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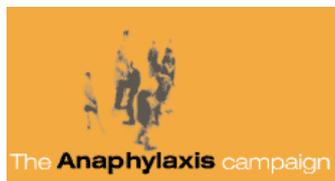
September 2005



# GUIDANCE ON ALLERGEN CONTROL AND CONSUMER INFORMATION

Best Practice Guidance on Controlling Food Allergens with  
Particular Reference to Avoiding Cross-Contamination and Using  
Appropriate Advisory Labelling (e.g. 'May Contain' Labelling)

With support from



**BRITISH RETAIL CONSORTIUM**



**LACORS** Local Authorities Coordinators of Regulatory Services

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## **FOREWORD**

[to be added]

We wish to acknowledge the valuable contributions made to these guidelines by the British Retail Consortium, the Food and Drink Federation, the Anaphylaxis Campaign, H J Heinz Co Ltd, Cullinane Associates Ltd, the Institute of Grocery Distribution, LACORS, Marks & Spencer plc, Somerfield Stores Ltd, and Unilever UK.

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## 1. INTRODUCTION

### 1.1 Why is this guidance needed?

The Food Standards Agency aims to protect consumers by improving food safety and by giving honest, clear information. A key aim set out in our Strategic Plan for 2005-10 is to enable consumers to make informed choices. For those consumers with food allergies and food intolerances, it is vital that they are fully informed about the nature and contents of the foods they are buying.

There is evidence that the number of people who have adverse reactions to foods such as cows' milk, tree nuts, and peanuts is increasing<sup>1,2</sup>. People with food allergies, and people shopping for them, need clear labelling of both the use of allergenic ingredients and identification of possible cross-contamination with allergens, in order to make informed food choices. Unlike the situation for deliberate ingredients, there are currently no statutory controls governing the labelling of possible allergen cross-contamination of foods along the food supply chain.

There is general agreement between the food industry, consumer support groups and enforcement bodies, that excessive use of warning labels about the possible presence of allergens not only unnecessarily restricts consumer choice but also devalues the impact of the warnings.

### 1.2 Who is this guidance intended for?

This document provides voluntary best practice advice to food producers and retailers on how to assess the risks of cross-contamination of a food product with an allergenic food or food ingredient and then to determine whether advisory labelling is appropriate. It is intended to give a generic overview of the approach to take in controlling allergens and providing advisory labelling and is aimed primarily at small and medium enterprises (SMEs). A summary of the guidance will also be provided to assist small businesses. Nevertheless the advice will also be helpful for larger companies, although they may wish to consult more detailed sector specific guidance, where this exists. It is also important that consumers with food allergies and food intolerances understand the meaning of any advisory labelling used on a product so that they can make appropriate food choices. The guidance is also relevant to enforcement bodies, who inspect and advise food businesses.

### 1.3 Where can I obtain further copies of this guidance?

This document is available from the Food Standards Agency website @ [???] and can also be obtained from [mailing house].

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<sup>1</sup> Howarth PH., Dec 1998, Is allergy increasing? Early life influences. Clin Exp Allergy, Vol. 28 Suppl. 6:2-7.

<sup>2</sup> Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), 2000 Adverse Reactions to Food and Food Ingredients, 11,91-97.

## **2. BACKGROUND AND PURPOSE**

### **2.1 Food Allergies and Intolerances**

True food allergies are reproducible adverse reactions to a particular food that involves the immune system. Virtually all known food allergens are proteins; they can be present in the food in large amounts and often survive food-processing conditions. Allergies are characterised by the rapid release of chemicals in the body that cause the symptoms of the allergic reactions, which can occur within minutes or up to an hour or more after ingestion. Whilst almost any food protein can cause an allergic reaction in some people, the most common food allergens in the UK include peanuts, nuts, milk, egg, fish and shellfish, soya wheat and sesame.

The proportion of the population with true food allergy is approximately 1-2% of adults and about 5-8% of children, which equates to about 1.5 million people in the UK. It is important to remember that reactions can be triggered by very small amounts of an allergen (sometimes less than one milligram) and can be severe or potentially fatal. The avoidance of low-level presence of allergens due to cross-contamination is particularly relevant for those allergenic foods which are more likely to have life-threatening consequences when present at very low levels in foods and those which affect a higher proportion of those with allergies.

Sulphites or sulphur dioxide are included because they can cause adverse reactions in some people. Those affected generally have asthma or other allergies already and exposure can trigger an asthma attack.

Gluten intolerance (coeliac disease) is not a true allergy; rather it is an adverse reaction to gluten, a protein found in cereals such as wheat, rye barley and oats. Other foods, such as the lactose present in milk, can also cause intolerances, but generally the amounts of these foods needed to cause adverse reactions are higher than for foods causing allergies. Although the risks to sensitive people from unintentional cross-contamination with these foods are generally lower than the risks posed by true allergens, some sensitive people may nevertheless react to relatively small amounts of the particular food.

### **2.2 Purpose of this Document**

Legislation and growing awareness of food allergy have focussed attention on the identification of the food allergens that affect the most people within the European Community, the means of their control and the provision of appropriate consumer information. Legislation is now in place (Directive 2003/89/EC and implementing Regulations in the UK) requiring that where specified allergenic foods or their derivatives are used as ingredients in food, the relevant allergenic food is indicated on the labelling. Products not complying with this legislation are prohibited as from 25 November 2005 (but products that have been labelled before that date may be sold while stocks last). However, the legislation does not cover allergenic foods that may be

present unintentionally as a result of cross-contamination at some point during the manufacture or transportation of the food.

Whilst guidance on this issue has already been produced by a number of organisations, the purpose of this document is to set out a unified approach that can be adopted across the various sectors of the food industry to help maintain food safety and also maximise consumer choice. This is so that there is a common understanding by food producers and retailers, enforcement bodies and consumers of when warning labels should, or should not, be used, and what they mean for the affected consumer. This guidance sets out general principles that can be applied to the control of specific allergenic ingredients in differing situations. The actions required in particular circumstances must be determined by each individual food business. However different sectors of the food industry may still wish to produce their own, more detailed guidance or codes of practice, that will build on the approach set out here but be focussed on the particular aspects that are relevant to their sector. This document builds on previous advice and provides best practice guidance on:

- a) the control of allergens in the manufacturing of food products; and
- b) the adoption of a risk-based approach to the appropriate use of label statements to advise consumers with food allergies or severe food intolerances of the risk of unintentional allergen cross-contamination with certain foods (see sections 4 and 5, and also Appendix III).

### 2.3 Scope

Historically 'May Contain' labels have been used to indicate cross-contamination with nuts (including peanuts) and, more recently, seeds such as sesame. However other allergenic foods, including egg, milk, fish and shellfish and soya can trigger potentially fatal anaphylactic reactions. In addition statutory rules will require the declaration of 12 allergenic foods and their derivatives as from November 2005. Appendix I describes the allergens currently covered by the labelling legislation. The guidance set out in this document has been drafted to be applicable to the control of any food allergen in any particular food-manufacturing environment. However, a risk-based judgement needs to be made regarding the allergens to which the generic approach set out here should be applied in any particular set of circumstances.

In reaching such a judgement, a number of factors have to be considered, including, but not exclusively, the following:

- the **amount** of the allergenic food generally needed to provoke a reaction in a sensitive individual (although it should be borne in mind that different people can have different levels of sensitivity, and that sensitivity can vary in the same person under different circumstances). The European Food Safety Authority (EFSA) has reviewed the 12 allergenic foods currently listed in the Annex of Directive 2003/89/EC in terms of what is known

about the amounts of allergen needed to trigger adverse reactions and also possible detection methods (see [www.efsa.eu.int/science/nda/nda\\_opinions/catindex\\_en.html](http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html)). However, in many cases, the scientific literature is not yet sufficient to draw firm conclusions regarding the highest dose that would not cause an adverse effect. Nevertheless, various test kits and commercial analytical methods (based on immunoassay or PRC methodology) do exist and many more are being developed – see Appendix III).

- **how common** adverse reactions are to that particular food in the population to which it will be marketed (see Appendix I). For example, celery and mustard allergy are not common in the UK but are much more prevalent in eastern Europe, and fish allergy is more prevalent in Scandinavian countries than in the UK. However it should be borne in mind that people from high prevalence areas may travel to low prevalence areas where the product is sold;
- whether there are particular **subgroups of the population** likely to be at particular risk, such as children (although allergy to egg and milk is relatively common in babies and young children, the allergy is often outgrown by the time the child reaches school age) or those who restrict their food choices to specialist ranges for dietary, religious or other reasons;
- the **relative allergenicity of the particular ingredient** being used. For example, possible cross-contamination with highly processed ingredients (such as refined nut oils) is likely to pose a lower risk than cross-contamination with whole nuts; and
- the **physical nature of the particular ingredients being used and the geography of the manufacturing environment**. For example, milk powder may represent a greater risk in situations where air-borne contamination of products is possible, but liquid milk may be of less concern if there was sufficient separation (e.g. by physical barriers, distance, timing or cleaning) between the products in which it is deliberately used and those where it is not.

Appendix I contains a list of the allergens specified in the EU legislation that have to be labelled wherever they, or products derived from them, are used, together with information on relative allergenicity and the prevalence of reactions to them. This information can be used in the case-by-case risk assessment process.

