

FOOD STANDARDS AGENCY CONSULTATION
Draft SI on the Food Labelling (Declaration of Allergens) (England)
Regulations 2009

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
6 July 2009	31 July 2009

Who will this consultation be of most interest to?

Wine producers, food manufacturers, producers, retailers and caterers. Also enforcement authorities.

What is the subject of this consultation?

Consultation on the draft SI on the Food Labelling (Declaration of Allergens) (England) Regulations 2009 and revised Guidance on Allergen and Miscellaneous Labelling Provisions.

What is the purpose of this consultation?

To obtain your comments on the impact of this SI and the wording of the draft SI on the Food Labelling (Declaration of Allergens) (England) Regulations 2009 and accompanying guidance notes.

Responses to this consultation should be sent to:

Name Olujuwon Adetokunbo

Division/Branch LSA Division, Food Allergy Branch

FOOD STANDARDS AGENCY

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Fax: 020 7276 8513

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Food Allergy Branch
Food Standards Agency
Room 511C Aviation House
125 Kingsway
London WC2B 6NH

Email: food.allergy@foodstandards.gsi.gov.uk

Is an Impact Assessment included with this consultation?

Yes

No See Annex A for reason.

Draft SI on the Food Labelling (Declaration of Allergens) (England) Regulations 2009

DETAIL OF CONSULTATION

Introduction

1. In 2008 there was a package of changes to allergen labelling legislation which meant that the temporary exemption from the allergen labelling provisions for a number of ingredients derived from the listed allergenic foods, including wine fining agents produced from egg and milk, expired with effect from 31 May 2009. This was enacted in England, and other devolved administrations, by the Food Labelling (Declaration of Allergens) Regulations 2008.
2. There has been a subsequent legal change by the Commission, which further extends from 31 May 2009 until December 2010 the temporary exemptions from the labelling provisions for egg- and milk-based fining agents used in wine.
3. This means that under current UK legislation we have the anomalous situation where enforcement officers have the powers to take action against products where the use of these wine fining agents has not been labelled but, under the Commission Regulation (EC) No 415/2009, producers are now not required to declare these ingredients on the label.

Proposals

4. The Food Labelling (Declaration of Allergens) (England) Regulations 2009 will resolve this anomaly and ensure clarity for food businesses and enforcement bodies.

Key proposal:

- **To provide an extension until December 2010 of the temporary exemption from labelling for egg albumin as a fining agent for wine and lysozym (produced from egg) used in wine and for milk (casein) used as a fining agent for wine.**

Consultation Process

5. The Food Allergy Branch has kept the relevant stakeholders informed about the progress of this Regulation and earlier this year conducted an informal consultation to seek views when the Regulation was discussed at the European Commission.

Questions asked in this consultation:

- Q1: The Agency is seeking your views on the draft SI and on the revised Guidance on Allergen and Miscellaneous Labelling Provisions.**
- Q2: The Agency has been advised that this change in enforcement powers does not have any financial impact. However, we would welcome your views on this issue.**

6. The Agency is interested in your views on these points and, in particular, in the views of the food industry and enforcement officers.

7. The Agency would also welcome your general feedback on both the consultation package and the overall consultation process. If you would like to help us to improve the quality of future consultations or comment on this consultation, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire.

Other relevant documents

8. Attached you will find copies of:

- Draft Food Labelling (Declaration of Allergens) (England) Regulations 2009
- Revised Guidance on Allergen and Miscellaneous Labelling Provisions.

Responses

9. Responses are required by **close 31 July 2009**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

10. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

SUE HATTERSLEY

(Head of Food Allergy Branch)
Food Allergy Branch
Labelling, Standards and Allergy Division

Enclosed

- Annex A: Standard Consultation Information
- Annex B: Draft Regulations
- Annex C: Revised Guidance Notes
- Annex D: List of interested parties
- Annex E: Cabinet Office Consultation Criteria (For those receiving this by post only)
- Annex F: Consultation Feedback Questionnaire (For those receiving this by post only)
- Annex G: Publication of Personal Data Form (For those receiving this by post only)

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf> Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex D. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: <http://www.berr.gov.uk/files/file47158.pdf> The Consultation Criteria are available at <http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>

8. **Criterion 2 of HM Government Code of Practice on Consultation states Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.** To resolve the situation described above, this consultation will be for 4 weeks to enable us to prepare the new legislation and lay it as soon as possible in the next parliamentary session.

