FOOD STANDARDS AGENCY

Guidance on Allergen Management and Consumer Information

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

This guidance is voluntary

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With support from

BRITISH RETAIL CONSORTIUM

Food and Drink Federation
www.fdf.org.uk

LACORS
promoting quality regulation

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Foreword

One of the Agency's key aims, as set out in our Strategic Plan for 2005-10, is to "enable consumers to make informed choices"

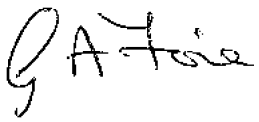
For consumers with food allergies or food intolerances, this is particularly important, as eating even a small amount of the food to which they are sensitive can make them very ill and in some cases, cause potentially fatal anaphylactic reactions.

Recent changes in food labelling legislation have led to significant improvements in the labelling of allergenic ingredients in foods, but this legislation does not address concerns about possible allergen cross-contamination. Whilst some food producers and retailers are already using various forms of advisory labelling to warn consumers about such risks, consumers are concerned about the possible overuse of such labelling and find the variety of phrases used confusing.

After being approached by industry, the Agency therefore decided to produce best practice guidance on how to manage food allergens during food production and the process for deciding whether or not advisory labelling is appropriate. This guidance builds on information that has already been produced by a number of industry organisations.

After consulting our stakeholders, we decided this guidance should be voluntary. We hope that it will help enforcement officers advise businesses on best practice but it should not be used as an enforcement tool.

I would like to express my sincere thanks to all the stakeholders who helped us in this task. Their input and expertise has helped produce a document that will be of great benefit to both the food industry and to the consumers who buy their products.



Gill Fine

The valuable contributions made by the Anaphylaxis Campaign, the British Retail Consortium, Cullinane Associates Ltd, the Food and Drink Federation, H. J. Heinz Co Ltd, the Institute of Grocery Distribution, LACoRS, Marks & Spencer plc, PepsiCo International, Sainsbury's Supermarkets Ltd, Somerfield Stores Ltd, and Unilever UK are gratefully acknowledged.

1. Introduction

1.1 Why is this Guidance needed?

A key aim of the Food Standards Agency 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[1,2,3]. People with food allergies, and the people shopping for them, need clear labelling of both allergenic ingredients and identification of possible cross-contamination[4] with allergens, in order to make informed food choices.

There is general agreement between the food industry, consumer support groups and enforcement bodies that excessive use of advisory warning labels about the possible presence of allergens, not only unnecessarily restricts consumer choice, but also devalues the impact of the warning labels. Unlike the situation for deliberate ingredients, there are currently no statutory controls governing labelling for the possible low level presence of allergens due to the cross-contamination of foods along the food supply chain.

The Agency, after being approached by the food industry and consulting our stakeholders, decided it would be helpful to produce voluntary best practice guidance to ensure allergen labelling could be as effective as possible.

Advisory labelling should only be used when, following a thorough risk assessment, there is a demonstrable and significant risk of allergen cross-contamination.

There is currently no consensus on the levels of allergens required to provoke allergic reactions in consumers sensitive to various foods. This document therefore sets out a qualitative approach to allergen management and risk assessment. We anticipate revising this document when further scientific evidence exists to enable quantitative allergen management levels to be set.

[1] Howarth P.H., Dec 1998, Is allergy increasing? Early life influences. Clin Exp Allergy, **28** (6):2-7.
[2] Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), 2000 Adverse Reactions to Food and Food Ingredients, **11:** 91-97.
[3] Buttriss and Schenker, Adverse Reactions to Food (Ed. J. Buttriss), British Nutritional Foundation 2002.
[4] In this document the term cross-contamination is used to describe accidental contact with an allergenic food. This does not imply that the food is unwholesome or unhygienic.

1.2 Who is this Guidance intended for?

This document provides voluntary best practice advice to help food producers and retailers assess the risks of cross-contamination of a food product with an allergenic food or food ingredient and then to determine whether or not advisory labelling is appropriate. It is intended to give a generic overview of an approach to take in managing allergens and providing advisory labelling. The overall approach described in this guidance is relevant to any size of food business, although some of the management techniques described will not be appropriate for smaller businesses. A leaflet aimed at small and micro businesses has been produced (for availability please see 1.3 below). In addition, the guidance will be helpful for enforcement bodies, who advise food businesses on best practice; however it should not be used as an enforcement tool.

Consumers with a food allergy, or those who buy for someone with a food allergy, need to read and understand food labels in order to buy food that is safe for them. It is important that consumers with food allergies and food intolerances understand the meaning of any advisory labelling used on a product in conjunction with the rest of the information provided on the label, so that they can make appropriate food choices. The Food Standards Agency provides guidance to help consumers understand food labels, for example, via our http://www.eatwell.gov.uk website.

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 Food Standards Agency Publications on telephone 0845 606 0667 or email: foodstandards@ecgroup.uk.com. Copies of the leaflet aimed at small and microbusinesses are also available from the above.