### 2.4 EU and National Legislation

Directive 2000/13/EC, as amended by Directive 2003/89/EC sets out a list of ingredients, including allergens, which must always be identified when used in the manufacture of pre-packed foods (OJ L 308, 25.11.2003 p.15) This applies no matter how small the amount used is and no matter that it is part of a compound ingredient. Some of these substances are not strictly allergens

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in the ordinary sense (e.g. sulphites and gluten) but can cause adverse reactions in some people.

Some highly processed ingredients derived from the allergenic foods listed in Directive 2003/89/EC are unlikely to trigger reactions in sensitive individuals and are therefore exempt from the requirement to label with reference to that source food. The European Commission has issued a provisional list of ingredients (Directive 2005/26/EC) which, based on the evaluation by the European Food Safety Authority (EFSA) of the evidence currently available, are exempt from labelling requirements until 25 November 2007, when a final list will be issued (OJ L 75, 22.3.2005, p.33). This will allow time for further scientific data to be assessed by EFSA. Derived ingredients not present on this list are considered to be capable of eliciting adverse reactions and should be handled accordingly.

Directives 2003/89/EC and 2005/26/EC have been implemented in England by the Food Labelling (Amendment) (England) (No.2) Regulations 2004), the Food Labelling (Amendment) (England) (No.2) Regulations 2005 and by parallel legislation in Scotland, Wales and Northern Ireland. Guidance on the first of these pieces of legislation and its practical implementation has been published by the Food Standards Agency at [www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/foodlabguidance](http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/foodlabguidance) [web ref for guidance on exemptions to be added when finalised <http://www.food.gov.uk/foodindustry/Consultations/consulteng/draftfoodlab2005>]

This legislation does not cover unintentional allergen cross-contamination.

Further information on the legislative background can be found in Appendix II.

### **3. NEW PRODUCT DEVELOPMENT AND REFORMULATION**

#### **3.1 Product Formulation**

Whenever possible, it is good practice not to include an allergenic ingredient in a product unless necessary. For example, manufacturers could consider using corn (maize) flour instead of wheat flour or using vegetable fat instead of butter. By using allergenic ingredients only when they are essential components of a food product, one element of the risk from unintentional cross-contamination will be minimised.

#### **3.2 Reformulating Products**

Reformulation of a product with the introduction of a new allergenic ingredient, may lead to contamination of other lines produced in the same premises, for which advisory labelling might then become appropriate.

When modifying a recipe or producing a new variety of an established product, businesses should consider whether an allergenic ingredient is critical to the character of the product, although there may be commercial reasons for choosing such an ingredient. Deliberate recipe modifications, which introduce allergens, and change the risk assessment of allergen cross-contamination should be very clearly communicated via labelling on-pack. This is important, as allergic consumers, who may have been consuming the product for some time, need to be informed of a new potential hazard. Where considered appropriate, additional measures could include informing allergic consumer support organisations, such as the Anaphylaxis Campaign – see Appendix IV.

Businesses can benefit from simplification programmes and these might provide opportunities to discontinue minor lines that bring allergen complexity in manufacturing, as well as reformulating products to avoid allergenic ingredients.

#### **3.3 Extending Brands**

If it is decided to extend a brand name into a different product sector (e.g. an established confectionery product giving its name to a dessert product or ice cream), care should be taken that the presence of any allergen not associated with the original product is clearly indicated. As consistent an approach to allergen labelling across a brand as possible, is essential in these circumstances.

#### **3.4 Factory Trials and Consumer Testing**

When conducting factory trials of allergen-containing products, measures should be taken to avoid allergen cross-contamination with existing products. Information on the presence, or potential presence, of allergens should be made available to those involved in factory trials and in taste testing and that

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information should be clearly conveyed with products presented for wider test and marketing purposes.

However clearly they are labelled, sample products containing the major food allergens should not be distributed indiscriminately or offered where they can be taken by unsupervised children (for example through letterboxes or in stores).

### **3.5 Advisory Labelling/Warning Statements**

Allergenic ingredients should always be declared using simple, common language, in the list of ingredients. Some manufacturers may also choose to declare the presence of allergens via an allergen advice box or statement. If such boxes or statements are used then they should be close to the ingredients' list in the same field of vision.

Derivatives of allergenic foods can include both the components of the food as well as products that can be made from it. For example, “allergenic derivatives” of milk include individual components such as casein and whey (milk proteins) as well as food products made from milk, such as yoghurt or cheese. The potential presence of any allergenic ingredient, or its derivatives, should be easily identifiable on the final product label by reference to the generic name of the allergen, as described in Directive 2003/89/EC, Annex 1.

There are statutory requirements governing the declaration of allergenic ingredients. However, before deciding whether to use advisory labelling to declare the possible presence of allergen cross-contamination, manufacturers should consider the following:

- a) the implementation of measures to avoid allergen cross-contamination of foods;
- b) a case-by-case evidence-based risk assessment on whether or not consumers should be advised of the possible presence of particular allergens in the final product;
- c) if advice is needed, the wording to be used to communicate that risk.

It is helpful to consumers if such labelling is consistent, both for products made by a particular manufacturer and also between manufacturers.

- Consider a review of existing ingredients use
- Take care in selecting ingredients for product reformulation and new product development.

## 4. MANUFACTURING

### Allergen Management

In order to manage allergens to avoid their unintentional presence in products wherever possible, it is necessary to evaluate the likelihood of allergen cross-contamination associated with every step of a process from sourcing raw materials through to marketing of a finished product. This is often referred to as 'Hazard Analysis' and it can be achieved by employing a 'Hazard Analysis Critical Control Point (HACCP)' – based food safety system, which will assist in identifying areas of potential contamination. A number of definitive guides to HACCP exist (for example, CODEX ALIMENTARIUS Food Hygiene Basic Texts – Third Edition 2003 ISSN 0259-2916, available at [www.codexalimentarius.net](http://www.codexalimentarius.net)).

#### 4.1 Hazard Analysis and Hazard Management

Hazard analysis and hazard management techniques are widely used in food manufacturing to control a variety of food safety issues, such as physical, chemical or microbiological contamination. The basic principles of hazard management, as set out below, can also be used to identify any risks associated with allergen cross-contamination that could unintentionally be present in the foodstuff. At present, as there are no firm conclusions about the amounts of some allergens needed to trigger adverse reactions (see Appendix I), assessments are being made on the basis of the detection or otherwise of the allergen. Further guidance is contained in Appendix III. Hazard analysis and hazard management is applied by taking a number of steps;

- look at the production process/product from start to finish;
- identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
- identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels ;
- establish criteria at the critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- establish and implement effective monitoring procedures at critical control points;
- establish corrective actions when monitoring indicates that a critical control point is not under control;
- establish procedures, to be carried out regularly, to verify that the measures outlined above are working effectively;

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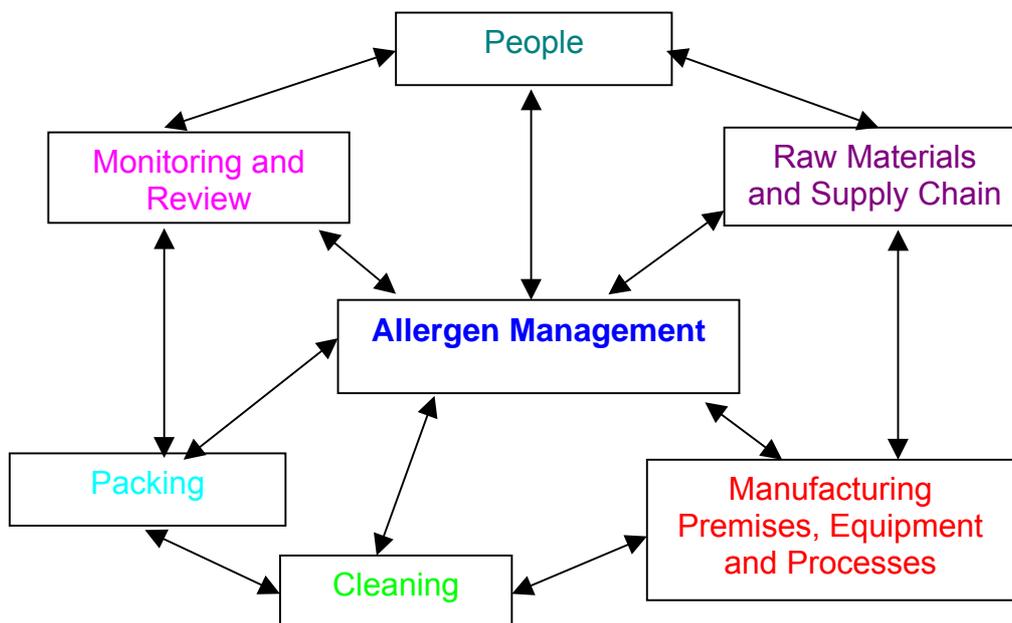
- ☑ establish documents and records that are appropriate for the nature and size of the food business to demonstrate the effective application of the measures outlined above; and
- ☑ ensure that the system continues to work effectively.

This can be a relatively simple procedure depending upon the particular products and processes involved.

### 4.2 Good Manufacturing Practice Aspects

Most food producers already employ Good Manufacturing Practices (GMP) to ensure that they are able to produce food safely. GMP requires appropriate manufacturing operations, effective food safety systems (using HACCP-based principles), and Quality Assurance systems, as well as a commitment and discipline to ensure products meet food safety, quality and legal requirements.