9. **The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation.** As producers are now not required to change the labels on their wine until the end of 2010, there is no

incremental impact from this legislation and therefore an Impact Assessment has not been prepared. However, if as a result of this consultation it was discovered that there was an unforeseen financial impact, an Impact Assessment would be prepared at that stage.

10. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at

<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>

12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at <http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc> The questionnaire can also be used to update us about your existing contact details.

S T A T U T O R Y I N S T R U M E N T S

2009 No. 0000

FOOD, ENGLAND

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

<i>Made</i> - - - -	2009
<i>Laid before Parliament</i>	2009
<i>Coming into force</i> - -	2009

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a) and 48(1) of the Food Safety Act 1990(a), and now vested in him(b).

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, application and commencement

1. These Regulations may be cited as the Food Labelling (Declaration of Allergens) (England) Regulations 2009, apply in relation to England only and come into force on [] 2009.

-
- (a) 1990 c. 16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), (“the 1999Act”). Section 48 was also amended by S.I. 2004/2990. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act..
- (c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 202/2008 (OJ No. L60, 5.3.2008, p.16).

Amendment of the Food Labelling Regulations 1996

2.—(1) The Food Labelling Regulations 1996(a) are amended (in so far as they apply in relation to England) in accordance with paragraph (2).

(2) In regulation 50 (transitional provision), omit paragraph (15) and substitute the following —

“(15) In any proceedings for an offence under regulation 44(1)(a) it shall be a defence to prove that —

- (a) (i) in the case of wine in which lysozym or albumin produced from egg or milk (casein) products has been used as a fining agent, the food concerned was sold before 31st December 2010 or marked or labelled before that date; or
- (ii) in the case of any other food, the food concerned was sold before 31st May 2009 or marked or labelled before that date; and
- (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations if the amendments made by regulation 2 of the Food Labelling (Declaration of Allergens) (England) Regulations 2008(b) had not been in operation when the food was sold.”.

Revocations

3. The following provision is revoked —

- (a) Regulation 2(6) of The Food Labelling (Declaration of Allergens) (England) Regulations 2008.

Signed by authority of the Secretary of State for Health

Date

Name
Minister of State
Department of Health

(a) S.I. 1996/1499, as last amended by S.I. 2008/1188. Regulations 13(8)(c) and 34B and the associated Schedule AA1 were inserted by S.I. 2004/2824. Regulation 34B was amended by S.I. 2005/2057; Schedule AA1 was amended by S.I. 2007/3256 and by SI 2008/1188. Paragraph (13) of regulation 50 was inserted by S.I. 2005/899, paragraph (14) of that regulation by S.I. 2007/3256 and paragraph 15 of that regulation by S.I. 2008/1188.

(b) S.I. 2008/1188.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations further amend the Food Labelling Regulations 1996 (“the principal Regulations”) in so far as they apply in relation to England. The principal Regulations extend to the whole of Great Britain.

2. These Regulations implement in England the amendment made to Directive 2007/68/EC by Commission Regulation (EC) No. 415/2009 (OJ No. L125, 21.05.2009, p.52). This Directive itself amends Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. The ingredients in question are those that are likely to cause an allergic reaction in some consumers.

3. The Regulations amend the principal Regulations in respect of the labelling requirements for foods containing allergenic ingredients, including labelling exemptions for certain processed forms of those ingredients, by extending the transitional period for lysozym and albumin produced from egg or milk (casein) products used as fining agents in wine from 31st May 2009 to 31st December 2010 in respect of foods that are marked, labelled or sold before that date.

4. An impact assessment has not been prepared for this instrument as it has no impact on business or the public or third sectors.



Guidance on Allergen and Miscellaneous Labelling Provisions

July 2009

If you require this information in an alternative format – such as audio, large print, Braille – please contact us.

