

**2007 No. 0000**

**FOOD, ENGLAND**

**The Food Labelling (Declaration of Allergens) (England)  
Regulations 2007**

<i>Made</i>	- - - -	2007
<i>Laid before Parliament</i>		2007
<i>Coming into force</i>	- -	23 <sup>rd</sup> December 2007

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a), (e) and (f), 17(2), 26(1)(a) and (3), and 48(1) of the Food Safety Act 1990(a), and now vested in her(b).

In accordance with section 48(4A) of that Act, she 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 2007, apply in relation to England only and come into force on 23<sup>rd</sup> December 2007.

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(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 26(3) was amended by Schedule 6 to the 1999 Act. 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 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. 575/2006 (OJ No. L100, 8.4.2006, p3).

## **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 paragraphs (2) and (3).

(2) In regulation 50 (transitional provision), after paragraph (13) insert the following —

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

- (a) the food concerned was sold before 23 December 2008 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(3) of the Food Labelling (Declaration of Allergens) (England) Regulations 2007(**b**) had not been in operation when the food was sold.”

(3) In Schedule AA1 (allergenic ingredients) —

- (a) after paragraph 2 insert “**2(a)**. Molluscs and products thereof”;
- (b) after paragraph 6 insert “**6(a)**. Lupin and products thereof”.

Signed by authority of the Secretary of State for Health

*Caroline Flint*  
Minister of State  
Department of Health

0th Month 2007

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(a) S.I. 1996/1499; the relevant amending instruments are S.I. 1998/1398, 1999/747, 1136, 1483, 2000/768, 2254, 2003/474, 2647, 2004/2145, 2824, 2005/899, 2057  
(b) S.I. 2007/

## **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 Commission Directive No. 2006/142/EC (OJ No. L368, 23.12.2006, pp.110-111) amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs. Two new ingredients are added to that list.

**3.** A full regulatory impact assessment of the effect that these Regulations will have on the costs of business has been prepared and placed in the Library of each House of Parliament together with a Transposition Note setting out how the main elements of Directive 2006/142/EC are transposed in these Regulations. Copies may be obtained from the Consumer Choice, Food Standards and Special Projects Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

## **PARTIAL REGULATORY IMPACT ASSESSMENT**

### **1. TITLE OF THE PROPOSAL**

THE FOOD LABELLING (DECLARATION OF ALLERGENS) (ENGLAND) REGULATIONS

### **2. PURPOSE AND INTENDED EFFECT**

#### **(i) Objective**

The proposed Regulation will implement into UK law Commission Directive 2006/142/EC which amends Directive 2000/13/EC of the European Parliament and 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 key objectives of the Food Labelling (Declaration of Allergens) (England) Regulations 2007 are as follows:

- the Regulations will amend the Food Labelling Regulations (FLR) 1996 by adding lupin and molluscs to Schedule AA1.
- the Regulations aim to ensure that consumers are properly informed about the presence of allergens in the foods they buy and are protected from false or misleading descriptions in relation to allergens.

Separate but parallel legislation will be made in respect of Scotland, Wales and Northern Ireland.

#### **(ii) Background**

Food labelling in Great Britain is governed by the Food Labelling Regulations 1996 (as amended), certain provisions of the Food Safety Act 1990 and the Trade Descriptions Act 1968. The rules aim to ensure that consumers are properly informed about the nature and substance of the foods they buy and are protected from false or misleading descriptions and that industry has a clear regulatory framework to work from, which does not restrict product innovation or inhibit the free movement of goods within the EU. Foods sold pre-packed for direct sale and non pre-packed (such as those sold at delicatessen counters or as meals in catering establishments) are exempt from many of the labelling requirements in the Food Labelling Regulations 1996.

The Food Labelling (Amendment) (England) (No.2) Regulations 2004 already contain a list of allergenic ingredients that must be declared on the labels of pre-packed foods whenever they are deliberately added to the food. This draft SI adds a further two ingredients, lupin and molluscs, to that list.

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

Due to increasing concerns about the allergenicity of both lupin and molluscs, and following advice from the European Food Safety Authority, the Commission has extended the list of 12 potential food allergens to include lupin and molluscs (gastropods, bivalves or cephalopods), and products obtained from them.

### **Lupin**

Lupin seeds have been eaten by humans since ancient times and are consumed as snacks in several European countries. Lupin flour was introduced into the UK in 1996 and is used, for example, in biscuits, pasta, sauces, as well as a soy substitute. As lupin flour does not contain gluten it is sometimes used in gluten-free foods.

Most allergic reactions to lupin have been reported in peanut-allergic individuals, with a cross-reactivity rate to lupin flour in peanut-allergic individuals of around 30%. Clinical symptoms reported after lupin flour inhalation or ingestion are similar to those reported for other inhalant or food allergens, ranging from mild local reactions to life-threatening systemic anaphylaxis. There is no information on the lowest dose of lupin that could cause a clinical allergic reaction.

### **Molluscs**

Some molluscs, like squid, mussels and snails, are an important food source, and are used as gourmet products or ingredients. Their use as an added ingredient appears to be limited, but they can be found in some processed foods like soups and sauces and in products like surimi.

There are little data on the age of onset and the lifetime course of mollusc allergy, but research<sup>1</sup> suggests that many of the reactions occur in school-age children and young adults. Mollusc allergenicity is not reliably reduced by food processing and the lowest dose of mollusc allergen that can cause a clinical reaction is not known. There is cross-reactivity between the mollusc species, as well as between molluscs and crustaceans. There is also evidence of cross-reactivity between both molluscs and crustaceans with insects like the house dust mite and cockroach.

Anaphylactic reactions and death have been reported in mollusc-allergic patients. Molluscs, specifically cuttlefish, squid, abalone, oyster and snail have been implicated in food-dependent, exercise-induced anaphylaxis.

### **Timetable for Directive**

- 22 December 2006 - EC Directive 2006/142/EC was published in the Official Journal and entered into force on 12 January 2007.

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<sup>1</sup>[http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda\\_opinions/1396.Par.0001.File.d at/nda\\_op\\_ej327\\_molluscs\\_en1.pdf](http://www.efsa.europa.eu/etc/medialib/efsa/science/nda/nda_opinions/1396.Par.0001.File.d at/nda_op_ej327_molluscs_en1.pdf)

- Member states must transpose the Directive into national legislation by 23 December 2007.
- 23 December 2008 – After this date all label changes should be in place.

### **(iii) Rationale for Government Intervention**

Directive 2006/142/EC will ensure that those consumers with lupin or mollusc allergies are properly informed about the allergens in the foods they buy and are protected from false or misleading descriptions. This is in line with the Agency's commitment to ensure that consumers are properly informed and can make informed choices through accurate labelling. Consumers who are allergic or intolerant to lupin or molluscs will be able to benefit from the declaration of this additional information of these specified allergens in food products.