The following diagram identifies key aspects of food and drink manufacturing operations to be considered in the control of allergens. This section then considers each of these aspects in more detail.



### 4.2.1 People

All staff (including temporary staff and contractors) involved in handling ingredients, equipment, utensils, packaging and products should be aware of food allergens and the consequences of their ingestion by sensitive individuals. They should be trained in avoiding cross-contamination of foods by the major food allergens. Appropriate procedures on the control of allergens should be available and/or posted in the reception and production areas so that employees and visitors are aware of them. Such procedures should include information on:

- Potential allergen cross-contamination situations
- Handwashing
- Clothing requirements
- Re-work
- Waste control
- Cleaning procedures
- Dedicated equipment if available

### 4.2.2 Raw Materials and Supply Chain

Food businesses should establish an appropriate and proportionate policy for assessing the allergen status of ingredients for use within their own manufacturing processes and premises, and for assessing those ingredients used by their suppliers or co-packers, if appropriate.

Manufacturers need to be aware of the presence of the major allergens in all raw materials, particularly the potential for allergen cross-contamination from manufacturing and handling activities on the raw material suppliers' sites, as well as earlier in the food chain during harvesting and transport. This may be through audits or from information provided by suppliers. Manufacturers should ensure that materials are ordered against a clear specification and that they ask appropriate questions of their suppliers. Raw material suppliers (and their agents) should be aware of the hazards arising from contamination by allergens and conform to the manufacturers purchase specification. However, commodity raw material suppliers should only use allergen warning statements on products such as spices and grains, based on an assessment of the risk of cross contamination. Scientific work currently underway to establish meaningful allergen thresholds and develop appropriate testing methodologies will help in making such assessments.

Ingredients should be fully described in specifications, for example, avoid the use of generic terms such as "vegetable" oils and fats, but using specified terms such as corn or rapeseed oil, especially where those allergens listed in Annex 1 of Directive 2003/89/EC are concerned.

Steps should be taken to ensure that non-allergenic ingredients do not come into contact with allergens in subsequent handling and storage (see Section 4.2.4 on cleaning). Allergenic raw materials should be stored in clearly

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identified areas e.g. using colour-coded boxes or demarcation of storage areas using painted lines on the floor.

Where allergenic raw materials are de-bagged or de-boxed, they should, if possible, be placed in dedicated lidded and labelled containers and made easily identifiable. Such containers should not be used for storage of any other raw materials.

If allergenic ingredients are sieved, then the sieving unit should be either:

- (i) dedicated or
- (ii) thoroughly cleaned after sieving allergenic ingredients.

If possible, allergenic ingredients should be sieved after all other raw ingredients have been sieved for the day.

Practices should ensure that the allergen status of all ingredients (including flavourings, additives, carriers and processing aids) is known:

- Check the allergen status of all ingredients with suppliers and review regularly
- Ask suppliers to notify changes in the allergen status of the materials they supply
- Clearly identify allergenic raw materials and segregate where possible
- Ensure the handling of allergenic ingredients does not cause contamination of other ingredients

### **4.2.3 Manufacturing Premises, Equipment and Processes**

Whilst the ideal approach to avoiding cross-contamination with allergens is to dedicate production facilities to specific allergenic products, it is recognised that food manufacturing premises and product ranges vary greatly and that this is not always an option. Where dedicated production facilities are not possible, there are a number of ways of separating the production of allergen-containing products from those that do not contain the allergen. These can include separation:

- in different parts of the factory
- by using physical barriers between the production lines
- by use of dedicated equipment
- by minimising unnecessary movement of materials
- by appropriate scheduling of production runs, including appropriate cleaning of equipment between production runs
- by control of rework, ensuring that residual material containing an allergen is not reworked into an allergen free product
- by separating the air supply, where this is practical.

It is recommended that, where practically possible, consideration be given to the dedication of equipment within production facilities. For example,

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weighing equipment, scoops and utensils should be dedicated and the weighed product should be placed in dedicated, lidded and labelled containers. Consideration should be given to colour coding equipment, although this may not be practical where a number of allergens are being handled, and colour coding is used already for the identification of cooked or raw ingredients or vegetarian products.

If it is possible to dedicate areas or equipment, it is important to avoid cross-contamination between these and other operations, including controlling the movement of equipment and personnel.

Physical separation should be considered for “high risk” products (such as milk in baby foods) and the implications of changes to factory layout should be assessed. Consideration should also be given to the ease of cleaning of equipment. Avoiding the crossover of production lines and allowing adequate space for effective cleaning will help minimise the risk of allergen cross-contamination.

It is recommended that wherever practically possible, consideration should be given to the implications of a common air supply; for example, milk powder used elsewhere in a factory may enter the air supply and then be deposited on the surface of dairy-free desserts. Where factories produce nut products and nut free products, dedicated air conditioning/extraction fan systems may be used to contain nut dust, or positive pressure may be used in nut free rooms to prevent nut traces entering the room on the air.

When scheduling the manufacture of allergenic products, there should be a consideration of whether it may be possible for products not containing the allergenic food to be manufactured first, with products containing the allergenic ingredients made at the end of a production run. Additionally, long runs of allergenic products should be undertaken wherever possible, to minimise changeovers and these should be followed by a major clean down.

Rework that contains allergenic ingredients should be reworked only into products that contain that allergen, for example chocolate that contains nuts or nut fillings should only be reworked into other nut-containing chocolates. Rework should be clearly identified in order that it may be tracked in the manufacturing process. Oils used for cooking allergenic foods (eg nuts, shellfish and fish) should not be used subsequently for cooking products not containing the allergen.

### 4.2.4 Cleaning

Very small amounts of some allergens, such as nuts, can cause adverse reactions, including potentially fatal anaphylactic shock. Therefore, thorough cleaning that is effective in reducing the risks of allergen cross-contamination should be used. Cleaning practices that are satisfactory for hygiene purposes may not be adequate for removing some allergens and their validity for such a purpose should be assessed e.g. via residue/environmental swab testing. Equipment may need to be dismantled and manually cleaned to ensure hard

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to clean areas are free from allergen residues. Particular food materials (e.g. powders) present significant cleaning problems and any relevant Industry Guidance, where this has been developed, should be followed. Adequate procedures must be in place for cleaning both production and packaging machinery. Where adequate cleaning is not possible, then the risk of allergen cross-contamination should be assessed and advisory labelling used, if appropriate.

Care is needed in cleaning to ensure that the cleaning of one line does not contaminate another (e.g. by use of compressed air cleaning), or an area which has already been cleaned (e.g. clean dry mix areas from the top down).

Any spillages that occur during production, storage and transportation should be cleaned up immediately to ensure that there is no subsequent allergen cross-contamination. Where known allergen contamination has occurred, the contaminated material should be labelled and physically moved away from the non-contaminated ingredients and work-in-progress.

Consideration should be given to maintenance activities, such as the use of dedicated tools or adequate cleaning procedures where tools are not dedicated.

Where adherence to a cleaning regime is part of a separation system, it should be validated as “fit for purpose” and compliance should be monitored.

Investment in developing and following appropriate cleaning regimes will help to minimise cross-contamination and can reduce the need for product recalls.

- Establish appropriate cleaning regime
- Validate cleaning regime
- Monitor that cleaning is being done properly
- Keep records of cleaning

### 4.2.5 Packing

Incorrect packaging and/or labelling is a significant cause of allergen related product recalls. Therefore, where possible consideration should be given to the provision of dedicated packing lines to reduce the risk of mislabelling. If this is not possible, procedures for checking that the correct labels are applied to products should be implemented and audited regularly, so that accurate information is provided to allergic consumers. Checks should be in place between processing and packing to ensure the correct packaging is used, for example the use of bar code scanners.

There should be systems to ensure packaging is removed at the end of a run, including any packaging that may be within the wrapping machine. This will help to avoid packaging mix-ups when the product to be packed is changed and, therefore, reduce the number of instances in which misleading information is passed to the consumer.

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

### 4.2.6 Monitoring and Review

Allergen control systems should be monitored and reviewed to provide assurance that they are working correctly. This is done most effectively by an audit or “health check” of the system. In addition to routine checks on manufacturing operations, an overall “health check” can find any weaknesses in the system and then corrective actions can be taken. A key benefit of auditing the system is to provide evidence of due diligence in managing allergens.

The “health check” should as a minimum include:

- Review and verification of the hazard analysis and hazard management system
- Product and ingredient specifications
- Operating procedures
- Cleaning procedures
- Training records – demonstration of competence
- Analysis of Customer complaints
- Good Manufacturing Practices

Customer complaints should be investigated and changes made where necessary.

### 4.2.7 Managing Changes

It should be borne in mind that any changes to one production process within a factory or introduction of a new product line can affect the risks of allergen cross-contamination of other products. Moving production of a product to another site may also result in a different allergenic risk, which needs to be relayed to the consumer. Following any such changes, it will be necessary to conduct a new assessment of the risks of allergen cross-contamination of a product, including an evaluation of any advisory labelling that might be necessary. Any changes to the allergen status of a product (for example, changes in the recipe, new risks of cross-contamination) need to be made clearly evident to the consumer, for example, by using prominent labelling flashes, preferably on the front of the packet.