CONTACT TELEPHONE

020 7276 8531

Summary

Intended audience:	Food manufacturers, producers, retailers and caterers. Also 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

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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

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

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

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

INTRODUCTION

1. These guidance notes cover the interpretation of the Regulations 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 and 2009 Regulations which amend the Food Labelling Regulations; 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 the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.

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 'crystallised 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 and the 2009 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 40 - 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 Agency’s Clear Food Labelling Best Practice Advice already 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 (IGD – Voluntary Labelling Guidelines for Food Allergens and Gluten – website: <http://www.igd.com>). Three illustrative examples are “stock (from fish)”, “couscous (wheat)”, and “tahini (sesame)”.

See <http://www.food.gov.uk/multimedia/pdfs/clearlabelling.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). The term 'celery' also includes celery seeds and celery oil.

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 wheat allergy.

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.

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.eu.int/science/nda_opinions_nda_04_en1.pdf

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).

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 2003 (as amended), the schedule to which was updated in 2006, with the latest version being found in The Fish Labelling (Amendment) (England) Regulations 2006 (SI 2006 No. 506) and parallel legislation elsewhere in the UK. In these Regulations the term "fish" also includes crustaceans and molluscs.

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 (England) Regulations 2003 (SI 2003 No. 461) and parallel legislation elsewhere in the UK⁴.

25. Please note that the schedule was updated in 2006, with the latest version being found in The Fish Labelling (Amendment) (England) Regulations 2006 (SI 2006 No. 506) and parallel legislation elsewhere in the UK⁵.

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 elsewhere in the UK are:-

The Fish Labelling (Scotland) Regulations 2003 (SI No. 145),

The Fish Labelling (Wales) Regulations 2003 (SI No. 1635 (W.177)),

The Fish Labelling Regulation (Northern Ireland) 2003 (S.R.2003 No.160).

⁵ The relevant Regulations elsewhere in the UK are:-

The Fish Labelling (Scotland) Amendment Regulations 2006 (SI No.105)

The Fish Labelling (Wales) (Amendment) Regulations 2006 (SI No. 1339 (W.131)),

The Fish Labelling (Amendment) Regulations (Northern Ireland) 2006 (S.R. 2006 No. 116).

Lupin

26. 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)

27. 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

28. 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 2003 (as amended), the schedule to which, was updated in 2006, with the latest version being found in The Fish Labelling (Amendment) (England) Regulations 2006 (SI 2006 No. 506) and parallel legislation elsewhere in the UK. In these Regulations the term “fish” also includes crustaceans and molluscs.

Mustard

29. 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. The rules do not name any particular species of mustard and therefore should be applied to all.

Nuts

30. 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.

BEST PRACTICE

Other types of nuts, and other foods which although, strictly speaking, are not nuts (ie pine nuts and coconut), are called nuts, are not named in the rules. Chestnuts and pine nuts are also known to cause allergy in some people. Best practice would therefore be to include them in allergen handling and labelling procedures.

Peanuts

31. 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.
32. Refined or 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

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

Soybeans

34. 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.)

35. 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

36. Certain ingredients 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 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 be exempt from labelling until 31 May 2009 but must be labelled after that date. Any products that have been labelled under the old rules and are still on the market at that date may continue to be sold until stocks are exhausted.

Derived ingredients

37. 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.
38. 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.
39. 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

40. 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

41. 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

42. 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

43. 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). These exemptions expired on 25 November 2007.

44. Following an assessment by the European Food Safety Authority (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.

See paragraph 36 for a list of ingredients that were on the temporary list but from 31 May 2009 are no longer exempt.

45. Under these 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

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

47. 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

48. 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

49. 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 <http://www.food.gov.uk/multimedia/pdf/maycontainguide.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 will be published before that date.
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)⁶, 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

⁶ The General Food Law Regulations (NI) 2004 (as amended) in Northern Ireland

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.

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

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

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

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

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 UK⁷ 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 UK⁸ implemented Directive 2005/63/EC,

⁷ 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)

⁸ 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)

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 have 12 months to make the necessary label changes. It will not be 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 may be sold while the stocks last.

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) Regulations 2005 and parallel legislation elsewhere in the UK⁹.