### **(iv) Risk Assessment**

There are three options for the implementation of the provisions of Commission Directive 2006/142/EC. These are:

**Option 1:** Do nothing

**Option 2:** Implement EC requirements

**Option 3:** Implement EC requirements and extend labelling to cover non-prepacked foods (loose and pre-packed for direct sale)

The preferred option of the Agency is Option 2.

#### **Option 1: Do nothing**

This would not fulfil the Agency's commitment to provide the consumer with comprehensive labelling information in order to allow them to make fully informed choices and would not provide adequate protection to the health of consumers who are allergic or intolerant to lupin or molluscs. This option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty. Other Member States could also initiate proceedings under Article 227. Option 1 is therefore not a practical or desirable option.

#### **Option 2: Implement EC requirements**

Implementing the Commission Directive would fulfil the UK's obligation under the EC Treaty, ensure consistency of labelling rules across the EU, facilitate informed consumer choice, improve health protection for certain consumers and allow UK manufacturers to operate freely and competitively within the single market. Allergen information is not be required in the case of food which is sold loose, food which is pre-packed for direct sale and fancy confectionery products and, therefore, it would not be required for lupin or molluscs either.

### **Option 3: Implement EC requirements and extend labelling to cover sold non-prepacked foods**

Under Directive 2000/13/EC Member States have the option to use national provisions to extend labelling requirements for pre-packed foods to food sold non-prepacked. An option is to extend the labelling requirements to cover foods which are sold non-prepacked, for instance in delicatessens, bakeries, some health food shops, restaurants, take-aways and sandwich bars etc. This proposal goes beyond the scope of Directive 2006/142/EC. The 2004 requirements for the 12 allergenic foods on the Annex IIIa list were not extended to cover allergen declaration for non-prepacked foods. Implementing this option would result in different requirements for lupin and molluscs, which would be confusing for consumers, industry, and enforcers.

### **3. Consultation**

#### **(i) Within Government**

The new measures do not impact directly on the work of other government departments but the Department for Environment, Food and Rural Affairs (DEFRA), the Department of Health (DH) and the Department for Trade and Industry (DTI) will be consulted since this Directive will impact on their responsibilities.

The Local Authorities Coordinators of Regulatory Services (LACORS) will be consulted and their response will be added when it is received.

#### **(ii) Public Consultation**

The Agency is consulting stakeholders from industry, consumer groups and enforcement. A meeting with representatives of small food businesses is being arranged as part of this consultation.

**If you operate a small business, and would like to take part in these discussions, please contact Olu Adetokunbo (contact details are at the end of this document) before 30 June 2007, giving your name, the name of your company and a daytime telephone number.**

### **4. OPTIONS**

There are three options for transposing the provisions of Directive 2006/142/EC. These are:

#### **Option 1 – Do nothing**

Do not implement Directive 2006/142/EC into UK law. However, this option could put consumers at risk from incomplete labelling. It would also create differences between Member States and lead to barriers to trade within the single European market. As mentioned previously, this option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty.

### **Option 2: Implement EC requirements**

Implementing fully the provisions of Directive 2006/142/EC into UK law would fulfil the Agency's commitment to ensure that consumers are properly informed through accurate labelling, which would enable food allergic consumers to make informed choices. The Agency believes that there may also be some associated benefits for businesses as a result of increased consumer confidence in products carrying more informative labels.

This option would fulfil the UK's obligation under the EC Treaty, ensure consistent labelling rules across the EU, facilitate informed consumer choice and allow UK manufacturers to operate freely and competitively within the single European market.

### **Option 3 – Extend implementation to cover foods sold non-prepacked**

This option would go beyond the provisions of Directive 2006/142/EC by extending consumer protection into an area previously not covered by legislation. In addition, any legislation to extend these provisions for lupin and molluscs to cover foods sold other than pre-packed or pre-packed for direct sale would not be consistent with the provisions for the other allergenic ingredients on Schedule AA1 of the Food Labelling Regulations 1996.

Food labelling legislation is harmonised at an EU level and currently does not address the issue of allergen advisory labelling for foods sold either pre-packed for direct sale or foods sold other than pre-packed. However, the European Commission is currently reviewing all food labelling legislation and could include this area, but this will take at least 4 years. It is difficult for the UK to introduce national measures in an area of EU competence. If the UK were to implement national legislation now, there could potentially be two changes for businesses – i.e. one now and another following the review by the European Commission.

## **5. COSTS AND BENEFITS**

### **(i) Sectors and Groups affected**

It is estimated that 1 in every 70 children have a peanut allergy<sup>2</sup> and it is thought that approximately a third of these children will react to lupin. In 1999 a French research team investigated the risk of cross-allergy to lupin in 24 people who were allergic to peanuts<sup>3</sup>. They found that 44 per cent reacted positively to a skin prick test with lupin flour and seven out of eight who took challenge tests reacted positively. The principal allergen in lupin flour was also found in peanuts.

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<sup>2</sup> Hourihane JO, Aiken R, Briggs R, Gudgeon LA, Grimshaw KE, Dunngalvin A, Roberts SR. The impact of government advice to pregnant mothers regarding peanut avoidance on the prevalence of peanut allergy in United Kingdom children at school entry. *J Allergy Clin Immunol*. 2007 May;119(5):1197-202

<sup>3</sup> Moneret-Vautrin DA, Guérin L, Kanny G, Flabbee J, Frémont S, Morisset M (1999). Cross-allergenicity of peanut and lupine: The risk of lupine allergy in patients allergic to peanuts *J Allergy Clin Immunol* 104:883-8

The proposed legislation will help those with food allergies to lupin and molluscs to avoid foods which contain these ingredients. However, the new legislation will potentially affect manufacturers and retailers of pre-packed foods as these businesses will need to review the origins and composition of all ingredients, flavourings and finished products to establish whether any of these newly-specified allergens are present. Labels and/or ingredient lists will also have to be amended to indicate the specified allergens, or product formulations changed to remove or replace them with non-allergenic materials.

## **(ii) Benefits**

### **Option 1 – Do nothing**

Under this option, the current rules would remain unchanged. Food manufacturers will continue to indicate the presence of the specified allergens as stipulated in Annex IIIa of Directive 2000/13/EC before it was amended by Directive 2006/142/EC.

### **Option 2: Implement EC requirements**

Implementing the Directive would fulfil the UK's obligation under the EC Treaty ensuring consistent labelling of pre-packed foods across the EU. Consumers will benefit from the new rules, as more comprehensive labelling will increase information and choice. In particular, those with food allergies and food intolerance to lupin and molluscs will find it easier to select products that do not contain the ingredients that they are trying to avoid.

There is evidence that those with food allergy spend a longer time doing their shopping<sup>4</sup>. The new rules may therefore reduce associated search costs for consumers as the labelling of products containing lupin and molluscs and their derivatives should be clearer and more consistent. However, the amount and value of time saved is difficult to quantify. In addition, potential reductions in fatalities or near fatal reactions requiring hospitalisation as a consequence of this legislation are likely to further increase the benefits.

