the finished product:
 - Where the composition of the compound ingredient is defined in EU law (e.g. jam and chocolate), the ingredients need not be listed.
 - Where the compound ingredient is a food for which an ingredients list is not required under Community law, the ingredients need not be listed.
 - A mixture of herbs and spices need not be listed individually.
 - Ingredients will not have to be listed in descending order of weight
 - The presence of similar or mutually substitutable ingredients could be indicated by use of "contains....and/or..." in certain circumstances.

These derogations do not override the allergen labelling requirements.
5. The new rules add a further category of substances not to be regarded as ingredients, and which accordingly do not have to be named.
6. The Regulations also delete the provision in regulation 23 of the Food Labelling Regulations 1996 as amended, which exempted flour confectionery in certain circumstances from most of the labelling requirements.

Organisation of the Regulations

¹ The Commission will issue technical guidance to help interpret the list in the Annex to Directive 2003/89/EC as required. The list may be updated (by Standing Committee procedure) on the basis of validated scientific knowledge. This could include an addition to or deletion from the list.

Title, application and commencement (regulation 1)

Contains the title by which the Regulations may be cited – The Food Labelling (Amendment) (No. 2) (England) Regulations 2004; the coming into force date – 25 November 2004; the country in which the Regulations apply - England.

Amendment of the Food Labelling Regulations 1996 (regulation 2)

Provides for the 1996 Regulations to be further amended as set out in regulations 3 to 15 of the Regulations.

Interpretation (regulation 3)

Includes a definition of 'allergenic ingredient' by reference to Schedule AA1 and a new definition of 'Directive 2003/13'.

Exemptions (regulation 4)

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

Order of ingredients (regulations 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 list of ingredients that need not be named.

Foods sold non-prepacked or pre-packed for direct sale (regulation 10)

Sets out provisions exempting food that is not pre-packed, similar food and certain fancy confectionery products from much of the ingredients listing requirements including the allergen labelling requirements.

Foods sold in catering establishments (regulation 11)

Sets out provisions exempting food sold in catering establishments from much of the ingredient listings requirement, including 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.

Transitional provisions (regulations 13)

Sets out transitional provisions for applying the new rules.

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

Indicates insertion point of new Schedule AA1 in the Food Labelling Regulations 1996.

Amendment of Schedule 3 of the Food Labelling Regulations 1996

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

Questions and Answers

Coming into force date

1. When do the Regulations come into force?

*Regulation 1 &
Regulation 13*

- 1.1 The Regulations come into force on 25 November 2004, from which date, products complying with the new rules may be sold. Products not complying will be prohibited from being sold from 25 November 2005. Products that were placed on the market or labelled before this date may be sold while the stocks last.

The scope of the new rules on allergen labelling

2. What categories of food are covered by the new rules?

- 2.1 The scope of application of the Regulations includes food in general including alcoholic drinks.

3. What about non-prepacked foods and foods sold in catering establishments?

*Regulation 10 &
Regulation 11*

- 3.1 The new rules do not apply to foods sold loose (non-prepacked), foods sold pre-packed for direct sale or certain confectionery products. The Agency is exploring options for making sure that under these circumstances, the consumer is still provided with adequate information.

4. What about foods in small packaging and certain indelibly marked bottles?

*Regulation 4 & Regulation 26 of
the Food Labelling Regulations
1996 as amended*

- 4.1 The new rules will apply.

5. Do the new rules apply to the use of 'may contain' (nut trace) warnings

- 5.1. No. The new rules relate to the indication of Schedule AA1 ingredients and their derivatives that have been deliberately added to foodstuffs. There is no legal requirement for food labels to carry 'may contain' or nut trace warnings, but 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.

- 5.2. Consumers have raised concerns about inappropriate use of nut trace warnings could unnecessarily restrict consumer choice and undermine valid warnings. The Agency is considering, along with stakeholders, how best to encourage provision of clearer, more helpful information for consumers with food allergies in these cases and will be consulting further on this later in the year.

Ingredient listing

6. Are there any changes to the order in which *Regulation 5* ingredients may be listed?

- 6.1. In some cases, yes. These are set out in regulation 5.
- 6.2. New regulation 13(5) removes 'mixed nuts' from the current exemptions in existing regulation 13(5) of the Food Labelling Regulations 1996 as amended.
- 6.3. New regulation 13(7) allows for ingredients making up less than 2% each of the finished product to be listed in a different order other than by ingoing weight after other ingredients.
- 6.4. New regulation 13(8) allows for ingredients other than additives or allergens listed in Schedule AA1, which are similar or mutually substitutable, that are not likely to alter the nature or perceived value and which make up less than 2% of the finished product, to be listed using the phrase 'contains and/or ', where more that one of such ingredients are present in the finished product. For example: varieties of dried vine fruit; varieties of citrus peel; sources of vegetable oil; glucose syrup or dextrose.