⁹ The relevant Regulations elsewhere in the UK are:-

The 2009 Regulations came into force on [xxxxx] 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 provide a temporary exemption from labelling for egg albumin as a fining agent for wine and lysozym (produced from egg) used in wine and for milk (casein) used as a fining agent for wine until December 2010.

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)

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 and 2009 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.
- Eggs¹⁰.
- 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.

¹⁰ There is a temporary exemption from labelling for egg albumin used as a fining agent for wine and lysozym (produced from egg) used in wine until December 2010.

(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)¹¹, 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.

¹¹ There is a temporary exemption from labelling for milk (casein) used as a fining agent for wine until December 2010.

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/cs_p/KSearch.do

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 – 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 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;
- The Food Labelling Regulations 1996 (as amended), which implement (among other EC legislation) Directive 2000/13/EC as amended;
- Directive 2000/13/EC as amended
<http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/2000/L/02000L0013-20040501-en.pdf>
- 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 1990¹² ; 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.

¹² 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.

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 – CONTACT DETAILS FOR FURTHER INFORMATION

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

In England: Labelling, Standards and Allergy Division
 Food Standards Agency
 Aviation House
 125 Kingsway
 London
 WC2B 6NH
 Tel: 0207-276-8531
 Fax: 0207-276-8193
 E-mail: dionne.davey@foodstandards.gsi.gov.uk

In Wales: Food Standards Agency Wales
 11th Floor, Southgate House
 Wood Street
 Cardiff
 CF10 1EW
 Tel: 029 2067 8911
 Fax: 029 2067 8918/8919
 E-mail: wales@foodstandards.gsi.gov.uk

In Scotland: Food Standards Agency Scotland
 St Magnus House
 6th Floor
 25 Guild Street
 Aberdeen
 AB11 6NJ
 Tel: 01224 285165
 Fax: 01224 285168

In Northern Ireland: Food Standards Agency Northern Ireland
 10 A-C Clarendon Road
 Belfast
 BT1 3BG
 Tel: 028 9041 7742
 Fax: 028 9041 7726
 E-mail: Mervyn.Briggs@foodstandards.gsi.gov.uk

List of Interested Parties List

3663 First for Foodservice	Barnet London Borough Council
4Children	Barry Atwood
A.G. Barr plc	Batemans
Abbot Laboratories Limited	Bee Farmers' Association of the UK
ABR Foods	Bee Services
Adamson BSMG	Belso's (UK) Cereals Ltd
Advertising Association	Bernard Matthews Farms Ltd
Advertising Standards Authority	Berry Ottaway and Associates Limited
Advisory Body for Social Services Catering	Beth-Din
Advisory Committee on Animal Feedingstuffs	BHF Health Promotion Research Group
Agricultural Industries Confederation	Bioforce (UK) Ltd
Agriculture and Horticulture Development Board	Bird & Bird
Alcontrol Laboratories	Bird & Bird
Al-Khoei Foundation	Birmingham Childrens Hospital
Allchem International	Birmingham City Laboratories
Allied Bakeries Lid	Birmingham Library Services
Allied Domecq Retailing Ltd	Bodycote Birmingham
Allied Technical Centre	Bodycote Lawlabs
Allsports International Ltd	Bolton Council
Alpha Flight Services	Bonnia Petite Banqueting Ltd
American Food International	Booker Ltd
American Peanut Council	Boots UK Limited
Amicus	Bourne Leisure
Anaphylaxis Campaign UK	Bourne Salads
Animal Medicines Inspectorate	Bournemouth University
An-Nisa Society	Bradford Council of Mosques
Asda Stores Limited	Brake Co Ltd
Asda Stores Limited	Brakes Group
Ashtown Food Research Centre	Brent Council
Ashwell Associates	Bristol City Council
Assistante Sectorielle Agro-Alimentaire	Britannia Health Products Ltd
Associated British Foods plc	British Airways Health Services
Association of British Abattior Owners	British Association for Shooting and Conservation
Association of Cereal Food Manufacturers	British Beekeeper's Association
Association of Convenience Stores	British Beer and Pub Association
Association of Muslim Scholars	British Caramel Manufacturers Association
Association of Pastry Chefs	British Cheese Board
Association of Port Health Authorities (APHA)	British Coffee Association
Association of Public Analysts of Scotland	British Dental Association
Association of Radical Midwives	British Dietetic Association
Assured British Meat	British Egg Industry Council
Assured Food Standards	British Essential Oils Association
Authentixs	British Fermentation Products
Baby Milk Action	British Food Importers & Distributors Association
Baker & McKenzie	British Frozen Food Federation
Bakkavor (Birmingham) Ltd	British Fruit Juice Association
Bangladesh Caterers Association UK	British Goat Society
Barbour Index plc	British Heart Foundation
Barentz BV	British Herbal Medicine Association