Industry may also gain benefits from the proposed Regulations through increased consumer confidence as a result of products carrying more informative labels and the facilitation of trade as UK manufacturers can operate freely and competitively within the single European market.

**The Agency would welcome comments and evidence from business and consumer groups on its view that these Regulations will result in benefits to business from increased consumer confidence**

### **Option 3: Extend implementation to cover foods sold non-prepacked**

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<sup>4</sup> Gowland 2002, 'May Contain' Labelling – The Consumer's Perspective.

Under this option consumers may benefit, as more comprehensive information on all of the ingredients in Schedule AA1 of the Food Labelling Regulations 1996 will be available to them from all outlets where foods are sold other than pre-packed, for example bakeries and restaurants.

There is evidence which suggests that foods purchased from catering and fast food outlets present a greater risk to food allergic consumers than pre-packed foods, in terms of the number of fatal and near-fatal allergic reactions occurring. Current estimates indicate that around 10 people die each year in the UK alone as a result of allergic reactions to food<sup>5</sup>. In 2004/5 there were 829 hospital admissions in England caused by anaphylactic reactions to food<sup>6</sup>. There is a cost to the person concerned and to the National Health Service for every anaphylactic shock reaction, which can result in a stay in hospital. In 2005 the average cost for (non-elective) treatments of shock and anaphylaxis was £471 per treatment<sup>7</sup>. Without intervention, allergic reactions as a consequence of allergic consumers not realising that a food contains an ingredient to which they are allergic, will continue to occur.

### **(iii) Costs**

#### **Option 1 – Do nothing**

Doing nothing has implications for both the direct costs to the NHS and indirect costs to the wider economy from allergy related illnesses. The direct cost to the NHS of managing allergic diseases has recently been estimated at over £1 billion per annum in the UK and primary care prescribing costs are around £0.9 billion per annum, or 11% of the total drugs budget. However, the proportion of this relating to lupin and mollusc allergy is likely to be low when compared to hay fever and asthma due to environmental factors. The recent Department of Health review on allergy services<sup>8</sup> highlighted that the indirect costs of allergic diseases, such as school or workdays lost, lower productivity or diminished quality of life, are potentially huge. However, these were not quantified.

This option would also risk infraction proceedings from the Commission against the UK under Article 226 of the EC Treaty; other member states could also initiate proceedings under Article 227. Option 1 is therefore not a practical option.

#### **Option 2 - implement fully the provisions of Directive 2006/142/EC**

Under this option, the new rules will affect producers of pre-packed foods that contain the specified allergens which are not currently identified on the label. We would expect some of the food industry to undertake a re-design of labels, with the effect varying according to the number and types of products they produce. It is anticipated that changes can be made within manufacturers'

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<sup>5</sup> Pumphrey and Gowland "The Journal of Allergy and Clinical Immunology" 2007

<sup>6</sup> <http://www.hesonline.org.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=214>

<sup>7</sup> <http://www.dh.gov.uk/assetRoot/04/13/32/28/041332328.xls>

<sup>8</sup> [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4137365](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137365)

existing labelling cycles. Any costs arising should therefore be minimal. The British Retail Consortium has estimated the costs of re-labelling at approximately £1000 per product. However, the one year transitional period will cushion this effect ensuring that no extra costs are incurred as a result of having to remove products from sale.

**The Agency would welcome comments and evidence from industry on the estimated costs of re-labelling, over and above what they would do normally during the normal course of business by the implementation of this option**

Moreover, we do not have evidence on the total number of food product lines that will be affected, but would expect this to be limited. In addition, it is likely that, because of the already existing requirement to declare crustaceans, many manufacturers are already declaring molluscs or the more generic “shellfish”, on the label.

**The Agency would welcome comments from industry on the extent to which mollusc and lupin are currently specifically declared on pre-packed food labels**

Businesses will need to allow time to read and understand these Regulations. however, due to the simplicity of these Regulations this should not be onerous. For most businesses we estimate that this would take approximately 20 minutes to read this,

**The Agency would welcome comments and evidence on the assumptions on length of time and costs to industry of reading and understanding these regulations.**

This option will also affect the public bodies (Local Authorities and Public Analysts) charged with responsibility for implementing and enforcing legislation in this area. LACORS have estimated [DN to be completed after the public consultation]

### **Option 3: Extend implementation to cover non-prepacked foods**

In terms of labelling or point of sale notices, staff training and traceability procedures, the costs of introducing this option are thought to be quite high for those businesses providing foods which are not pre-packed or pre-packed for direct sale and these businesses may find this cost difficult to absorb. However, the numbers of businesses affected and to what extent is not known.

**The Agency would welcome comments and evidence from business on the costs involved in introducing this option.**

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The addition of lupin and molluscs to Schedule AA1 of the Food Labelling 1996 will affect a limited number of businesses. It is understood that many small bakers are in the process of re-formulating to remove the lupin content from their products in an effort to avoid additional labelling requirements.

However, an initial assessment of the impact to small businesses shows that the main impact will be the work needed to determine whether or not allergenic ingredients are used in part-prepared foods or ingredients that are bought in and any re-labelling cost. Businesses of all sizes which handle these ingredients are likely to incur some additional costs from setting in place these additional information checks and for re-labelling products to reflect the new requirements. These costs will be in relation to their size, turnover and number of product ranges.

Evidence from the Taskforce Report on the burdens of food regulations on Small Businesses suggests that some small food businesses have difficulties in keeping up to date with changes in legislation and getting advice on legal requirements. Failure to do so can prove expensive and the cumulative effect is often significantly burdensome. To help businesses understand the changes to the legislation the Agency has produced comprehensive guidance on allergen labelling requirement.

## **7. Race, Gender Equality and Sustainability Impacts**

The FSA does not consider that the new legislation has any impact on race or gender equality as there is no evidence to suggest that any group is likely to react to either molluscs or lupin more than any other group.

There may be a small impact on sustainability as some labels which remain unused by 22 December 2008 will have to be discarded at the end of this period.

There are no impacts on rural issues.

## **8. Environmental Impact**

There are no environmental effects of the proposals/new legislation other than the health benefits and consumer choice.

## **9. Competition Assessment**

The results from the competition filter and new Competition Assessment Guidelines indicate that the proposed Regulations will have little impact on the competitive structure or process within the pre-packed food markets. The potential costs are those relating to the updating of labels to reflect the new requirements of disclosing lupin and molluscs ingredients in pre-packed foods. In most cases it is likely that these changes will be absorbed into the

normal labelling changing cycle. All manufacturers would be affected and therefore there appears to be little significant threat to competition.

## **10. Enforcement, Sanctions and Review**

Port Health Authorities (in relation to imported food) and Local Authority Trading Standards and Environmental Health Departments will be responsible for the enforcement of the new provisions. Enforcement authorities' representatives will be consulted on the indication of enforcement costs.

The effectiveness of the Regulations will be monitored through feedback from stakeholders. Agency mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries from the public.