7. What about the 25% compound ingredients *Regulation 7* exemption?

- 7.1. The new rules remove the 25% compound ingredient exemption. With the exception of a very few cases, all ingredients will now have to be listed on food labels. The allergen labelling requirements override these exceptions.

8. Are there any ingredients that do not have to be *Regulation 7* listed?

- 8.1. Yes. The new rules exempt a small number of compound ingredients from the requirement to list their ingredients in cases where:
- (a) the composition of the compound ingredient is defined in Community legislation and it makes up less than 2% of the finished product (for

example, spreadable fats, fruit jams, cocoa and chocolate products – Appendix 3.A of the Regulations).

- (b) 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;
- (c) the compound ingredient is a foodstuff for which an ingredient list is not required under EU law (for example, fermentation vinegars, cheese, butter and fermented milk and cream)

8.2. The allergen labelling requirements override these exceptions, and they are also subject to special rules in the case of ingredients which are additives or have been irradiated.

Indication of allergenic ingredients

9. What categories of ingredients are covered by the new allergen labelling requirements?

9.1 The following categories of ingredients are covered by the new requirements, if they are present in the finished product, even in an altered form:

- all added ingredients and components of added ingredients (this includes items in Article 6.2 of Directive 2000/13/EC that are otherwise exempt from labelling requirements (eg fresh fruit, carbonated water, fermented vinegars and all compound ingredients);
- carry-over additives;
- additives used as processing aids;
- solvents and media for additives or flavourings; and
- any other substances used as processing aids.

10. Do the new rules require declaration of all ingredients known to cause allergy? *Regulation 12 & Schedule AA1*

10.1 No. Only the ingredients specified in Schedule AA1 to the Regulations and their derivatives will trigger the need to give allergen information.

10.2 The ingredients listed in Schedule AA1 include the following and their derivatives:

- Cereals containing gluten
- Crustaceans
- Fish
- Eggs
- Peanuts
- Soybeans
- Milk
- Nuts (namely, almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut)

- Celery
- Mustard
- Sesame seeds
- Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO₂

10.3 This list may 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.

11. Guidance on which foods fall within the list in Regulation 12 & Schedule AA1

- 11.1 The following is meant to provide guidance on the scope of each allergenic ingredient in Schedule AA1 to the Regulations. The terms used in listing allergenic ingredients should closely resemble those used in Schedule AA1 list 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 EFSA opinion (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.eu.int/science/nda_opinions_nda_04_en1.pdf).
- 11.2. **Cereals containing gluten:** 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 new rules.
- 11.3. **Eggs:** The new rules do not specify any species of eggs, but 'eggs' refer to eggs from laying hens as well as eggs from other birds, eg broiler chicken, duck, turkey, quail, goose, gull, and guinea fowl.
- 11.4. **Fish:** The new rules do not name any species of fish. However, 'fish' includes fish from all species of fish and fish products. Use of the common species names (eg 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 appreciated and to ensure that the nature of any exotic fish is made clear.
- 11.5. **Crustaceans:** The new rules do not name any species of crustaceans. However, 'crustaceans' includes all species of crustaceans (for example lobster, crab, prawns and langoustine). Although **molluscs** are known to cause allergic reactions in those who are susceptible, they are not currently included in the list of specified allergens. The Commission has indicated that they will be asking EFSA's opinion on this in the near future.

- 11.6. **Peanuts:** 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 the Directive.
- 11.7. **Soybeans:** In this case, terms such as 'soya' or 'soy' would be sufficient to indicate the soybean origin.
- 11.8. **Milk:** The new rules do not define any species of milk. However, 'milk' includes not only cows' milk, but also milk from sheep, goats and buffaloes etc. Care should be taken to ensure that unfamiliar dairy products used as ingredients (eg fromage frais, Mascopone, Cantal, quark) are clearly labelled by reference to milk. The presence of the milk sugar lactose also needs to be indicated as 'milk sugar' or with some other reference to milk.
- 11.9. **Nuts:** The new rules list these as: almond, hazelnut, walnut, cashew nut, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut. Other types of nuts, and other foods called nuts, for example pine nut and coconut, are therefore not included in the scope of the new rules. Nevertheless, chestnuts and pine nuts (which are not 'nuts') are also known to cause allergy in those who are susceptible. Best practice would therefore be to include them in allergen handling and labelling procedures.
- 11.10 **Celery:** This term is used generically in the new Regulations to refer both to celery (stick celery) and celeriac (root celery), and would be sufficient for the indication of both for allergen labelling purposes.
- 11.11 **Mustard:** This term refers to the mustard plant and other forms which originate from it, such as leaves, sprouted seeds, mustard flour, table mustard and mustard oils. The appropriate terms should be used in labelling.
- 11.12 **Sesame seeds:** This clearly refers to the seeds of sesame, but products deriving from it such as tahini and sesame oil would also trigger the allergen derivative labelling requirement.
- 11.13 **Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO₂:** This ingredient must be labelled when present above the level indicated (calculated in terms of the total SO₂ in the finished product). This additive should be declared by reference to the term 'sulphur dioxide' or 'sulphite' depending on the chemical nature. 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 SO₂) followed by the E-number (E-220 series), which is permitted under the additives Directive (95/2/EC) alone, would not be sufficient.