## 5. COMMUNICATION OF ALLERGEN INFORMATION

This section provides advice on the provision of allergen cross-contamination information. However, much of the advice about the manner in which the information is provided is equally applicable to the provision of information on allergenic ingredients.

### 5.1 Allergenic Ingredients Listing

With a few limited exceptions, all deliberate ingredients and components of ingredients in pre-packed food and drink products must be declared in an ingredients' list. The terms used for listing of allergenic ingredients and their derivatives, including processing aids, need to follow the Annex IIIa list of Directive 2003/89/EC. Further information can be found on the Food Standards Agency website at

<http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/foodlabguidance>

### 5.2 Recipe Changes

Consumers may unknowingly consume allergen-containing products where changes have been made to recipes of familiar products and allergenic ingredients have been introduced. Recipe changes should be very clearly indicated, preferably on the front of the pack, in addition to the amended ingredients list. Suitable warnings might be, for example, "New recipe" and "Now Contains". In addition, there is considerable value in food manufacturers and retailers providing information to consumer support organisations.

### 5.3 Allergen Statements

When communicating with allergic consumers through labelling, point of sale information, leaflets and websites, consumers should be advised always to refer to the ingredients' list, and the labelling generally, for detailed information about the composition of the product and the presence of particular allergens. Where a product contains a deliberate allergenic ingredient, its presence may also be indicated separately by means of an allergy information/advice panel, statement or "contains" box. It is best practice for such information to be clearly associated with the ingredients' list. If such devices are employed, all allergenic foods or ingredients used in the food should be listed in such a box, panel or statement. An example of how this may be done is given below, but other formats for the box or statement may be used:

<p><b>INGREDIENTS</b> Wheat Flour, Sugar, Fat, Syrup, Egg, Malt Extract, Ground Ginger, Raising Agents, Flavouring</p>
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<p><b>CONTAINS</b> Wheat, Egg <b>MAY CONTAIN</b> Peanuts</p>
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## Guidelines on Allergen Control and Consumer Information

Advisory labelling on possible cross-contamination with allergens should be justifiable only on the basis of a risk assessment applied to a responsibly managed operation. It should not be used as a substitute for Good Manufacturing Practices.

The use of detailed explanations of the mechanisms by which contamination occurs ('made on a line that also handles allergen X' or 'made in a factory that also handles allergen X') are often confusing to consumers who do not have experience of food manufacturing conditions, separation techniques and cleaning procedures. Such consumers may therefore either ignore or incorrectly interpret such statements in terms of the risk of allergen cross-contamination that they represent. Research demonstrates that these consumers want clear and consistent statements about what they can and cannot eat, with the same phrases used by all manufacturers and retailers<sup>3</sup>.

However, in the recent consultation on possible phrases to be used to convey allergen advisory information there was a significant proportion of respondents who did not like phrases such as "Not suitable for" or "Not recommended for" (<http://www.food.gov.uk/multimedia/pdfs/maycontainconsummary.pdf>). Some consumers prefer to be presented with the facts and allowed to make their own decisions on whether or not to eat the food. In addition, some parts of the food industry consider that it is not appropriate for companies to make decisions on the suitability of a food for a particular consumer as this would be making a medical judgement in respect of consumer health.

The consensus view of those stakeholders involved in producing this guidance was to advise that one of the following phrases (which communicate the risk, whilst taking up the least space and are easily translated into other languages) be used:

- **may contain (traces of) X** - to be used, for example, where the product may be contaminated in the factory
- **ingredient Y may contain (traces of) X** - to be used, for example, where an ingredient may be contaminated further back along the supply chain.

Manufacturers may also choose to make positive statements if they have taken steps to prevent allergen cross-contamination by introducing procedures to ensure that a factory does not use any ingredients containing a certain allergen, for example '**Made in a nut-free factory**'.

A number of illustrative examples of particular products and situations and the resulting suggested warning labels are given in Appendix III.

Warning statements need to be easily visible and clearly legible. Fonts should be simple, with an ideal minimum font size of 10 point. There needs to be good tonal contrast between the type and the background (see the FSA Clear

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<sup>3</sup> Nut Allergy labelling: Report of Research into the Consumer response. 2002. Creative Research/COI Communications.

Labelling Guidance <http://www.food.gov.uk/multimedia/pdfs/clearlabelling.pdf> for general advice on labelling clarity).

In the past 'May Contain' labels have tended to use the word 'nuts' without specifying the particular type of nut involved. Whilst this may be justifiable in certain situations where mixed or multiple nut ingredients are used or are supplied by the same suppliers, this may not always be the case. However, it is known that some people are only allergic to peanuts and others are only allergic to tree nuts, and sometimes only to specific tree nuts. Consideration should therefore be given to whether it is possible on the label to indicate the species of nut involved.

If an allergenic food, or a derived ingredient, is listed in the ingredients list it is not necessary to additionally provide a "may contain" label for possible cross-contamination with the same source allergenic food. For example, if an Indian-style ready meal contained peanuts, it would not be necessary to use warning labelling that the spices used in the sauce may contain peanuts due to potential contamination during growing or harvesting.

It is recommended that there should be a clear distinction in the labelling information provided between ingredients that are deliberate components of the food (whatever the level of incorporation) and any possible allergen cross-contamination arising from production of the raw ingredients or during the manufacture or transport of the food. Ingredients lists should include only ingredients deliberately added to the product. The practice of including possible contaminants in the ingredients' list is illegal under Section 15(1)(a) of the Food Safety Act 1990 and possible allergen cross contaminants should be declared separately.

However, information on deliberate ingredients and possible contaminants should be adjacent to each other and in the same field of vision as the ingredients' list. If using a box headed, for example, "Allergy Advice", make sure that there is a clear distinction between allergens that are deliberate ingredients ("contains allergen X" and those that are possible contaminants (e.g. using the phrases set out above).

### **'Free From'**

A growing number of food manufacturers and retailers are providing ranges of substitute foods made without certain common allergic foods, such as milk, egg or cereals containing gluten. It should not be assumed that the lack of a need to use "may contain" warnings entitles a product to make a "Free From" claim. Consumers are likely to actively seek such products if they need to avoid particular ingredients and it is essential that any such claims be based on specific, rigorous controls to ensure their validity.

A "Free From" claim is an absolute claim, which may be interpreted by consumers to mean a complete absence, whereas the best that can be scientifically demonstrated at present, is that samples of the food were shown to be below the analytical limit of detection of a testing method on one or more

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occasions. However, when there is general agreement on the concern levels below which adverse reactions are unlikely to be triggered, appropriate thresholds for claiming that a product is free from a particular allergen can be set. In making such a claim, it is essential that the analytical limit of detection is not exceeded and “due diligence” requires in addition that such a claim is supported with strict procedures throughout the supply chain (for example, traceability records), recorded checks on these and a risk based analysis used to confirm compliance. Currently available allergen testing methods are described in Appendix III.

There are no established standards for any residual levels of allergens in products labelled as “Free From” those allergens. However, there is a Codex Alimentarius Standard for Gluten Free Products **which are produced from gluten-containing cereals** and this permits a maximum of 200 parts per million (ppm or mg/kg) gluten in the finished product and allows for a cereal-derived product to be labelled “gluten free” if it does not exceed that limit.

**This Codex standard does not apply to products which are made from ingredients which naturally do not contain gluten**, where there is a proposal for a maximum of 20ppm (mg/kg). This is the same level used by Coeliac UK when licensing products to bear their symbol. The figure of 20ppm is not selected as a threshold limit below which consumption is proven to be safe but, in the absence of formally validated methods of analysis, is a best practice analytical figure for the level of quantification at which reliable results should be expected in most product matrices.

Threshold levels for true food allergens, although not yet fully confirmed (see Appendix I) may range from a few milligrams of the whole food up to a few grams.

## APPENDIX I: Allergen Prevalence and Severity

This Appendix lists the allergens in Directive 2003/89/EC that have to be labelled when used as ingredients and includes information on the severity of allergic reactions to these foods and how common they are. It also lists the main derivatives of these allergenic foods that may be used in food manufacture.

At present there is a lack of scientific and clinical evidence on which to base firm conclusions regarding the minimum amounts of some allergens needed to trigger adverse reactions in sensitive individuals. The available evidence was evaluated by the European Food Safety Authority in 2004 \* and by the US Food and Drug Administration in 2005 \*\*and this table reflects their conclusions regarding the range of amounts of the various allergens that have been reported to trigger adverse reactions. Collaborative work to establish agreed concern levels for the most significant food allergens is currently underway (for example, the US Food and Drug Administration draft report on 'Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food', that was issued for consultation in June 2005\*\* and the Food Allergy Research and Resource Programme Scientific Roundtable on Thresholds in October 2004 (in press).

Ingredients derived from micro-organisms fermented on source materials such as cereals, are not covered by the labelling requirements of this Directive.

However, there are other foods, not on this list, to which people may be allergic, such as lupins and pulses, but these do not (at the time this document was produced) have to be specifically labelled as allergens.