Guidance notes on the application of the new requirements are being drawn up in full consultation with stakeholders and their impact kept under regular review.

***Sections 11 and 12 will be completed after consultation***

## **11. Implementation and Delivery Plan**

## **12. Post-implementation Review**

## **13. Summary and recommendations**

The proposals here provide for new legislation amending the list of ingredients.

## **14. Declaration and publication**

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed.....

Date

Minister's name, title, department

Contact point for enquiries and comments

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**THE INGREDIENTS LISTED IN SCHEDULE AA1**

- . Celery
- . Cereals containing gluten (namely, wheat, rye, barley, oats, spelt, kamut or their hybridised strains)
- . Crustaceans
- . Eggs
- . Fish
- . Milk
- . Mustard
- . Nuts (namely, almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut)
- . Peanuts
- . Sesame seeds
- . Soybeans
- . Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO<sub>2</sub>

# Guidance Notes on Allergen and Miscellaneous Labelling Provisions

## 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 2004
- The Food Labelling Amendment (Scotland) (No. 2) Regulations 2004
- The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2004
- The Food Labelling (Amendment) (Northern Ireland) (No. 2) Regulations 2004
- The Food Labelling (Amendment) (England) (No. 2) Regulations 2005<sup>1</sup>
- The Food Labelling Amendment (No.3) (Scotland) Regulations 2005<sup>2</sup>
- The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2005<sup>3</sup>
- The Food Labelling (Amendment No. 2) Regulations (Northern Ireland) (2005)<sup>4</sup>
- Food Labelling (Declaration of Allergens) (England) Regulations 2007
- Food Labelling (Declaration of Allergens) (Scotland) Regulations 2007
- Food Labelling (Declaration of Allergens) (Wales) Regulations 2007
- Food Labelling (Declaration of Allergens) (Northern Ireland) Regulations 2007

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<sup>1</sup> 1 As amended by The Food Labelling (Amendment) (England) (No.2) (Amendment) Regulations 2005 (SI 2005/2969)

<sup>2</sup> The Food Labelling (Scotland) (No.2) Regulations 2005, have been revoked and replaced by The Food Labelling Amendment (No.3) (Scotland) Regulations 2005 (SSI 2005/542), which implement Directives 2005/26/EC and 2005/63/EC

<sup>3</sup> As amended by The Food Labelling (Amendment) (Wales) (No.2) (Amendment) Regulations 2005

<sup>4</sup> As amended by The Food Labelling (Amendment) (No.2) (Amendment) Regulations (Northern Ireland) 2005 (SRNI 2005/475)

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

- The Regulations listed above;
- 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 Directive 2000/13/EC of the European Parliament and of the Council on the indication of ingredients in foodstuffs;
- Directive 2003/89/EC of the European Parliament and the Council of 10 November 2003, amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs and introducing Annex IIIa of Directive 2000/13/EC;
- Commission Directive 2005/26/EC, establishing 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;
- 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 listing the ingredients which must under all circumstances appear on the labelling of foodstuffs;
- The Food Standards Agency's Clear Labelling Advice, published in 2002 [*Drafting Note: Currently under revision and due to be published in October 2007*];
- Other relevant guidance notes that are available on the Food Standards Agency's website ([www.food.gov.uk](http://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. These Guidance Notes, including the advice and the best practice examples, should not be taken as an authoritative statement or interpretation of the law, as only the Courts have this power and will ultimately decide whether, in particular circumstances, an offence has been committed.

5. Our aims in producing these Guidance Notes are to help:

- manufacturers, producers, retailers and caterers to adopt consistent, transparent labelling practices;
- enforcement authorities to identify and clamp-down on misleading labelling; and
- consumers by encouraging industry to adopt consistent and transparent labelling practices in providing the required information.

## Overview of the Rules

Separate but parallel Regulations exist for England, Scotland, Northern Ireland and Wales. However, for the purposes of illustration the English Regulations are referred to throughout the following guidance.

### Introduction

1. The Food Labelling (Amendment) (England) (No.2) Regulations 2004, which in these notes are referred to as 'the 2004 Regulations', (the allergen labelling rules), implement Directive 2003/89/EC, which is an amendment to Directive 2000/13/EC, and came into force in England on 26 November 2004. There was a transitional provision in those Regulations as regards products marketed or labelled before 25 November 2005. These allergen labelling rules 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)). These ingredients must be indicated whenever they or their derivatives are present in pre-packed food, including alcoholic drinks.

2. There are exemptions for food sold loose, food that is pre-packed for direct sale and certain fancy confectionary products. However, these rules do apply to small packages and certain reusable glass bottles

3. The Commission recognised that not all ingredients that have to be indicated according to the allergen labelling rules would necessarily be allergenic in practice. This is because, in some cases, processing removes the allergenic factor. Directive 2005/26/EC therefore made 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 – Drafting Note: To be updated in the light of Commission decision on the basis of new EFSA opinion].*

4. The Food Labelling (Amendment) (England) (No. 2) Regulations 2005, which in these notes are referred to as 'the 2005 Regulations', implemented Commission Directive 2005/26/EC, that 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 came into force on 25 November 2005. The 2005 Regulations set out temporary 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. *[Drafting Note: to be updated in the light of decisions on permanent exemptions.]*

5. The Food Labelling (Amendment) (England) (No.2) (Amendment) Regulations 2005 implement Directive 2005/63/EC, 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.

6. The Food Labelling (Declaration of Allergens) (England) Regulations 2007, which in these notes are referred to as 'the 2007 Regulations', implement 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 listing the ingredients which must under all circumstances appear on the labelling of foodstuffs.

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

### **Purpose of Guidance Notes**

8. These Guidance Notes have been produced with the aim of providing informal, non-statutory guidance on both the 2004, the 2005 and the 2007 Regulations and should be read in conjunction with them. **These Guidance Notes are not exhaustive.**

### **Status**

9. These Guidance Notes are advisory only. Any legal queries should be resolved by reference to the 2004 Regulations, the 2005 Regulations and the 2007 Regulations, the Food Labelling Regulations 1996 (as amended) and Directives 2000/13/EC, 2003/89/EC, 2005/26/EC, 2005/63/EC and 2006/142/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 these Regulations**

10. 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 either the 2004 Regulations, the 2005 Regulations or the 2007 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.

11. In the case of small businesses or individuals that do not have a Home Authority, queries should be forwarded to the enforcement authority, i.e. 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.

## **Brief overview of the 2004 Regulations**

12. Directive 2003/89/EC amends Directive 2000/13/EC, mainly in respect of Article 6 on the definition and declaration of ingredients including additives. It deletes two entries from Annex 1 to Directive 2000/13/EC ('crystallised fruit' and 'vegetables'), so that that these terms may no longer be used as 'category names' without specifying their ingredients. It also introduces a list of 12 ingredients known to cause allergies or intolerances (Annex IIIa to Directive 2000/13/EC and Schedule AA1 to the Food Labelling Regulations 1996 (as amended))<sup>5</sup>.

