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Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2005

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) (England) (No. 2) Regulations 2005
   - The Food Labelling Amendment (Scotland) (No. 2) Regulations 2005
   - The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2005
   - The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) (2005

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

   - The Regulations listed above;
   - Commission Directive 2005/26/EC, establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC EC of the European Parliament and of the Council;
   - 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, as amended by Directive 2003/89/EC;
   - The Food Labelling Regulations 1996 (as amended), which implement Directive 2000/13/EC;
   - Guidance Notes on the Food Labelling (Amendment) (No. 2) Regulations 2004;
   - 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, (in Northern Ireland the Food Safety (N.I.) Order 1991 applies).

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.

Overview of the New Rules

Introduction

1. The Food Labelling (Amendment) (England) (No.2) Regulations 2004 (allergen labelling rules), implementing Directive 2003/89/EC came into force in England on 26 November 2004. There is a transitional provision in those Regulations as regards products marketed or labelled before 25 November 2005. The rules establish a list of allergens that have to be indicated whenever they or their derivatives are present 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).

2. The Commission recognised that not all ingredients that have to be indicated according to the allergen labelling rules will necessarily be allergenic in practice. This is because in some cases, processing removes the allergenic factor. Directive 2005/26/EC therefore makes provision for allergen derivatives that are no longer allergenic (based on the opinion of the European Food Safety Authority-EFSA) and are therefore unlikely to trigger allergic reactions, to be temporarily exempted from allergen labelling rules. Pending final results of studies being carried out to demonstrate their non-allergenicity, the Commission will finalise the list by 25 November 2007 at the latest.

3. The Food Labelling (Amendment) (England) (No. 2) Regulations 2005, in these notes referred to as 'the Regulations', implement Commission Directive 2005/26/EC, establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC EC of the European Parliament and of the Council. This will come into force on 25 November 2005. The Regulations set out 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.

4. Separate, but parallel legislation applies in respect of Scotland, Wales and Northern Ireland.

Purpose of Guidance Notes

5. 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

6. These notes are advisory only. Any legal queries should be resolved by reference to the Regulations, the Food Labelling Regulations 1996, as amended, and Directives 2005/26/EC, 2003/89/EC, and 2000/13/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

7. 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.

8. 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 Authorities or Port Local Authorities should be contacted. Importing agents in the UK should contact the local authority in which their business head office is based.

DRAFT

Questions and Answers

Coming into force date

1. When do the Regulations come into force? *Regulation 1*

1.1 The Regulations come into force on 25 November 2005.

1.2 From this date ingredients in the Schedule to the Regulations will not have to be indicated according to the allergen labelling rules until 25 November 2007, although they will still have to be indicated according to the general labelling rules set out in the Food Labelling Regulations 1996, as amended.

The scope of the Regulations

2. What is the scope of the Regulations?

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

Labelling of non-allergenic derived ingredients

3. What ingredients do the Regulations exempt from allergen labelling rules? *Schedule to the Regulations*

3.1 Ingredients exempt from allergen labelling rules are listed in the Schedule to the Regulations and set out in the table below. The list is based on EFSA's assessment of the individual dossiers submitted by manufacturers. Full details of the opinions on these may be obtained from the EFSA website (**http://www.efsa.eu.int**), the reference for individual opinions is attached in the Annex to the Guidance Notes.

Column 1 **Allergenic ingredient**	**Column 2** **Ingredients derived from allergenic ingredient in Column 1 that do not have to be labelled as allergens**
Cereals containing gluten	Wheat based glucose syrups including dextrose.[1] Wheat based maltodextrins.[1] Glucose syrups based on barley. Cereals used in distillates for spirits.

Eggs	Lysozym (produced from egg) used in wine. Albumin (produced from egg) used as fining agent in wine and cider.
Fish	Fish gelatine used as carrier for vitamins and flavours. Fish gelatine or Isinglass used as fining agent in beer, cider and wine.
Soybean	Fully refined soybean oil and fat.[1] Natural mixed tocopherols (E306), natural D–alpha tocopherol, natural D–alpha tocopherol acetate, natural D–alpha tocopherol succinate from soybean sources. Vegetable oils derived phytosterols and phytosterol esters from soybean sources. Plant stanol ester produced from vegetable oil sterols from soybean sources.
Milk	Whey used in distillates for spirits. Lactitol. Milk (casein) products used as fining agents in cider and wines.
Nuts	Nuts used in distillates for spirits. Almonds and walnuts used as flavour in spirits.
Celery	Celery leaf and seed oil. Celery seed oleoresin.
Mustard	Mustard oil. Mustard seed oil. Mustard seed oleoresin.

[1]And their products, in so far as the process they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

4. Is the exemption for ingredients in the Schedule to the Regulations final?

4.1. No. The exemption is provisional and lasts until 25 November 2007.

4.2. The Commission has asked industry to provide final results of studies currently being carried out to demonstrate the non-allergenicity of ingredients in the Schedule to the Regulations. Following evaluation by EFSA, the Commission will decide by 25 November 2007 whether or not to retain the exemptions. This decision will be incorporated into UK legislation by means of new legislation.

4.3. Industry can also make submissions for exemption of other derived ingredients at any time for consideration [by the 25 November 2007 deadline].

5. Can the exemptions be extended generically to other similar derived ingredients manufactured by methods other than that specified in the dossiers submitted to EFSA?