### Notes

\* [http://www.efsa.eu.int/science/nda/nda\\_opinions/catindex\\_en.html](http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html)

\*\* <http://www.cfsan.fda.gov/~dms/alrgn.html>

\*\*\* Some ingredients derived from the source allergenic foods are sufficiently processed so as to remove protein and are thus unlikely to trigger allergic reaction in sensitive individuals. The European Commission has produced a list of such derived ingredients that are exempt from the labelling requirements of Directive 2003/89/EC - this is to be found in Commission Directive 2005/26/EC. This list is based on advice from EFSA who rejected some of the ingredients proposed for exemption – see [www.efsa.eu.int/science/nda/nda\\_opinions/catindex\\_en.html](http://www.efsa.eu.int/science/nda/nda_opinions/catindex_en.html).

\*\*\*\* Although **molluscs** are known to cause allergic reactions in those who are susceptible, they are not currently included in the list of specified allergens. The European Commission have agreed to reconsider this issue.

## Table of allergens

**Note: Data on doses of allergens that have been reported to trigger allergic reactions have been reviewed by EFSA (2004\*) and by the US FDA (2005\*), but firm data on clinical thresholds are generally not yet available.**

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
<p>Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut or their hybridised strains)</p>  	<p>Coeliac disease or intolerance to gluten is a reaction to this protein found in a variety of cereals. A protein of similar structure is also found in oats and can cause similar problems. A recent study suggests that based on blood tests, the prevalence of coeliac disease is about 1%.</p> <p>There is a Codex Alimentarius Standard for Gluten Free Products which are produced from gluten-containing cereals that permits a maximum of 200 parts per million (ppm) gluten in the final product. This standard does not apply to products made from ingredients that do not naturally contain gluten, where there is a proposal for a maximum of 20 ppm.</p> <p>Cereals can also cause food allergy, although this is not common in the general population. Cereal allergens can cross-react with pollen allergens.</p> <p><b>REACTION LEVEL</b> The lowest doses of wheat proteins reported to cause allergic reactions, are in the high milligram range.</p>	<ul style="list-style-type: none"> <li>• Flour</li> <li>• Starches</li> <li>• Bran</li> <li>• Bread, breadcrumbs</li> <li>• Semolina</li> <li>• Cous cous</li> <li>• Hydrolysed vegetable protein (if made from wheat)</li> </ul> <p>***Note: Wheat based glucose syrups including dextrose<sup>†</sup>, glucose syrups based on barley, wheat based maltodextrins<sup>†</sup>, and cereals used in distillates for spirits are unlikely to trigger allergic reactions in allergic people or intolerance in those with coeliac disease.</p> <p><sup>†</sup>Derivatives of these ingredients are also exempt.</p>

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<p>Crustaceans (includes all species of crustaceans, eg lobster, crab, prawns and langoustine).</p> 	<p>Allergy to crustacea is quite common. People who are sensitive can react to different types of crustacean, eg shrimps, prawns and lobsters.</p> <p>Crustacea often cause severe reactions, and some people can react to cooking vapours. Some people allergic to crustacea also react to molluscs****.</p> <p><b>REACTION LEVEL</b></p> <p>For those sensitive to the cooking vapours, the amount of crustacea that can cause a reaction is likely to be very small. However, for oral sensitivity, eating as few as 3 or 4 medium sized shrimps is sufficient to trigger a severe reaction in allergic individuals.</p>	<ul style="list-style-type: none"> <li>• Chitosan</li> <li>• Shrimp paste</li> </ul>
<p>Eggs</p> 	<p>Egg allergy is common in young children, but more than half the children affected grow out of this allergy by age 3. Egg can cause anaphylactic reactions in some individuals.</p> <p><b>REACTION LEVEL</b></p> <p>The lowest doses of egg protein reported to cause allergic reactions are in the high microgram to low milligram range.</p>	<ul style="list-style-type: none"> <li>• Egg powder, dried egg or pasteurised egg</li> <li>• Albumin</li> <li>• Egg glaze</li> <li>• Mayonnaise</li> <li>• Lecithin (E322), if made from egg.</li> </ul> <p>***Note: Lysozym (produced from egg) used in wine and albumin (produced from egg) used as fining agent in wine and cider are unlikely to trigger adverse reactions. However Lysozym used for other purposes may trigger adverse reactions.</p>

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<p>Fish</p> 	<p>Fish allergy is more common in adults than in children but it can often be severe, and frequently causes anaphylaxis.</p> <p>All the major fish allergens cross-react in terms of their allergenicity and no fish is safe for fish allergic patients.</p> <p><b>REACTION LEVEL</b> The lowest doses reported to trigger allergic reactions are in the milligrams of fish protein range, which is equivalent to around 1g of whole fish.</p>	<ul style="list-style-type: none"> <li>• Fish (all species)</li> <li>• Fish extracts</li> <li>• Fish sauce</li> <li>• Fish oils</li> <li>• Fish paste</li> <li>• Worcester sauce (some brands)</li> <li>• Omega-3 rich oils derived from fish.</li> </ul> <p>***Note: Fish Gelatine used as a carrier for vitamins and flavours, and fish gelatine and Isinglass used as fining agent in beer, wine and cider are unlikely to trigger allergic reactions. However other uses of fish gelatine that may result in higher levels being present in the food as consumed are not exempt as such doses may be sufficient to trigger allergic reactions.</p>
<p>Peanut</p>  	<p>Peanuts (also known as groundnuts and monkey nuts) are a common cause of food allergy, affecting 1-2% of the UK population. They can cause severe, anaphylactic reactions, and are the most common cause of fatal food allergy. Peanut allergy is commonly acquired in childhood and seldom resolves with age.</p> <p>A significant proportion of people with peanut allergy also react to tree nuts, and there is also allergenic cross-reactivity with other members of the legume family, such as soya and lupin.</p> <p>Heat treatment, especially roasting, increases the allergenicity of peanuts.</p> <p><b>REACTION LEVEL</b> Reactions can be triggered by less than 1 milligram of peanut protein, equivalent to a few 1/1000<sup>ths</sup> of a peanut.</p>	<ul style="list-style-type: none"> <li>• Unrefined, cold-pressed peanut oil (also known as arachis oil)</li> <li>• Peanut butter</li> <li>• Peanut flour</li> <li>• Various peanut protein products</li> <li>• Satay sauce</li> <li>• Refined peanut oil (this has not been exempted from the requirement to label as an allergen under EU Directive 2003/89/EC, although according to the Anaphylaxis Campaign, most peanut allergic consumers do not react to it)</li> </ul>

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<p>Soy(a) beans</p> 	<p>Soya allergy is more common in young children but children often grow out of soya allergy by 2 years of age. Adults are occasionally affected. Symptoms are usually mild and anaphylactic reactions occur rarely.</p> <p>Allergenic cross-reactivity between soya and other legumes, including peanut, is possible and there are some reports of cross-reactivity between soya and cows' milk.</p> <p><b>REACTION LEVEL</b></p> <p>The lowest doses of soy protein reported to cause reactions are in the low to mid milligram range.</p>	<ul style="list-style-type: none"> <li>• Soya flour</li> <li>• Soya tofu</li> <li>• Soya protein isolates</li> <li>• Soya protein concentrates</li> <li>• Textured soya protein</li> <li>• Hydrolysed vegetable protein, if made from soya</li> <li>• Soya infant formula</li> <li>• Soy sauce</li> <li>• Lecithin (E322) if made from soya.</li> </ul> <p>***Note: Fully refined soya bean oil and fat, and natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources, vegetable oil-derived phytosterols and phytosterol esters from soybean sources and plant stanol ester produced from vegetable oil sterols from soybean sources are unlikely to trigger allergic reactions.</p>
<p>Milk</p>   	<p>Cows' milk allergy is the most common food allergy in young children and affects 2 to 7% of babies under one year of age. About 87% of children grow out of milk allergy by age 3.</p> <p>There is a high degree of cross-reactivity between cows milk and milk of other mammals such as sheep, goats and buffalo.</p> <p>Symptoms are often mild but milk can cause anaphylactic reactions in some individuals.</p> <p><b>REACTION LEVEL</b></p> <p>People can react to low milligram amounts of milk proteins, equivalent to a few millilitres of whole milk.</p> <p>Some people cannot tolerate milk because they lack the enzyme that breaks down lactose, the sugar found in milk. Milk from mammals including cows, goats and sheep all contain lactose and so goats' milk and sheep's milk are not suitable alternatives to cows' milk for people who are intolerant to lactose.</p>	<ul style="list-style-type: none"> <li>• Whey</li> <li>• Caseinates</li> <li>• Milk powder</li> <li>• Lactose</li> <li>• Butter, cheese, cream, yoghurt, ghee</li> </ul> <p>***Note: Whey used in distillates for spirits, milk (casein) products used as fining agents in cider and wines and lactitol are unlikely to trigger allergic reactions</p>