13. The 2004 Regulations require foods containing ingredients on the list in Schedule AA1,(as amended) or their derivatives to make a clear reference to the Schedule AA1 name whenever they are used in foods that are pre-packed, including alcoholic drinks. There are exemptions for foods sold loose, food that is pre-packed for direct sale and certain fancy confectionery products. However, these rules do apply to small packages and certain reusable glass bottles.

14. The 2004 Regulations removed the so-called '25% rule', under which individual components of a compound ingredient making up less than 25% of the finished product did not have to be listed.

15. However, in order to take account of technical constraints in the manufacture of foodstuffs, the 2004 Regulations allow the following derogations for compound ingredients used at less than 2% of the finished product:

- Where the compound ingredient is a food whose composition is defined in EU law (e.g. jam and chocolate), the names of the ingredients of the compound ingredient need not be listed;
- Where the compound ingredient consists of a mixture of herbs and/or spices, their names need not be listed individually

**However, these derogations do not override the labelling requirements in respect of allergens, additives or irradiated ingredients.**

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<sup>5</sup> The Commission will issue technical guidance to help interpret the list in the Annex to Directive 2003/89/EC as required. The list may be updated (by Standing Committee procedure) on the basis of validated scientific knowledge. This could include an addition to or deletion from the list.

16. Additionally, the 2004 Regulations provide:

- Where a food contains or consists of a mixture of herbs and spices and or particular herb or spice predominates significantly by weight, the mixture can be listed otherwise than in descending order of weight and the names of these ingredients should be accompanied by 'in variable proportion';
- Where ingredients constitute less than 2% of the finished product, they may be listed in a different order after the other ingredients;
- Where ingredients constitute less than 2% of the finished product and they are similar or mutually substitutable, their presence can be indicated by the use of 'contains...and/or...' in certain circumstances, providing that the ingredients are not additives, allergenic or allergenic derivatives.

### **Organisation of the 2004 Regulations**

#### Title, application and commencement (regulation 1)

Contains the title by which the Regulations may be cited – The Food Labelling (Amendment) (England) (No. 2) Regulations 2004; the coming into force date – 26 November 2004; the country in which the Regulations apply – i.e. England.

#### Amendment of the Food Labelling Regulations 1996 (regulation 2)

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

#### Interpretation (regulation 3)

Includes a definition of 'allergenic ingredient' by reference to Schedule AA1 and a new definition of 'Directive 2000/13'.

#### 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.

Transitional provisions (regulations 13)

Sets out transitional provisions for applying the new rules.

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.

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.

# Questions and Answers

## Coming into force date

### **1. When did the 2004 Regulations come into force?** *Regulation 1 & Regulation 13 to the Food Labelling (Amendment) (No. 2) Regulations 2004*

1.1 The 2004 Regulations came into force on 26 November 2004, from which date products complying with the new rules could be sold. Products produced and labelled after 25 November 2005 that did not comply were prohibited from being sold from 25 November 2005. However, products that were labelled before this date could be sold while the stocks lasted.

### **2. When did the 2005 Regulations come into force?** *Regulation 1 of the Food Labelling (Amendment) (No. 2) Regulations 2005*

2.1 The 2005 Regulations came into force on 25 November 2005.

2.2 From that date ingredients in the Schedule to the 2005 Regulations did not have to be indicated in accordance with the allergen labelling rules until 25 November 2007, although they would still have to be indicated according to the general labelling rules set out in the Food Labelling Regulations 1996 (as amended).

### **3. When do the 2007 Regulations come into force?** *Regulation 1 of the Food Labelling (Declaration of Allergens) (England) Regulations 2007*

3.1 The 2007 Regulations come into force on 23 December 2007, from which date products complying with the new rules may be sold. Manufactures will have a further 12 months to make the necessary label changes. It will not be permitted to produce incorrectly labelled products from 23 December 2008. However, products that were labelled before this date may be sold while the stocks last.

## The scope of the rules on allergen labelling

### **4. What categories of food are covered by the new rules?**

4.1 The scope of application of the 2004 Regulations, the 2005 Regulations and the 2007 Regulations includes pre-packed food in general, including alcoholic drinks.

**5. What about allergen labelling of non-prepacked foods and foods sold at catering establishments?** *Regulation 11 to the Food Labelling (Amendment)(No. 2) Regulations 2004*

5.1 The new rules do not apply to foods sold loose (non-prepacked) or foods sold pre-packed for direct sale. The Agency has published voluntary guidance on the provision of allergen information on food sold loose or pre-packed for direct sale. See <http://www.food.gov.uk/>. [Drafting Note: This guidance is not yet available but will be published during 2007]

**6. What about foods in small packaging and certain indelibly marked bottles?** *Regulation 4 to the Food Labelling (Amendment)(No. 2) Regulations 2004 as read with Regulation 26 of the Food Labelling Regulations 1996 (as amended)*

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

**7. Do the rules apply to the use of ‘may contain’ (nut trace) warnings to indicate possible allergen cross-contamination?**

7.1. No. The rules relate to the indication of Schedule AA1 ingredients and their derivatives that have been deliberately 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.

7.2. 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 allergens. See <http://www.food.gov.uk/multimedia/pdfs/maycontainguide.pdf>.

**8. Do the rules cover claims that products are ‘free from a particular allergen’?**

8.1. No. Currently there are no specific regulations covering such claims, but under the provisions of the General Food Law Regulations 2004 (as amended), labelling, advertising and presentation of food, including the information made available, should not mislead consumers. In addition, under the general provisions of the Food Safety Act 1990 claims must not be false or mislead as to the nature, substance or quality of the food. Manufacturers should ensure that

they have adequate Quality Assurance and GMP to back up any such claims that are made.

## Ingredient listing

### **9. Are there any changes to the way in which ingredients may be listed?** *Regulations 5 & 15 to the Food Labelling (Amendment)(No. 2) Regulations 2004*

9.1. In some cases, yes.

9.2. Regulation 15 of the 2004 Regulations deleted the terms 'crystallised fruit' and 'vegetables' from the collective (generic) names permitted to be used in a list of ingredients. This means that 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'.

9.3. Regulation 5 of the 2004 Regulations removed 'mixed nuts' from the exemptions in existing regulation 13(5) of the Food Labelling Regulations 1996 (as amended) but included mixed mushrooms.

9.4. Regulation 5 of the 2004 Regulations allowed for ingredients, each making up less than 2% of the finished product, to be listed in a different order after other ingredients.

9.5. Regulation 5 of the 2004 Regulations 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: varieties of dried vine fruit; varieties of citrus peel; sources of vegetable oil; glucose syrup or dextrose. **However, the allergen labelling requirements override this concession.** It should be noted that this regulation does not apply in the case of ingredients that are additives.