British Hospitality Association
 British Humanist Association
 British Meat Processors Association
 British Nutrition Foundation
 British Pig Association
 British Potato Marketing
 British Poultry Council
 British Retail Consortium
 British Sandwich Association
 British Soft Drinks Association Ltd
 British Standards
 British Sugar plc
 British Veterinary Association
 Britvic plc
 Buckinghamshire County Council
 Buckinghamshire Health Authority
 Business In Sport and Leisure
 Cadbury Schweppes plc
 Camacom Law Solicitors Ltd
 Camacon Law Solicitors Ltd
 Cambridge Manufacturing Company Ltd
 CAMedica
 Campden & Chorleywood Food Research Association
 Campden BRI
 CAMRA (Campaign for Real Ale Ltd)
 Cantox Health Sciences International
 Cartmel Sticky Toffee
 Carver Wilde Communications Ltd
 Catalent Pharma Solutions
 Caterer & Hotelkeeper
 Catering Update
 CCI
 Cellife UK Ltd
 Centre for Food & Health Studies Ltd
 Cereal Partners UK
 Charles arker plc
 Chartered Institute of Environmental Health
 Chemist & Druggist
 Child Action Prevention Trust
 Chilled Food Association Ltd
 Chinese National Healthy Living Centre
 Chocolates for Chocoholics Ltd
 Christchurch
 Churches' Commission for Inter-Faith Relations
 Clarke Willmott Solicitors
 Coastal Trading
 Cobra
 Coca Cola Trading Company
 Coca-Cola Great Britain & Ireland
 Coeliac UK
 Community Foods Ltd
 Community Nutrition Group
 Community Practitioners and Health Visitors Association
 Confederation of British Industry
 Confederation of Indian Organisations (UK)
 Constellation Europe (Holdings) Ltd
 Consumer Focus
 Consumer Focus Wales
 Contract Food Ltd
 Cookie Man Ltd.
 Co-operatives UK
 Coors Brewers Plc
 Cosucra
 Cott Beverages Ltd
 Council For Responsible Nutrition
 Counsel Ltd
 Countryside Alliance
 Coventry Health Authority
 Craigavon Area Hospital Group NSS
 Cranberry Foods
 Cullinane Associates Ltd
 Cumbria County Council
 D & T Association
 Dabur India Ltd
 Dabur Research Foundation
 Dailycer Ltd
 Dairy Council
 Dairy Crest Group PLC
 Dairy UK Ltd
 Dale Farm (GB) Ltd
 Dame Diana Mossop
 Danish Bacon & Meat Council Ltd
 DBC Foodservice
 Del Monte Foods (UK) Ltd
 Department for Business, Enterprise and Regulatory Reform
 Department for Culture, Media and Sport
 Department for Environment, Food and Rural Affairs
 Department for Innovation, Universities and Skills
 Department of Local Government & Environment
 Dept of Agriculture for NI
 Derbyshire County Council
 Diageo
 Dr Andrew Smith
 Dr Juliet Gray
 Dr Len Levy
 Dr Oswald Morton
 Dr Paul Brantom
 Dr Richard Moody
 Dr Robert Woodward
 Dr Stuart's Botanical Teas
 Dr T Knowles
 Dr WR Hare
 Dr YK Tohani
 Druces & Attlee
 Durham County Council
 EA Griffiths and Son
 East and North Herts. NHS Trust
 East Riding of Yorkshire Council