12. How should allergenic ingredients be indicated in the labelling of food? *Regulation 12 & Schedule AA1*

- 12.1. Where a food contains an allergenic ingredient or derivative and the allergenic ingredient is not clearly identified in the name of the food (eg scotch egg, peanut brittle and crab spread), the ingredient should always be identified with a clear reference to the name of the allergenic ingredient concerned. For example, fish gelatin, vegetable oil (with soya). It would be acceptable for an asterisk referring to the source allergen to be used in a footnote, provided that this would not be confused with other uses of asterisks (eg with reference to GM ingredients).
- 12.2. Note that the Agency's Clear Food Labelling Best Practice Advice already recommends the use of simple language, eg using "milk protein" instead of "casein". It also refers to examples of recommended ingredient names for consistent identification of the presence of food allergens and gluten (IGD – Voluntary Labelling Guidelines for Food Allergens and Gluten – website: <http://www.igd.com>). Three illustrative examples are "whey (from milk)", "couscous (wheat)", and "tahini (sesame)".
See <http://www.food.gov.uk/multimedia/pdfs/clearlabelling.pdf>
- 12.3. As there is no provision 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 (eg *from soya), provided that this would not be confused with other uses of asterisks (eg with reference to GM ingredients). Note that this will only work where there is one allergen source for an ingredient or ingredients. Where there is more than one, multiple asterisks could make the information confusing.
 - It would also be acceptable to identify the allergens in an allergen advice box without also including the allergen sources in brackets in the ingredients list.

13. What about drinks with an alcoholic strength by volume (abv) of more than 1.2%? *Regulation 12*

- 13.1. 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. For drinks with an alcoholic strength by volume (abv) of less than 1.2%, where ingredient listing is required, the provisions for indication of allergenic ingredients and their derivatives is the same as for other foods.

14. What about the derived ingredients?

*Regulation 12 &
Schedule AA1*

- 14.1. The scope of the requirements includes derivatives of ingredients listed in Schedule AA1. This is understood to mean any number of generations of derivation and assumes that, unless otherwise demonstrated, the allergenic potential remains. Following submission of data to the Commission demonstrating the lack of allergenic potential of an ingredient derived from an allergenic source, these derivatives may in future become exempt from the requirement to be declared by reference to the Schedule AA1 names (timetable at Appendix to the Guidance Notes).
- 14.2. For foodstuffs that are products of allergenic ingredients where the allergen would not normally be listed as an ingredient (eg cheese, yoghurt), best practice would be to declare the presence of the allergenic ingredient by reference to the Schedule AA1 name, eg 'contains milk'. The allergen labelling rules override generic name rules.

Contact Details for further information

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

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Appendix

Commission timetable for exemption of non-allergenic derivatives

Directive 2003/89/EC makes provision for future exemption by the Commission for derivatives which are no longer allergenic from the requirement to be listed by reference to the source allergen, provided there is supporting validated scientific data. The following sets out the Commission timetable for developing an initial list of derived ingredients that are not likely to trigger adverse reactions and may therefore be excluded from the requirement to be listed by reference to the source allergen in future.

- The Commission can be notified by 25 August 2004 of studies in hand to establish non-allergenicity of derived ingredients.²
- The Commission will decide by 25 November 2004 on a provisional list of derivatives to be excluded in consultation with the European Food Safety Authority (EFSA).
- Based on EFSA's opinion, the Commission will decide by 25 November 2007 whether or not to retain the exemption for the derivatives.

² Commission's guidelines on notification dossiers may be obtained by post or e-mail (please contact Andrew Stephenson (tel 020 7276 8147; e-mail Labelling@foodstandards.gsi.gov.uk).