### **10. What about the 25% compound ingredients exemption?** *Regulation 7 to the Food Labelling (Amendment)(No. 2) Regulations 2004*

10.1. The 2004 Regulations removed the 25% compound ingredient exemption. With the exception of a very few cases, all ingredients now have to be listed on food labels. In addition, **the allergen labelling requirements override any exceptions.**

### **11. Are there any changes in ingredients that do not have to be listed?** *Regulation 7 to the Food Labelling (Amendment)(No. 2) Regulations 2004*

11.1. Yes. The 2004 regulations exempted a small number of compound ingredients from the requirement to list their ingredients in cases where:

(a) 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** it made up less than 2% of the finished product,

(b) 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

(c) the compound ingredient is made up of a mixture of spices or herbs or both **and** made up less than 2% of the finished product.

11.2. **The allergen labelling requirements override these exceptions.** There are also special rules in the case of ingredients that are additives or have been irradiated.

## **Indication of allergenic ingredients**

### **12. What categories of ingredients are covered by the allergen labelling requirements?**

12.1. 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 used as processing aids;
- solvents and media for additives or flavourings; and
- any other substances used as processing aids.

**13. Do the rules require declaration of all ingredients known to cause allergy?** *Regulation 12 & Schedule AA1 to the Food Labelling (Amendment)(No. 2) Regulations 2004 and Regulation ? of the Food Labelling (Declaration of Allergens) (England) Regulations 2007*

13.1. No. Only the ingredients and their derivatives specified in Schedule AA1 to the Regulations (as amended) will trigger the need to give allergen information.

13.2. The ingredients listed in Schedule AA1 (as amended) are as follows:

- Celery
- Cereals containing gluten (namely, wheat, rye, barley, oats, spelt, kamut or their hybridised strains)
- Crustaceans
- Eggs
- Fish
- Lupin
- Milk
- Molluscs
- Mustard
- Nuts (namely, almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut)
- Peanuts
- Sesame seeds
- Soybeans
- Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO<sub>2</sub>

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

#### **14. Guidance on which foods fall within the list in Schedule AA1** *Regulation 12 & Schedule AA1 to the Food Labelling (Amendment)(No. 2) Regulations 2004 and Regulation ? to the Food Labelling (Declaration of Allergens) (England) Regulations 2007*

14.1. The following is meant to provide guidance and best practice advice on the scope of each allergenic ingredient in Schedule AA1 (as amended) to the Regulations. The terms used in listing allergenic ingredients should closely resemble those used in Schedule AA1 (as amended) to avoid confusing the consumer. Whilst there is no official guidance regarding terms that should be used in every case, where species are identified (for example for cereals containing gluten and for nuts) the common names listed are those that should be used in labelling. In other cases, guidance is provided here, which is based on EFSA opinion (the opinion of the Scientific Panel on Dietetics Products, Nutrition and Allergies, Request No.: EFSA-Q-2003-016 adopted 19 February 2004. Website: [http://www.efsa.eu.int/science/nda\\_opinions\\_nda\\_04\\_en1.pdf](http://www.efsa.eu.int/science/nda_opinions_nda_04_en1.pdf)).

14.2. **Celery.** This term is used generically in the Regulations to refer to both celery (stick celery) and celeriac (root celery). Best practice would be to use the distinguishing terms of celery and/or celeriac to identify the nature of the ingredient to consumers. The term 'celery' also includes celery seeds.

14.3. **Cereals containing gluten.** The Regulations define these as: wheat, rye, barley, oats, spelt, kamut or their hybridised strains. Other types of cereals containing gluten would therefore not be included in the scope of these rules. Spelt is a variety of wheat, which is not usually a suitable substitute for people with coeliac disease and wheat allergy. There is no requirement for gluten itself to be indicated in the ingredient list but manufacturers who wish to may declare it in an allergy information/alert box.

14.4. **Crustaceans.** The rules do not name any species of crustaceans. However, 'crustaceans' includes all species of crustaceans (for example lobster, crab, prawns and langoustine). 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 presence might not be appreciated and to ensure that the nature of any exotic crustacean is made clear. The generic terms provisions only allow the generic name 'crustacean' to be used in an ingredient list where there is no other reference to a species of crustacean on the label.

14.5. **Eggs.** The rules do not specify any species of eggs, but 'eggs' refer to eggs from laying hens as well as eggs from other birds, e.g. broiler chicken, duck, turkey, quail, goose, gull, and guinea fowl.

14.6. **Fish.** The rules do not name any species of fish. However, 'fish' includes fish from all species of fish and fish products. Use of the common species names (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 appreciated and to ensure that the nature of any exotic fish is made clear. The generic terms provisions only allow the generic name "fish" to be used in an ingredient list where there is no other reference to a species of fish on the label, for example fish stock. A list of common species names to be used for different types of fish can be found in the schedule to the Fish Labelling (England) Regulations (SI 2003 No. 461) and parallel legislation elsewhere in the UK.

14.7. **Lupin.** The term is used generically in the Regulations to refer both to 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 define 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 peanut.

14.8. **Milk.** The rules do not define any species of milk, but we understand this to include not only cows' milk, but also milk from sheep, goats, and buffaloes etc.

Under general food labelling rules, dairy products, such as 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, whey and lactose, should be declared with reference to milk. 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.

14.9. **Molluscs.** The rules do not name any species of molluscs. However, 'molluscs' includes all species of mollusc (for example oyster, squid, cockles, mussels, periwinkle and scallops as well as land molluscs like snails). 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. The generic terms provisions only allow the generic name 'molluscs' to be used in an ingredient list where there is no other reference to a species of mollusc on the label.

14.10. **Mustard.** This term refers to the mustard plant and other forms which originate from it, such as leaves, sprouted seeds, mustard flour, table mustard and mustard oils. The appropriate terms should be used in labelling. The rules do not define any particular species of mustard and therefore should be applied to all.

14.11. **Nuts.** The rules list these as: almond, hazelnut, walnut, cashew nut, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut. For deliberately added nuts the type of nut should be listed in the ingredients panel. Other types of nuts, and other foods called nuts, for example pine nut, coconut, and chestnuts, are therefore not included in the scope of the rules. Nevertheless, chestnuts and pine nuts (which are not 'nuts' as botanically defined) are also known to cause allergy in some people. Best practice would therefore be to include them in allergen handling and labelling procedures.

14.12. **Peanuts.** Whilst these may also be commonly referred to as groundnuts or monkey nuts, the term 'peanuts' should be used for allergen labelling purposes, as this is the term specified in the Directive.

14.13. **Sesame seeds.** This clearly refers to the seeds of sesame but products deriving from it such as tahini, humous and sesame oil would have to be labelled under the allergen derivative requirement.

14.14. **Soybeans.** In this case, terms such as 'soya' or 'soy' would be sufficient to indicate the soybean origin.