East Sussex County Council
Edlong Company Ltd
Elks Biscuits
Ellis Labels & Systems Ltd
English Tourist Board
Environmental Data Services
Environmental Health and Trading Standards Service
Essential Trading Co-operative Ltd
Essfoods Limited
Eurofins Laboratories Ltd
European Federation of Health Product Manufacturers Association
European Food Law Association UK
Eversheds
F I Data Services
Farm Retail Association
Federation of Bakers
Federation of Danish Pig Producers & Slaughterhouses
Federation of Jain Organisations
Federation of Synagogues
Fibrisol Service Ltd
Firmenich, Wellingborough (UK) Ltd
Fish Technology Consultant
Fishmonger's Company
Food Additives and Ingredients Association
Food and Drink Federation
FOOD BRAND GROUP (THE)
Food Brands Group
Food Commission UK Ltd
Food Consultancy
Food Engineering International Magazine
Food GB Ltd
Food Labelling Database
Food Law Group
Food Standards Agency - Northern Ireland
Food Standards Australia New Zealand
FoodChain Europe Ltd
Foods Matters Magazine
Forum Products Ltd
Frensenius Kabi Ltd
Fresh Produce Consortium
Fresh-Pak Chilled Foods Limited
Friday's Ltd
Friends of the Earth
FSA Advisory Committee for Wales
Fuel PR (Clients Include Danone)
G R Lane Health Products Ltd
Galactosaemia Support Group
General Dietary Ltd
Gin & Vodka Association
Giract
Girag SA
Glenryck Foods Ltd
Gloucester City Council
Gm Freeze Campaign
Goodman Derrick
Government Of Western Australia
Greencity Wholefoods
Greencore Grocery
Greenwoods Solicitors LLP
H J Heinz
H M Prison Service
H T Webb & Co Ltd
Halal Food Authority
Halal Meat
Halewood International Ltd
Halton Borough Council
Hampshire County Council
Hampshire Scientific Services
Handmade Cake Company
Harrods Ltd
Harrow London Borough Council
Hartwell Food Research Ltd
Hazlewood
Healan Ingredients Ltd
Health Care Products
Health Food Manufacturers' Association
Heather Paine Associates
High Commission for the Republic of South Africa
Hildreth & Cocker Ltd
HM Prison Service Catering Group, Peat House
Honey Association
Hospital Caterers Association
Howard Foundation Research Group
HUSH (Haemolytic Uraemic Syndrome Help)
Ice Cream Alliance
Ice Fresh Foods LTD
Ilchester Cheese Co Ltd
ILS Ltd
Imams and Mosques Council (UK)
Incorporated Society of British Advertisers
Independent Nutrition Logic
Innocent Ltd
Institute of Education
Institute of Food Research
Institute of Food Science & Technology (IFST)
Institute Of Refridgeration
Inter Faith Network for the UK
International Fish Meal & Oil Manufacturers Association
International Flight Catering
International Marketing
International Meat Trade Association
International Pectin Producers' Association
International Soft Drink Council
Interserve (Facilities Management) Limited
Isbourne Environment Ltd
Iskcon
Islamic Centre of Glasgow