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<p>Nuts</p>  	<p>Tree nuts (almond, hazelnut (also known as cob nut or filbert), walnut, cashew, pecan, Brazil nut, pistachio, macadamia nut and Queensland nut) are a common cause of food allergy and are capable of producing anaphylactic reactions in susceptible individuals. Multiple nut sensitivities are frequent, as well as cross-reactivity with peanuts. People rarely grow out of nut allergy.</p> <p><b>REACTION LEVEL</b> Reactions can be triggered by low milligram amounts of nut protein.</p> <p>Other nuts, such as pine nut, chestnut and coconut are not covered by the legislation.</p>	<ul style="list-style-type: none"> <li>• Nut butters</li> <li>• Praline (hazelnut)</li> <li>• Marzipan (almond)</li> <li>• Frangipane (almond)</li> <li>• Nut essences and flavourings</li> <li>• Nut oils (eg walnut oil in salad dressings)</li> <li>• Worcester sauce (some brands contain walnuts)</li> </ul> <p>*** Note: Nuts used in distillates for spirits and nuts (almonds and walnuts) used (as flavour) in spirits are unlikely to trigger allergic reactions.</p>
<p>Celery and Celeriac</p>  	<p>Common cause of oral allergy syndrome amongst adults in mainland Europe, where allergy to celeriac is also common. Symptoms range from mild to severe (anaphylaxis). However celery allergy is not common in the UK.</p> <p><b>REACTION LEVEL</b> The lowest doses of celery reported to trigger allergic reactions are a few grams of whole celery.</p>	<ul style="list-style-type: none"> <li>• Celery powder</li> <li>• Celery seeds</li> <li>• Celariac powder</li> </ul> <p>***Note: Celery leaf and seed oil and celery seed oleoresin are unlikely to trigger allergic reactions</p>
<p>Mustard</p> 	<p>Mustard allergy is not common in the UK. However, it is more common in France where it has been reported to cause severe reactions including anaphylaxis.</p> <p><b>REACTION LEVEL</b> The lowest doses of mustard reported to cause allergic reactions are in the milligram range.</p>	<ul style="list-style-type: none"> <li>• Mustard paste</li> <li>• Mustard seed</li> <li>• Mustard leaves</li> <li>• Mustard flour</li> <li>• Mustard powder.</li> </ul> <p>***Note: Mustard oil, mustard seed oil and mustard seed oleoresin are unlikely to trigger allergic reactions.</p>

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<p>Sesame</p> 	<p>Allergy to sesame is increasing in the UK and sesame can cause severe reactions including anaphylaxis. There is some allergenic cross-reactivity between nuts and seeds.</p> <p><b>REACTION LEVEL</b> The lowest doses of sesame protein reported to cause allergic reactions are in the low milligram range, equivalent to a few sesame seeds.</p>	<ul style="list-style-type: none"> <li>• Sesame seeds</li> <li>• Sesame oil</li> <li>• Sesame paste</li> <li>• Tahini</li> <li>• Houmous</li> <li>• Halva</li> <li>• Furikake and Gomashio (oriental seasonings).</li> </ul>
<p>Sulphur dioxide and sulphites (above 10mg/kg or litre expressed as SO<sub>2</sub>)</p>	<p>Sulphite additives in wine have been associated with triggering asthmatic responses in sensitive individuals, mostly in asthmatic patients. Symptoms can be severe in a minority of asthmatics.</p> <p><b>REACTION LEVEL</b> Most sulphite-sensitive individuals react to ingested sodium metabisulphite in doses of 20-50 milligrams.</p>	<p>E 220 Sulphur dioxide E 221 Sodium sulphite E 222 Sodium hydrogen sulphite E 223 Sodium metabisulphite E 224 Potassium metabisulphite E 226 Calcium sulphite E 227 Calcium hydrogen sulphite E 228 Potassium hydrogen sulphite Sulphur dioxide and sulphites used as a preservative in many foods, including dried fruits and vegetables, soft drinks, fruit juices, fermented drinks (wine, beer and cider), sausages and burgers.</p>

## **APPENDIX II: Legal Considerations of Allergen Cross-Contamination<sup>4</sup>**

*There are both criminal and civil legal regimes relevant to the sale of foods containing allergens and the provision of 'allergen-free' lists. It is essential that these are given careful consideration. The following is a brief outline of the main provisions to assist manufacturers in identifying their legal obligations and the appropriate courses of action in respect of good manufacturing practice and the provision of information to, or for communication to, consumers.*

*Manufacturers should seek their own legal advice as appropriate.*

### **Criminal Law**

#### **Regulations implementing Directive 2003/89/EC: requirements for the labelling of allergenic foods, or their derivatives, used as ingredients in pre-packed foods**

The Food Labelling (Amendment) (England) (No. 2) Regulations 2004,<sup>5</sup> implement Directive 2003/89/EC of the European Parliament and the Council of 10 November 2003, which amends Directive 2000/13/EC as regards indication of ingredients present in foodstuffs. The Regulations for England came into force on the 26 November 2004 and amend the Food Labelling Regulations 1996, as amended. Sale of products that do not comply with the new rules will be prohibited from 25 November 2005, but products that have been labelled before that date may be sold while stocks last. The provisions in this legislation do not relate to foods sold loose or non-pre-packed or those pre-packed for direct sale.

The Food Labelling Amendment (England) (No 2) Regulations 2005 will exempt various ingredients derived from the listed allergenic foods from the labelling requirements of 2003/89/EC, as set out in Directive 2005/26/EC.

*The following addresses legal aspects of possible allergen cross-contamination of foods that do not deliberately contain one of the EC listed foods, or their derivatives, with that allergenic food and any advisory labelling that might be used to inform the consumer of that possibility.*

#### **Article 14 of EC Regulation 178/2002 (General Food Law Regulation)**

This provision applies from 1/1/ 2005. Paragraph (1) prohibits unsafe food from being placed on the market. For the purposes of the Regulation, placing on the market means the holding of food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves. Food is

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<sup>4</sup> These legal provisions are correct at the date the document was drafted but may be subject to amendment

<sup>5</sup>Scotland, Wales and Northern Ireland have equivalent Statutory Instruments to implement the directive.

deemed to be unsafe if it is injurious to health or unfit for human consumption, and Article 14 contains provisions for determining whether food falls within this prohibition. Paragraphs (3) and (4) are particularly relevant as regards allergens. Regard must be had to various criteria, including information provided to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods (see Article 14(3)(b)); and also the particular health sensitivities of a specific category of consumers where the food is intended for that category of persons (see Article 14(4)(c)).

This Article is enforced in Great Britain by means of the General Food Regulations 2004. Equivalent legislation applies in Northern Ireland.

### **Section 14 of the Food Safety Act 1990**

This provision makes it an offence for anyone to sell to the purchaser's prejudice, any food which is not of the nature, substance or quality demanded by the purchaser.

### **Section 15 of the Food Safety Act 1990**

This provision makes it an offence to falsely describe or present food. More particularly, it is an offence for food labelling to be false or likely to mislead as to the nature, substance or quality of the food. The section also applies in relation to the advertising and presentation of food.

The inadvertent presence of allergenic material which is not mentioned in the ingredient list or elsewhere on the packaging, could give rise to a criminal offence being committed, as it could lead to the food not being of the nature, substance or quality demanded, or falsely described or likely to mislead as to the nature, substance or quality of the food.

There is, however, a due diligence defence available to manufacturers in the event of proceedings under both the General Food Regulations 2004 and the Food Safety Act 1990 which would require the manufacturer to prove that he had taken all reasonable precautions and exercised all due diligence to prevent such inclusion of an allergenic material. Food manufacturers can reduce the risk of prosecution and contribute substantially to the establishing of a due diligence defence by implementing good manufacturing practice controls such as those advocated in this guidance.

A manufacturer can also contribute to a due diligence defence if, having carried out the exercise of assessing and attempting to reduce the risk of inadvertent allergen inclusion, the manufacturer comes to the conclusion that a risk is still present and inevitable, and so labels the product with a suitable warning to the allergic consumer. This may take the form of 'may contain X' or similar wording, as appropriate.

It remains widely accepted that individuals who suffer allergic reactions to certain foods owe themselves a particular duty of care to scrutinise food labels more closely than an average consumer does.

## **Enforcement**

It should be noted that the criminal legislation is enforced through local enforcement authorities. It would be prudent for manufacturers to advise their local officers of the control measures they have adopted, to obtain advice on the adequacy of the measures and to increase the likelihood of the acceptability of such measures as constituting a defence of due diligence should the need arise. Ultimately, however, in the event of a prosecution the adequacy of a manufacturer's due diligence procedures would be a matter for the Courts.

## **CIVIL LAW**

In addition to the criminal regime, liability can also arise at civil law under the product liability provisions of the Consumer Protection Act 1987 or under the common law of negligence.

### **Consumer Protection Act 1987**

Under the Consumer Protection Act 1987 (CPA) a manufacturer can be held liable to consumers for injury, loss or damage suffered as a result of his supplying a "defective" product, whether or not he is negligent.

### **Negligence**

In negligence, it is well established that manufacturers owe a duty of care to their consumers to supply safe products. In order to discharge their duty satisfactorily they are required to take all the steps a reasonable manufacturer in the same circumstances would have taken to ensure the safety of his products.

### **Labelling Implications**

A manufacturer's position under the CPA for supplying a defective product and under the rules of negligence will vary in different circumstances and may or may not be affected by advisory notices.

### **Unintentional presence**

Allergens that are or may be unintentionally present in products will not, of course, be labelled as ingredients.

Under the CPA, a product unintentionally containing an allergen is likely to be defective especially when the presence is outside the specification. The question then arises as to whether or not advice about the possible presence of the allergen will effectively "cure" such a defect. The ability of such advice to cure such a defect may depend on a number of factors, for example the size and prominence of the advisory statement and consumer expectation as to the nature of the product, and would be decided on a case by case basis.

A manufacturer may be deemed to be negligent either in the manufacture of the product or in its presentation. Where good manufacturing practices or other due diligence measures are in place, they will go a long way to rebutting negligence in manufacture. Nonetheless, a manufacturer could be negligent in respect of his labelling if he fails to give advice in a situation where, despite the operation of GMP, he should have been aware of a significant likelihood of product contamination.