14.15. **Sulphur dioxide and sulphites at levels above 10mg/kg or 10mg/litre expressed as SO<sub>2</sub>.** The requirement to label only applies to deliberately added ingredients. Certain foods may naturally contain sulphur dioxide and sulphites (for example garlic, onion and certain dried fruits), 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 SO<sub>2</sub> in the finished product as consumed, i.e. prepared according to the manufacturer's instructions). This additive should 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, would not be sufficient. The use of the chemical symbol 'SO<sub>2</sub>', would also not be sufficient.

## **15. How should allergenic ingredients be indicated in the labelling of food?** *Regulation 12 & Schedule AA1 to the Food Labelling (Amendment) (No. 2) Regulations 2004*

15.1. 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.

15.2. It should be noted that 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><sup>6</sup>

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<sup>6</sup> Currently under revision.

15.3. 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.<sup>7</sup>

15.4 It is important to ensure that the correct outer packaging is used for multi-pack products and that allergen information appears on, or is visible through, both the inner and outer wrappers.

15.5 There is an exemption for ingredient listing on seasonal selection packs (Regulation 28 of the Food Labelling Regulations 1996 (as amended)), that states that such packs do not need to be marked or labelled with any of the particulars specified in the Food Labelling Regulations 1996 (as amended), provided that the individual packs are labelled.

15.6 Allergy information/alert boxes are not covered by the legislation and their use is entirely voluntary. However, 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 peanut in the generic term and to list this separately.

15.7 Although foods that are sold non-prepacked are exempt from providing most of the general labelling requirements, in many cases foods being supplied to businesses should be accompanied by full labelling information, including ingredients information. This could be on the packaging itself or on the documentation delivered alongside the goods.

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<sup>7</sup> 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.

**16. What about drinks with an alcoholic strength by volume (abv) of more than 1.2%?** *Regulation 12 to the Food Labelling (Amendment)(No. 2) Regulations 2004*

16.1. Alcoholic drinks are subject to special rules. Drinks with an alcoholic strength by volume (abv) of more than 1.2% are exempt from ingredient listing under general food labelling rules. In these cases, the label should declare the allergenic ingredient with the word 'contains' followed by the Schedule AA1 name, unless already in the name of the drink or any list of ingredients provided. 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.

**17. What about the derived ingredients?** *Regulation 12 & Schedule AA1 to the Food Labelling (Amendment)(No. 2) Regulations 2004 and Regulation ? of the Food Labelling (Declaration of Allergens) (England) Regulations 2007*

17.1. The scope of the allergen labelling extends to ingredients originating from ingredients listed in Schedule AA1 (as amended). This is understood to mean any number of generations of derivation and assumes that, unless otherwise demonstrated, the allergenic potential remains. A provisional list of temporary exemptions from the requirement to label was published by the Commission on 22 March 2005 (Commission Directive 2005/26/EC, as amended by Directive 2005/63/EC - Annex to the Guidance) and is incorporated into UK legislation by means of the Food Labelling (Amendment) (England) (No.2) Regulations 2005 (as amended) in England and by similar legislation in Scotland, Wales and Northern Ireland.

17.2. Based on the European Food Safety Authority's (EFSA's) opinion, the Commission will decide by 25 November 2007 whether or not to retain these temporary exemptions for the derivatives. Once the decision has been made, the implementing legislation will be amended accordingly, and ingredients not deemed to be allergenic will continue to be exempt, whilst those deemed to be allergenic will no longer be exempt and will have to be labelled accordingly. *[Drafting Note: If the Commission's decision is known before publication of this document, it will be amended to reflect the latest position.]*

17.3. Micro-organisms that have been fed on allergenic substrates are not considered to be derived from the allergenic substrates for the purposes of labelling.

17.4. 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 2005 Regulations, which only apply to ingredients added to foodstuffs and not contamination.

17.5 Regulation 34B(1) provides that any allergenic ingredient must be labelled **and** any ingredient **originating from** one of these specified allergenic ingredient (excluding sulphites)

**18. Are there any changes to the way in which additives and flavourings may be listed?** *Regulation 12 & Schedule AA1 to the Food Labelling (Amendment)(No. 2) Regulations 2004 as read with Regulation 14 of the Food Labelling Regulations 1996 (as amended)*

18.1. Yes. 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.

**19. What ingredients do the 2005 Regulations temporarily exempt from allergen labelling rules?** *Schedule to the Regulations of the Food Labelling (Amendment) (No. 2) Regulations 2005*

19.1 Ingredients exempt from allergen labelling rules are listed in the Schedule to the 2005 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.

*[Drafting notes: This table will be amended to reflect the regulations on exempt derived ingredients.]*

<b>Allergenic ingredient</b>	<b>Ingredients derived from allergenic ingredient in Column 1 that do not have to be labelled as allergens</b>
Cereals containing gluten	Wheat based glucose syrups including dextrose. <sup>1</sup> Wheat based maltodextrins. <sup>1</sup> 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 a carrier for vitamin or carotenoid preparations and flavours Fish gelatine or Isinglass used as fining agent in beer, cider and wine.
Soybean	Fully refined soybean oil and fat. <sup>1</sup> Natural mixed tocopherols (E306), natural D–alpha tocopherol, natural D–alpha tocopherol acetate, natural D–alpha tocopherol succinate from soybean sources. Phytosterols and phytosterol esters derived from vegetable oils obtained

	from soybean sources. <sup>2</sup> 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.
<sup>1</sup> 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. <sup>2</sup> This text is taken from the UK Statutory Instrument, which differs slightly from Directive 2005/26/EC. The Commission has agreed this description, which is clearer but essentially has the same meaning as the text in the Directive.	

## **20. Is the exemption for ingredients in the Schedule to the 2005 Regulations final?**

20.1. No. The exemption is provisional and lasts until 25 November 2007.<sup>8</sup>

20.2. 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 2005 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 [*Drafting Note: and this guidance will be amended accordingly.*].

20.3. Industry can also make submissions for the exemption of other derived ingredients at any time.

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

21.1. 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

<sup>8</sup> This guidance note will be amended to take account of any decision taken by EFSA with regard to the provisional list of temporary exempt ingredients.

opinions, including descriptions and intended applications, on the ingredients for which exemptions have been granted is attached at the Annex to these Guidance Notes.

## **22. How should exempt ingredients be labelled?**

22.1. 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). 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”.

## **23. 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?**

23.1. Although the 2005 Regulations temporarily exempt ingredients listed 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 in such situations.

## **24. What about refined peanut oil?**

24.1. Refined peanut oil is not included on the list of temporarily 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.

## **25. 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?**

25.1. Ingredients derived from those ingredients in the Schedule to the 2005 Regulations which are marked with footnote<sup>1</sup> 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.