Islamic Food & Nutrition Council	Lovells
Islamic Forum of Europe	Lyons Tetley Ltd
Islamic Shariah Council	Lysi HS
Isle of Man Government	Macfarlanes
ISP Alginates	Maltsters Association of Great Britain
J Ralph Blanchfield Consultancy	Manchester Rusk Co Ltd
J Sainsbury plc	Mardon Plc
Jain Network	Markazi Jamiat Ahle Hadith
James Gilbertson & Co	Marks and Spencer Plc
Jean Garon Public Relations	McCormack FOODS
Jetro London	McDonald's Restaurants Ltd
John Russell Associates/FAIA	Mckenna & Co
John Taylor and Son	Med & Healthcare Prod Reg Affairs (MHRA)
John West Foods Ltd	Meridian Foods
Johnston Consulting	Micron2 Ltd
Joint Council for Anglo Caribbean churches	Midwives Information and Resource Service
Just Rachel Quality Desserts	Milton Keynes Council
K J Lovering & Co Ltd	Ministry of Defence
Kapajo.com	MJSR Associates
Keller & Heckman LLP	Moy Park Ltd
Kellogg Company (GB) Ltd	MP Media Services
Kellogg Europe Trading Limited	Mr Andrew Murphy
Kelloggs Europe Trading Ltd	Mr B Prouse
Kent County Council Trading Standards	Mr David Clarke
Kerry Foods UK	Mr Dennis T Gordon
Kettle Foods	Mr DW Williams
Kikkoman Trading Europe GmBH	Mr Edward Langridge
Kinnerton Confectionary Co Ltd	Mr Ewan McLachlan
Kitchen Range Foods Ltd	Mr Gifts
Kraft Foods UK Ltd	Mr H Plant
L Hepner & Associates Ltd	Mr HA Prowse
La Leche League (Great Britain)	Mr J Marsh
Laboratory of The Government Chemist (LGC)	Mr Keith Lister
Lambeth Trading Standards	Mr Leon Hanson
Lancashire County Council	Mr M Coleman
Law Commission	Mr Matti Alderson
Lawcode	Mr Paul Anthony Taylor
Lawdata Ltd	Mr R McKinley
Lawrence Graham	Mr RJ Brien
Lead Development Association International	Mr Robert Lippett
Leatherhead Food International	Mr T Lynn
Leeds Metropolitan University	Mrs A Campbell
Leicestershire County Analyst Lab	Mrs Brenda Mitchell
LGC (Teddington) Ltd	Mrs Bunty Benham
LGC Limited	Mrs Fiona Horne
Lidl UK GmbH	Mrs G Ward
Linx Printing Technologies Plc	Mrs Helen Gardiner
Local Authorities Co-Ordinators Of Regulatory Services	Mrs Holland
London Borough of Barking & Dagenham	Mrs I Warn
London Borough of Brent (Environmental Health)	Mrs J Ammon
London Borough of Southwark	Mrs J Hinchcliffe
London Metropolitan University	Mrs J Partridge
London Retail Meat Traders Association	Mrs Margaret Spirito-Perkins
Lovell White Durrant Solicitors	Mrs S Hammond

Mrs S Whittle
Mrs SJ Higgins
Mrs Sue Caden
Mrs Tracy Adams
Mrs V Reville
Ms alice mthijssen
Ms Anna Morris
Ms Anne Clayson
Ms Barbara Saunders
Ms Christine Seymour
Ms Colette Whitehead
Ms Eva Lewis
Ms helen Turbball
Ms J Fleming-Yates
Ms Jacquie Salfield
Ms Joan Sitett
Ms Joanne Woolgar
Ms Lucy Eldridge
Ms Lyn Anderson
Ms Margaret Anderson
Ms Michelle La Belle
Ms Paulette Jones
Ms Pauline Rigby
Ms Shirley Bond
Ms Valerie Thomas
Muller Dairy (UK) Limited
Multi Labels Limited
Muslim College
Muslim Doctors & Dentists Association
National Association of British and Irish Millers
National Association of Cider & Perry Makers
National Association of Health Stores
National Association of Master Bakers
National Beef Association
National Childbirth Trust
National Consumer Federation
National Council of Hindu Temples UK
National Council of Women of Great Britain
National Dried Fruit Trade Association
National Edible Oil Distributors Association
National Farmers Union (NFU)
National Federation of Fisherman's Organisations
National Federation of Meat and Food Traders
National Federation Of Women's Institutes
National Heart Forum
National Institute For Health & Clinical Excellenc
National Institute of Medical Herbalists
National Market Traders' Federation
National Pig Association
National Society for Phenylketonuria
NCH Action For Children
Nestle Confectionery (UK)
Network of Sikh Organisations UK
Neville Craddock Associates
New Covent Garden Food Co Ltd
Newcastle Upon Tyne City Library
Newspaper Society
North Yorkshire East Federation of Women's Institute
Northamptonshire County Council Trading Standards
Norton Rose
Nottinghamshire County Council
Nutragen Ltd
Nutricia Ltd
Nutrilaw
Nutrilicious
Nutritional Healthcare R & D
O&F Consulting
Oddbins
Odysea Ltd
Orafti
Orangina Group
Organix Brands plc
Oxfam Fair Trading Company
PepsiCo UK
Perrigo UK
Pizza Hut (UK) Limited
Plymouth and District Soroptimist International
Potters Herbal Supplies Ltd
Power Health Products Ltd
Premier Foods Ltd
Premier Foods plc
Premier Grocery Products Ltd
Prime Minister's Office
Professor Peter Aggett
Proprietary Association of Great Britain
Protein Technology International
Provision Trade Federation
Quality Meat Scotland
Queen Elizabeth Hospital
Quest Vitamins Ltd
QVC
R Twining and Co Ltd
Reigate and Banstead Borough Council
RHM Grocery
Rio Trading Company (Health) Ltd
Rocwell Natural Mineral Water
Ron Dewdney Ltd
Rotherham Health Authority
Royal College of Midwives
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal Commission on Environmental Pollution
Royal National Institute for the Blind
Royal National Institute of Blind People
Royal Pharmaceutical Society of Great Britain
Royal Society for Public Health
Royal Society for the Promotion of Health
Rupert Stanley College of Further Education