5.1. 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 is attached at the Annex to these Guidance Notes.

6. How should these ingredients be labelled?

6.1. Under the new rules, these ingredients do not have to be indicated on the labelling with a reference to the parent allergen. However, they would still have to be indicated according to the general food labelling rules in the Food Labelling Regulations 1996, as amended.

7. Can I still label materials listed in this legislation with reference to the source allergen, even though they are exempt from the allergen labelling requirements?

7.1. Although the Regulations exempt ingredients in the Schedule to the Regulations from the requirement to make reference to the source allergen on the labelling, there is no legal requirement not to do so. So, manufacturers can still make reference to the source allergen on the labelling if they want to, without breaking the rules. However, in order to avoid consumer confusion by flagging up a non-allergenic ingredient as an allergen, best practice would be not to make reference to the source allergen on the labelling.

8. What about refined peanut oil?

8.1. Refined peanut oil is not included on the list of exempt derived ingredients and therefore has to be labelled with reference to peanut. There is no requirement to indicate whether the oil has been refined or is cold-pressed (unrefined) although manufacturers may wish to provide this information voluntarily.

9. I use ingredients made from soya oil (such as lecithin and mono and di-glycerides of fatty acids and their esters (E471 and E472) – do I need to label them as derived from soya?

9.1. Ingredients derived from those ingredients in the Schedule to the Regulations which are marked with footnote[1] 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 if products are made from fully refined soya oil, they would not have to be labelled with reference to soya; however if they are made from unrefined or partially refined soya bean oil or fat they would have to be labelled with reference to soya.

10. What about ingredients produced using micro-organisms that have been fed on the specified allergens?

10.1. Micro-organisms that have been fed on the specified allergens, or their derivatives, are not considered as derivatives of these allergens.

10.2. However, 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 contamination and whether any precautionary labelling (such as “may contain”) is required. Such a situation is outside the scope of the Regulations, which only apply to ingredients added to foodstuffs and not contamination.

Contact Details for further information

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

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In Scotland:

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Annex

Opinions on requests from the Commission, adopted by the Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) on 22 February 2005

1. Opinion on a notification from Cognis, ADM and Cargill on natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate and natural D-alpha tocopherol succinate from soybean sources (Request N° EFSA-Q-2004-132)

2. Opinion on a notification from Cognis, ADM and Cargill on vegetable oils-derived phytosterols and phytosterol esters from soybean sources (Request N° EFSA-Q-2004-132)

3. Opinion on a notification from Raisio Life Sciences on plant stanol esters produced from soybean oil sterols (Request N° EFSA-Q-2004-131)

4. Opinion on a notification from CTPC on milk products, egg products and fish products used as fining agents in cider (Request N° EFSA-Q-2004-136)

5. Opinion on a notification from ONIVINS on milk products, egg products and fish products used as fining agents in wines (Request N° EFSA-Q-2004-137)

6. Opinion on a notification from DWV on milk products, egg products and fish products used in the manufacture of wine (Request N° EFSA-Q-2004-142)

Opinions adopted by the NDA Panel on 2 December 2004

7. Opinion on a notification from EPA on lactitol (Request N° EFSA-Q-2004-117)

8. Opinion on a notification from IFF on mustard seed oil (Request N° EFSA-Q-2004-128)

9. Opinion on a notification from EFFA on mustard seed oil and mustard seed oleoresin (Request N° EFSA-Q-2004-129)

10. Opinion on a notification from EFFA on celery leaf oil, celery seed oil and celery oleoresin (Request N° EFSA-Q-2004-129)

11. Opinion on a notification from Givaudan Schweiz AG on fish gelatine used as carrier for flavour (Request EFSA-Q-2004-126)

12. Opinion on a notification from DSM on fish gelatine for use as a formulation aid (carrier) in vitamin and carotenoid preparations (Request EFSA-Q-2004-121)

13. Opinion on a notification from BSI on nuts (almonds, walnuts) extracts used as flavours in distillates (Request EFSA-Q-2004-134)

14. Opinion on a notification from Brewers of Europe and BFBi on isinglass used as a clarifying agent in brewing (Request EFSA-Q-2004-123

15. Opinion on a notification from FEDIOL and IMACE on fully refined soybean oil and fat (Request N° EFSA-Q-2004-098)

DRAFT

Opinions adopted by the NDA Panel on 19 October 2004

16. Opinion on a notification from the Winemakers' Federation of Australia on milk products, egg products and fish products used in the manufacture of wine (Request EFSA-Q-2004-084)

17. Opinion on a notification from CEPS on distillates made from nuts (Request N° EFSA-Q-2004-118)

18. Opinion on a notification from CEPS on distillates made from whey (Request N° EFSA-Q-2004-119)

19. Opinion on a notification from CEPS on distillates made from cereals (Request N° EFSA-Q-2004-120)

20. Opinion on a notification from Finnsugar on glucose syrups produced from barley starch (Request N° EFSA-Q-2004-092)

21. Opinion on a notification from AAC on wheat-based maltodextrins (Request N° EFSA-Q-2004-091)

22. Opinion on a notification from AAC on wheat-based glucose syrups including dextrose (Request N° EFSA-Q-2004-091)

(List obtained from the *British Retail Consortium – Guidance on Directive 2005/26/EC*)

Full details of the opinions are available from the EFSA website at:

http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html