In practice, it will become more difficult for a manufacturer who does not provide the relevant advice to establish that his product is not defective under the CPA or that he is not negligent in the labelling of his product where a significant number of other suppliers are providing advice on the potential presence of allergens in their products.

### **Consumer Redress**

In civil law, individual consumers have the right to bring actions against manufacturers directly for compensation in respect of any loss, damage or injury they have suffered.

### **Allergen-Free Claims**

Some food manufacturers make 'allergen-free' claims on their products and/or provide lists of products free from specified allergens to consumers via leaflets, carelines and websites. Such lists should be clearly dated and limited in time and/or scope by including a disclaimer along the following lines:

*"This list is valid at time of publication/will remain valid until the end of [x]. However, recipes may change so always check ingredients lists, and/or contact us on [telephone number] for an up to date list or for information about new products or variants of existing products."*

Manufacturers who employ good manufacturing practices reduce the risk of cross-contamination of their food products by any allergens, and should therefore minimise their legal liability in respect of on-pack claims or other indications of freedom from specified allergens. However, the provision of an incorrect list could bring such manufacturers within the food safety and consumer protection controls detailed above and it is thus a matter for individual companies' commercial judgement to decide whether or not such claims should be made or lists compiled. Such advice should not be provided unless supported by an appropriately documented quality system.

### **APPENDIX III: Hazard analysis and hazard management practices to minimise allergen cross-contamination**

This Appendix gives more advice on the use of hazard analysis and hazard management systems to control food allergens and to determine whether or not advisory labelling is appropriate (see section 4). It also describes currently available allergen testing methods.

When carrying out a hazard assessment for possible allergen cross-contamination, to be used in determining appropriate advisory labelling, the following steps should be followed:

#### Step 1:

The sector of the food industry and the intended use of the final food product should be identified. The hazard should be assessed by people with knowledge and expertise in these areas. For larger companies, it would be good practice for the hazards to be assessed by a multidisciplinary team, but for small companies one person with the appropriate expertise would be sufficient. If the required expertise is not available in-house, it may be necessary to obtain expert advice from other sources – such as Industry or Trade Associations, Food Consultants, Regulatory Authorities, including enforcement bodies, or HACCP literature, including sector-specific guides, where these have been developed.

#### Step 2:

A process flow diagram, including all the process steps involved, should then be constructed by the person or team assessing the hazard.

#### Step 3:

The process flow should be confirmed for all stages of the processing operation; for any off-site operations (for example in ingredients' suppliers), it might be necessary to audit these activities directly or obtain the suppliers confirmation of activities undertaken.

#### Step 4:

The person or team assessing the hazard should identify and list all potential sources of hazards that are associated with each process step from the process flow. The existing control measures used to control the hazards identified should be assessed.

#### Step 5:

If appropriate, additional controls should be identified and the hazard should be re-assessed.

#### Step 6:

It should be determined whether the process step is a Critical Control Point (CCP) in the hazard control system. The point critical aspects are to ensure that all the information about the ingredients used appears on the label or packaging and also that the correct label and packaging is used for the

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particular product. There may be more than a single CCP to address the same hazard.

### Step 7:

If it is confirmed that the hazard in Step 6 is a CCP for allergen control, the control criteria should be identified, specified and validated. Where control criteria cannot be established, then advisory labelling would be appropriate. In the absence of chemical analytical thresholds, other criteria will need to be identified.

### Step 8:

Monitoring procedures should be implemented to identify and detect any loss of control at the CCP. These should provide early warning of any impending loss of control. Data from monitoring activities should be evaluated by a designated person.

### Step 9:

Appropriate corrective actions should be developed for each CCP to resolve any process deviations as they occur.

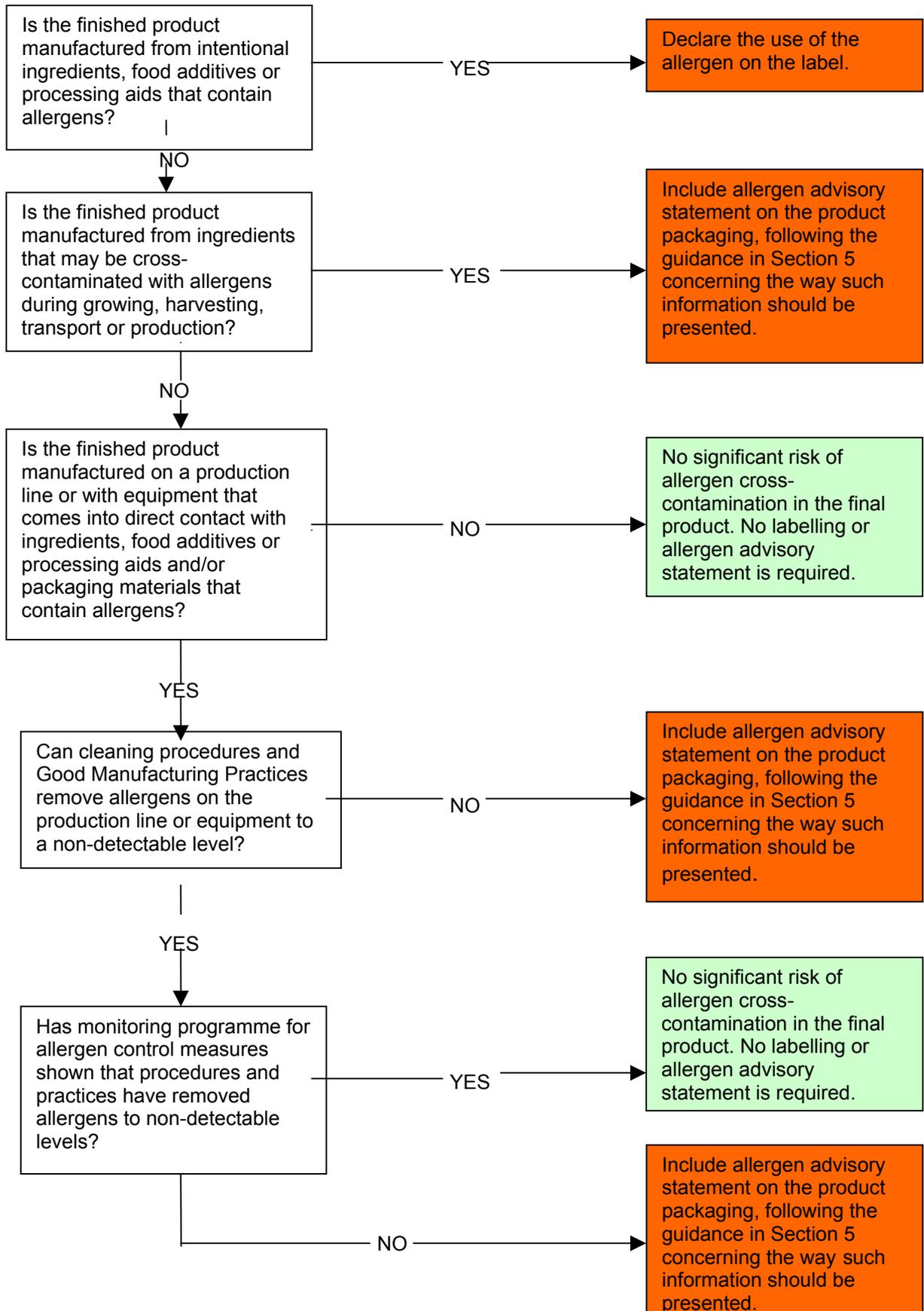
### Step 10:

CCP validation and verification procedures should be implemented to confirm that the hazard control system is working correctly. This may include auditing of control procedures and any tests, random sampling and analysis. The hazard control system should be reviewed regularly, and also after any changes in the manufacturing process or premises to confirm that all CCPs are under control.

Following completion of this hazard assessment, manufacturers should then determine whether allergen advisory statements are appropriate. This can be done by following a decision tree, such as that set out below. This decision tree is based on one developed by the Australian Food and Grocery Council in November 2002 (see [www.afgc.org.au/cmsDocuments/Allergen-Management.pdf](http://www.afgc.org.au/cmsDocuments/Allergen-Management.pdf)), and is intended to help businesses approach the risk assessment process, including the decision on whether or not advisory labelling is appropriate.

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### Decision tree to be used for Allergen Risk Assessment and Determination of appropriate Advisory Labelling



### Currently available allergen testing methods

Testing methods play an important part in the validation and ongoing verification of Allergen Control Plans and need careful consideration. Local Authority Environmental Health Officers and Trading Standards Officers can provide advice on appropriate testing methods. The process of detection usually begins by obtaining a sample of the food and, in the laboratory, preparing a Test Portion for extraction and analysis. Sampling methods must be carefully considered, depending on the particular allergen being tested for. Foods used as liquids or fine powders (such as egg, milk, cereal flours) tend to be spread throughout food products but distribution can be very uneven for peanuts, nuts and whole seeds. Food matrices, composition (acidity, salinity), processing techniques, and length of storage all affect the survival of allergens and the ability to detect trace levels. Differences in kits must also be thoroughly investigated before choosing the best method available and any limitations of the testing method being used should be recognised. The amount of allergen detected by the different test kits can be expressed in different ways and it is important to understand exactly what is being measured. This could be expressed as the amount of the specific allergenic protein, such as casein in milk, or the equivalent amounts of total milk protein or whole milk.