## 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: 0207-276-8513  
                              E-mail: [Dionne.Davey@foodstandards.gsi.gov.uk](mailto:Dionne.Davey@foodstandards.gsi.gov.uk)

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

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

In Northern Ireland: Food Standards Agency Northern Ireland  
                              10C Clarendon Road  
                              Belfast  
                              BT1 3BG  
                              Tel: 028 9041 7714  
                              Fax: 028 9041 7726

## List of Interested Parties

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- INSTITUTE OF GROCERY DISTRIBUTION
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- INSTITUTION OF MECHANICAL ENGINEERS (IMECHE)
- INTER FAITH NETWORK FOR THE UK
- INTERNATIONAL ASSOCIATION FOR THE STUDY OF OBESITY
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- LOCAL AUTHORITIES CO-ORDINATORS OF REGULATORY SERVICES
- LONDON BOROUGH OF BARKING & DAGENHAM
- LONDON BOROUGH OF BRENT
- LONDON BOROUGH OF ENFIELD
- LONDON BOROUGH OF HAVERING
- LONDON BOROUGH OF SOUTHWARK
- LONDON RETAIL MEAT TRADERS ASSOCIATION
- LONDON SOUTH BANK UNIVERSITY
- LORD CHANCELLOR'S DEPARTMENT
- LOVELL WHITE DURRANT SOLICITORS
- LOVELLS
- LOVERING FOODS LTD
- LYN ANDERSON
- LYONS TETLEY LTD
- LYSI HS
- MACFARLANES
- MALTSTERS ASSOCIATION OF GREAT BRITAIN
- MANCHESTER METROPOLITAN UNIVERSITY
- MANCHESTER RUSK CO LTD
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- MARKAZI JAMIAT AHLE HADITH
- MARKETING LAW ADVISORY SERVICE
- MARKS & SPENCER PLC
- MARS CONFECTIONERY LTD
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- MATTHEW CLARK LTD
- MAYER BROWN ROWE & MAWE LLP
- MCCAIN FOODS
- MCCORMACK FOODS
- MCDONALD'S RESTAURANTS LTD
- MCKENNA & CO
- MEAD JOHNSON NUTRITIONAL GROUP
- MEAT & LIVESTOCK COMMISSION (MLC)
- MEDICAL & HEALTHCARE PRODUCT REGULATORY AFFAIRS (MHRA)
- MEDICAL RESEARCH COUNCIL
- MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY
- MEL CALABY
- MERIDIAN FOODS
- MERRYDOWN PLC
- METAL PACKAGING MANUFACTURERS ASSOCIATION
- MIDWIVES INFORMATION & RESOURCE SERVICE
- MIGRAINE TRUST
- MILTON KEYNES COUNCIL
- MILUPA LTD
- MISS ANGELA VAN DER BERG
- MISS D LOVE
- MISS JACQUIE SALFIELD
- MJSR ASSOCIATES
- MOTHERHEMP LTD
- MOY PARK LTD

- MP MEDIA SERVICES
- MR AIAN BAKER
- MR ALAN TURNER
- MR B PROUSE
- MR B STEINHOUSE
- MR BARRY ATWOOD
- MR C DREW
- MR CLIVE WEBSTER
- MR D VIGGERS
- MR D W WILLIAMS
- MR DAVE EDWARDS
- MR DAVID CLARKE
- MR DAVID GREEN
- MR DAVID SMITH
- MR DENNIS T GORDON
- MR EDWARD LANGRIDGE
- MR EDWARD LANGRIDGE
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- MS SHIRLEY BOND
- MS V WOOLL
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- MULTILABELS LTD
- MUNROE & FORESTER
- MUSHROOM GROWERS ASSOCIATION
- MUSLIM COLLEGE
- MUSLIM COUNCIL OF BRITAIN
- MUSLIM DOCTORS & DENTISTS ASSOCIATION
- NATIONAL ASSOCIATION OF BRITISH & IRISH MILLERS (NABIM)
- NATIONAL ASSOCIATION OF CIDER & PERRY MAKERS
- NATIONAL ASSOCIATION OF HEALTH STORES
- NATIONAL ASSOCIATION OF MASTER BAKERS, CONFECTIONERS & CATERERS
- NATIONAL BEEF ASSOCIATION
- NATIONAL CHILDBIRTH TRUST
- NATIONAL CHILDREN'S BUREAU
- NATIONAL COLLEGE OF FOOD TECHNOLOGY
- NATIONAL CONSUMER COUNCIL
- NATIONAL CONSUMER FEDERATION (NCF)
- NATIONAL COUNCIL OF HINDU TEMPLES UK
- NATIONAL COUNCIL OF WOMEN
- NATIONAL DRIED FRUIT ASSOCIATION (NDFTA)
- NATIONAL EDIBLE OIL DISTRIBUTORS ASSOCIATION
- NATIONAL FARMERS UNION (NFU)
- NATIONAL FEDERATION OF FISHERMAN'S ORGANISATIONS
- NATIONAL FEDERATION OF MEAT & FOOD TRADERS
- NATIONAL FEDERATION OF WOMEN'S INSTITUTES
- NATIONAL FOOD CENTRE
- NATIONAL HEART FORUM
- NATIONAL INSTITUTE FOR HEALTH & CLINICAL EXCELLENCE
- NATIONAL INSTITUTE OF MEDICAL HERBALISTS LTD
- NATIONAL PHARMACEUTICAL ASSOCIATION
- NATIONAL PIG ASSOCIATION

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- NATIONAL SOCIETY FOR PHENYLKETONURIA (UK)
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- NCH ACTION FOR CHILDREN
- NESTLE ROWNTREE HQ
- NESTLE UK LTD
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- NEVILLE CRADDOCK ASSOCIATES
- NEW COVENT GARDEN FOOD CO LIMITED
- NEW FOREST FOODS LTD
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- NORTH YORKSHIRE EAST FEDERATION OF WOMEN'S INSTITUTE
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- NORWEGIAN FOOD CONTROL AUTHORITY
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- ORGANIX BRANDS PLC
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- PROSPER
- PROTEIN TECHNOLOGY INTERNATIONAL

- PROVISION TRADE FEDERATION
- QUAKER TRADING LIMITED
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- ROYAL DANISH EMBASSY
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- ST GEORGE'S HOSPITAL MEDICAL SCHOOL
- ST IVEL SPREADS
- STAFFORDSHIRE COUNTY ANALYST
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- STEPHEN RHODES ASSOCIATES
- STEPNEY NEIGHBOURHOOD CENTRE
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- TEA BUYERS ASSOCIATION
- TESCO STORES PLC
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- THE DIABETES INSTITUTE FOUNDATION
- THE FOOD BRAND GROUP
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- WELSH ASSEMBLY GOVERNMENT
- WELSH CONSUMER COUNCIL
- WELSH FOOD ALLIANCE
- WESSEX FOODS
- WEST BERKSHIRE DISTRICT COUNCIL
- WEST YORKSHIRE JOINT SERVICES
- WESTERN GROUP ENVIRONMENTAL HEALTH COMMITTEE
- WESTERN RESEARCH LABORATORIES
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- WILTSHIRE DIRECT SERVICES
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- WINKWORTH & PEMBERTON
- WOMEN'S FOOD & FARMING UNION
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- WRIGHTS OF MURPHY
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- YORK NUTRITIONAL LABORATORY

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