Russell Hume
Ryvita Co Ltd
S M A Nitrician
S&N UK
Samuel Smith Brewery
School of Science & Technology
Scotch Whisky Association
Scottish Executive Rural Affairs Dept
Scottish Federation of Meat Traders Association
Scottish Food and Drink Federation
Scottish Salmon Producers' Organisation
Seafish
Sefcol Ingredients Limited
Shellfish Association of Great Britain
SHS International Limited
Simkins Partnership
Simmons & Simmons solicitors
Simply Organic
Simtom Food Products
SiS (Science in Sport) Ltd
Sleaford Quality Foods Limited
Slough Borough Council
SMA Nutrition
Small Independent Brewers Association
SMH Consultancy
Snack, Nut & Crisps Manufacturers Association
Sodexo UK & Ireland
Somerfield Stores Limited
South Bank University
Southall Area Community Network
St George's, University of London
Staffordshire County Analyst
Starbake Yorkshire Ltd
Stephen Rhodes Associates
Stute Foods Ltd
Surrey County Council
Surrey Trading Standards
Taylor Joynson Garrett
Tesco Stores plc
The Basic Skills Agency
The British Standards Institution
The Co-operative Group
The Dairy Council
The Food Commission
The London Beth Din - Kashrut Division
The Nutrition Society
The Royal College of Midwives
The Sugar Bureau
Thomas Lownes and Co Ltd
Thompson & Capper Ltd
Thorntons plc
Traditional Farmfresh Turkey Association
Transport and General Workers' Union
Treats Ice Cream Ltd
Tulip Ltd
Udex Ltd
UK Action Committee on Islamic Affairs
Unigreg Limited
Unilever plc
Unilever UK limited
Union of Muslim Organisations of UK & Eire
Union PSD
United Biscuits (UK) Ltd
United Group RMD
United Kingdom Vineyards Association
University Glyndwr
University of Birmingham
University of Bradford
University of Dundee
University of Reading
University of Sussex
Univ-Vite Export Ltd
Vegan Society
Vegetarian & Vegan Foundation
Vegetarian Economy and Green Agriculture
Vegetarian Society of the United Kingdom
Venture Foods (UK) Limited
Vinegar Brewers' Federation
Vion Food Group UK
Vitrition UK Ltd
Voicevale Ltd
Walker & Sons (Leicester) Ltd
Walkers Charnwood Bakery
Walsall Metropolitan Borough Council
Warwickshire County Council
Weetabix Limited
Welsh Assembly Government
Welsh Food Alliance
Wessex Foods
West Berkshire District Council
West Yorkshire Joint Services
Western Group Environmental
Westler Foods Ltd
Which?
Whitby Seafoods Ltd
Whitehouse Consultancy Ltd
Whitehouse Consulting
Wickham Laboratories Ltd
Wiltshire County Council
Wiltshire Direct Services
Wine and Spirit Trade Association
Women's Food & Farming Union
Worcestershire Scientific Services
www.clearlabelling.com
Xyrofin (UK) Ltd
Yakult UK Ltd
Young's Seafood Limited
Zoroastrian Trust Funds of Europe