Immunoassay-based laboratory kits, mostly using Enzyme Linked Immuno Sorbent Assay (ELISA) techniques, are one of the most commonly used techniques for detecting allergens. They are both specific and sensitive and can be used for most food-related analytical samples.

DNA based detection, based on Polymerase Chain Reaction (PCR) techniques, is growing in popularity. It requires sophisticated laboratory conditions and lacks the ability of ELISA to quantitate allergen levels in foods. Results need to be carefully interpreted to avoid false positives. This is because of the absence of threshold levels, the fact that this method detects DNA from the allergenic source food and not the protein itself, and it is both highly sensitive and lacks quantitation.

Swabbing techniques are currently only used in conjunction with immunoassay kits, but may have the potential to be extended to DNA detection. These can be particularly useful tools in the validation and ongoing verification of allergen risk management plans

In the manufacturing environment, where time may be limited and analytical capabilities are limited, raw materials, environmental swabs or final products can be tested using rapid, simple 'pregnancy test'-type immunoassays within a few minutes to give simple visual readouts of the presence or absence of the allergen. However some of these tests are significantly less sensitive than laboratory methods. Rapid tests are available for gluten and more recently tests for peanut have emerged.

Another rapid test is available which measures the presence of ATPase. A positive with this method is an indication only of the presence of any protein,

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rather than the presence of specific proteins from an allergenic food. This test can be used for checking general cleaning efficiency but a positive result cannot give information on which protein is present.

### Illustrative examples

For illustrative purposes, a number of situations are described below where possible allergen cross-contamination could occur, together with an assessment of the risk, leading to a decision on allergen advisory labelling. These are included to help companies understand how to approach this problem and are not intended to provide definitive advice for individual situations. Each manufacturer will need to make their own assessment of the particular risks associated with the products that they produce.

#### a) Production of 2 pasta products on the same line, only one of which contains egg

- A wheat-based pasta is made on the same line as a pasta containing egg and wheat;
- The production line is cleaned between runs using dry cleaning, but this is not sufficient to remove residues of egg to a non-detectable level;
- Egg is not a deliberate ingredient in the wheat-based pasta.
  
- **The manufacturer's risk assessment is therefore that there is a real risk of egg being present in the wheat-based pasta. Therefore the decision is to include advisory labelling, using the phrase "May Contain egg". If an allergy box or statement is also used on this product, this would state that the product "Contains wheat" and "May Contain egg".**

#### b) Production of a salad dressing containing cold-pressed olive oil, that was supplied from a factory also producing cold pressed nut oils

- The salad dressing contains olive oil as a deliberate ingredient;
- The supplier provides information that the olive oil has not undergone a significant degree of refinement and that analysis shows that some batches, but not all, contain detectable levels of walnut protein;
- The salad dressing does not contain any deliberate nut ingredients.
  
- **The manufacturer's risk assessment is therefore that there is a real risk that walnut protein may be present in the oil used in the salad dressing. Therefore the decision is to include advisory labelling, using the phrase "the olive oil in this product may contain traces of walnut".**

#### c) Production of oven chips with sunflower oil that was refined in a factory also refining peanut oil

- The oven chips contain refined sunflower oil as a deliberate ingredient;

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- The supplier states that the sunflower oil was refined in a factory that also refines peanut oil and that there is a risk of cross-contamination between the oils;
- Both the sunflower and the peanut oil are highly refined and undergo alkali refining, bleaching, winterization and deodorization/steam refining and analysis demonstrates that batches of the sunflower oil consistently do not contain peanut protein.
- **The manufacturer's risk assessment is therefore that there is no risk that peanut protein will be present in the oven chips. Therefore the decision is not to any include advisory labelling.**

**d) APPENDIX IV: Sources of Further Information**

**Anaphylaxis Campaign**

PO Box 275

Farnborough

Hampshire

GU14 6SX

Tel: 01252 542029

[www.anaphylaxis.org.uk](http://www.anaphylaxis.org.uk)

**British Retail Consortium**

21 Dartmouth Street

London

SW1H 9BP

Tel: 020 7854 8900

Fax: 020 7854 8901

[www.brc.org.uk](http://www.brc.org.uk)

**Coeliac UK**

PO Box 220

High Wycombe

Bucks

HP11 2HY

Tel: 01494 437278

Fax: 01494 474349

[www.coeliac.co.uk](http://www.coeliac.co.uk)

**EC Seed Crushers' and Oil Processors' Federation (FEDIOL)**

168, Avenue de Tervueren (bte 12)

B-1150 Brussels

Belgium

Tel: +32 2 771 5330

Fax: +32 2 771 3817

[www.fediol.be](http://www.fediol.be)

**Food and Drink Federation**

6 Catherine Street

London

WC2B 5JJ

Tel: 020 7836 2460

Fax: 020 7836 0580

[www.fdf.org.uk](http://www.fdf.org.uk)

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### Food Standards Agency

Aviation House  
125 Kingsway  
London  
WC2B 6NH  
Tel: 020 7276 8000  
Fax: 020 7276 8004  
[www.food.gov.uk](http://www.food.gov.uk)

### Institute of Food Science and Technology

5 Cambridge Court  
210 Shepherd's Bush Road  
London  
W6 7NJ  
Tel: 020 7603 6316  
Fax: 020 7602 9936  
[www.ifst.org](http://www.ifst.org)

### LACORS

10 Albert Embankment  
London  
SE1 7SP  
Tel: 020 7840 7200  
Fax: 020 7735 9977  
[www.lacors.gov.uk](http://www.lacors.gov.uk)

## **APPENDIX V: Glossary/Abbreviations**

### **Allergen**

A substance, usually a protein, capable of inducing an allergic reaction.

### **Anaphylaxis/anaphylactic shock**

Acute form of allergy characterised by urticaria, swelling of the lips, shortness of breath, and rapid fall in blood pressure. Without immediate treatment which consists of intramuscular injection of adrenaline, anaphylaxis can be fatal.

### **Antibody**

A blood protein, also known as immunoglobulin, which can bind to an antigen or food allergen. An immunoglobulin is a member of a family of proteins from which antibodies are derived. There are five main classes of immunoglobulin in humans, including IgE and IgG.

### **Antigen**

Substance, often protein in nature, capable of inducing an immune response e.g. a food allergen.

### **Arachis Oil**

Peanut oil.

### **Atopy**

The inherited tendency to develop immune responses dominated by IgE in response to environmental antigens. It is by far the most influential risk factor known that predisposes to asthma, eczema and hayfever.

### **ATPase Test**

A quick, simple test used to check the effectiveness of wet cleaning procedures. ATPase is an enzyme involved in cell metabolism in plants, animals and microbes and so, if it is detected, it shows that some organic matter is present, although it cannot be used to distinguish whether the ATPase comes from food residues or microbes.

### **Changeover**

When a production line is being used to produce more than one end product, the switch between products, which normally involves a thorough cleaning procedure, is known as a changeover.

### **Coeliac Disease**

A condition characterised by damage to the small intestinal wall due to intolerance of gluten protein present in wheat, rye, barley, oats, spelt, kamut or their hybridised strains.

### **Consumer Testing**

This refers to test trials carried out in public places such as supermarkets etc.

**Cross-Contamination**

Unintentionally including another substance in the final product. In this context it often refers to the presence of a food allergen not deliberately present in the product.

**Derivative/Derived ingredient**

An ingredient produced from one of the 12 specified allergens in annex IIIa of Directive 2000/13/EC.

**ELISA**

Enzyme Linked ImmunoSorbent Assay: a sensitive technique for the detection and measurement of compounds, including proteins such as food allergens.

**Food Allergy**

A reproducible adverse reaction to a food or food ingredient that involves the immune system –e.g. allergy to peanut, nut, fish, shellfish, egg or milk.

**Food Intolerance**

A reproducible adverse reaction to a food or food ingredient that does not involve the immune system – e.g. gluten, lactose.

**Factory Taste Trial**

This refers to a small-scale pilot taste trials carried in-house on employees.

**GMP**

Good Manufacturing Practice

**Hazard Analysis**

Practice by which a process is examined to identify potential hazards that can arise and determine measures by which they can be controlled.

**HACCP**

Hazard Analysis Critical Control Point. A means for controlling hazards.

**PCR**

Polymerase Chain Reaction: a sensitive method used to amplify a specific region of DNA (genetic material).

**Processing Aid**

An additive or material used in the production of a food, where there are only unavoidable residues remaining in the final food and these residues do not perform any technological function in the final food.

**Refined Oil**

Oil which has been highly processed and therefore contain only minute quantities of protein (e.g. highly refined peanut oil as opposed to unrefined or cold-pressed oils).

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### **Rework**

This is the material left over product, which is often reused to make the same or similar product.

### **Small or Medium Enterprise**

A small, independent business, managed by its owner or part owners and having a small market share.

### **Unintentional Presence**

Refers to the accidental inclusion or contamination of a food by another ingredient (in this context an allergen).

### **Urticaria**

An itchy rash which results from inflammation and leakage of fluid from the blood into superficial layers of skin in response to various mediators. The symptoms are often referred to as 'nettle rash' or 'hives'.