2. Background and Purpose

2.1 Food Allergies and Intolerances

True food allergies are reproducible adverse reactions to a particular food that involve 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. Allergic reactions are characterised by the rapid release of chemicals in the body that cause symptoms, which can occur within minutes or may take an hour or more after ingestion of the allergen. Whilst almost any food protein can cause an allergic reaction in some people, the most common food allergens in Europe are listed in the current allergen labelling legislation, these are:

cereals containing gluten – wheat, rye, barley, oats, spelt, kamut;
crustaceans;
egg;
fish;
peanuts;
milk;
nuts – Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoiesis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*);
soya;
sesame;
celery;
mustard; and
sulphur dioxide and sulphites.

Sulphur dioxide and sulphites are included in the EU list of allergens because they can cause adverse reactions in some people. Those affected generally already have asthma or other allergies and exposure can trigger an asthma attack.

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. Very small amounts of an allergen, sometimes less than one milligram (one thousandth of a gram), can trigger a reaction which can be severe and on rare occasions fatal.

Coeliac disease is not an allergy, it is a life-long autoimmune disease, which means that the body produces antibodies that attack its own tissues. In coeliac disease this attack is triggered by gluten, a family of proteins found in wheat, rye, barley and oats, which cause an inflammatory response that damages the gut. Villi (tiny, finger-like projections that line the gut) become inflamed and then flattened, leading to a decreased surface area for absorption of nutrients from food. People with coeliac disease can, as a result, have a wide range of digestive symptoms and can suffer from nutritional deficiencies. However, other people who do not have coeliac disease can be allergic to cereals, such as wheat.

The avoidance of allergens due to cross-contamination is particularly important for those allergenic foods which affect a higher proportion of people as well as for those allergic people who are more likely to have life-threatening reactions.

2.2 Purpose of this Document

Legislation and growing awareness of food allergies have focussed attention on the identification of the food allergens that affect the most people within the European Community; how they can be managed; 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 prepacked foods, the relevant allergenic food is indicated on the labelling. From 25 November 2005 products not complying with this legislation were prohibited (but products that were labelled before that date could continue to be sold whilst stocks lasted). This legislation however does not cover allergenic foods that are unintentionally present in food products as a result of cross-contamination at some point during the manufacture or transportation. Further information on the legislative background can be found in Appendix II.

Whilst guidance on this issue has already been produced by some industry organisations, such as the Food and Drink Federation and the Institute of Grocery Distribution, the purpose of this document is to set out best practice guidance which food businesses can choose to follow if they wish, that could be used 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 might or might not be used, and what they mean for the affected consumer.

This guidance sets out general principles that could be used to manage specific allergenic ingredients in differing situations. The focus of this guidance is the production of prepacked foods (for instance, food put into packaging before sale, normally at a site separate from that where

the product is sold to the consumer), however, the general principles could also be applied to non-prepacked foods.

Actions that may be appropriate in each specific situation need to be determined by each individual food business. Different sectors of the food industry may also wish to produce their own, more detailed guidance or codes of practice, that 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 management 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 in certain foods (see section 3).

2.3 Scope

For some time now food manufacturers have recognised that in certain situations, there is a risk of cross-contamination of a food with nuts and/or peanuts, which are not deliberately added to the food. This risk was conveyed to customers in advisory warning statements such as "may contain nuts". More recently this sort of advisory labelling has been extended to seeds such as sesame and other allergenic foods that can also trigger potentially fatal anaphylactic reactions such as egg, milk, fish and shellfish.

As well as the 12 allergenic foods for which there is statutory ingredient listing in Europe, there are other allergens, where evidence is growing of their public health importance. These may, in due course, be considered for addition to the list of 12 allergens that require mandatory ingredients labelling, for example: lupin, molluscs and kiwi fruit. Some people are also allergic to latex that can be used in food packaging or in gloves used by food handlers.

Appendix I describes the allergens currently covered by this legislation. The guidance set out in this document has been drafted for the management of any food allergen in any particular food-manufacturing environment.

3. Allergen Risk Assessment, Management and Communication

In order to avoid the unintentional presence of allergenic foods in products it is necessary to evaluate the **likelihood of unintentional allergen cross-contamination** across the supply chain, from raw materials through to the finished product. Following completion of such a risk analysis, manufacturers can then determine whether or not allergen advisory labelling is appropriate on the finished product as sold to consumers.

Risk analysis is made up of four stages:

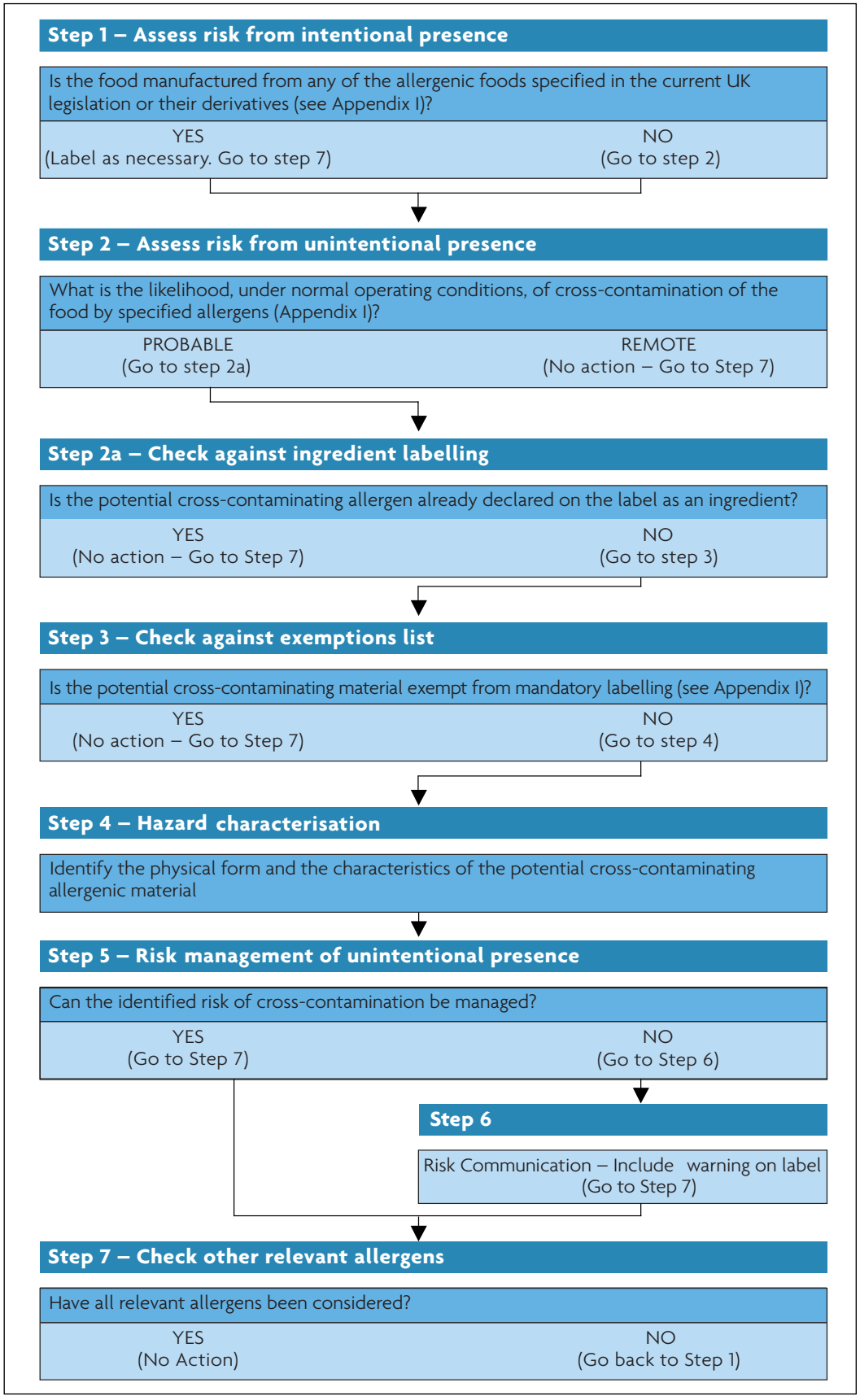
1. *Risk assessment*– what is the risk?
2. *Risk management* – can the risk be managed?
3. *Risk communication* – how should the risk be communicated?
4. *Risk review* – has the risk changed?

Figure 1 sets out as a flow chart, the steps involved in this risk analysis. Figure 4 shows the steps in the decision tree for managing allergens.

3.1 Allergen Risk Assessment

The first step in the risk assessment process is to consider if the ingredient/product **intentionally contains** an allergenic foodstuff, and whether any of these allergenic ingredients have the potential to cross-contaminate either foods produced on the premises, or ingredients coming into the premises. Current legislation recognises 12 foods known to commonly produce severe adverse reactions across the EU (see Annex IIIa of Directive 2000/13/EC and Appendix I of this document), those foods listed in the Annex have to be labelled whenever they are intentionally used in a product. The 12 allergenic foods specified in the legislation were determined by the European Food Safety Authority (EFSA) Scientific Panel on Dietetic Products, Nutrition and Allergens, to be important allergens that required food labels because of the severity and prevalence of the allergy in Europe. These food types present the greatest risk if present inadvertently and therefore should all be considered in the risk assessment process. Other allergenic foods, for example, lupin, molluscs, kiwi fruit, may be added to Annex IIIa in future, dependent on the prevalence of adverse reactions in sensitive consumers and their inherent potency to trigger severe reactions.

Figure 1: Allergen advisory labelling decision tree



Appendix I contains further details on these 12 foods including information on the prevalence of reactions to them. This information can be used in the case-by-case risk assessment process. It should be noted that Appendix I also includes information on ingredients derived from the listed allergenic foods that are exempt from the allergen labelling directive; these are not an allergen cross-contamination risk.

In reaching a judgement on the need for allergen warning labels 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). EFSA has reviewed the 12 allergenic foods currently listed in Annex IIIa 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). However, the scientific literature is not yet sufficient to draw firm conclusions regarding the highest dose that would not cause an adverse effect.

- **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 and that some food may not be consumed at the intended destination;

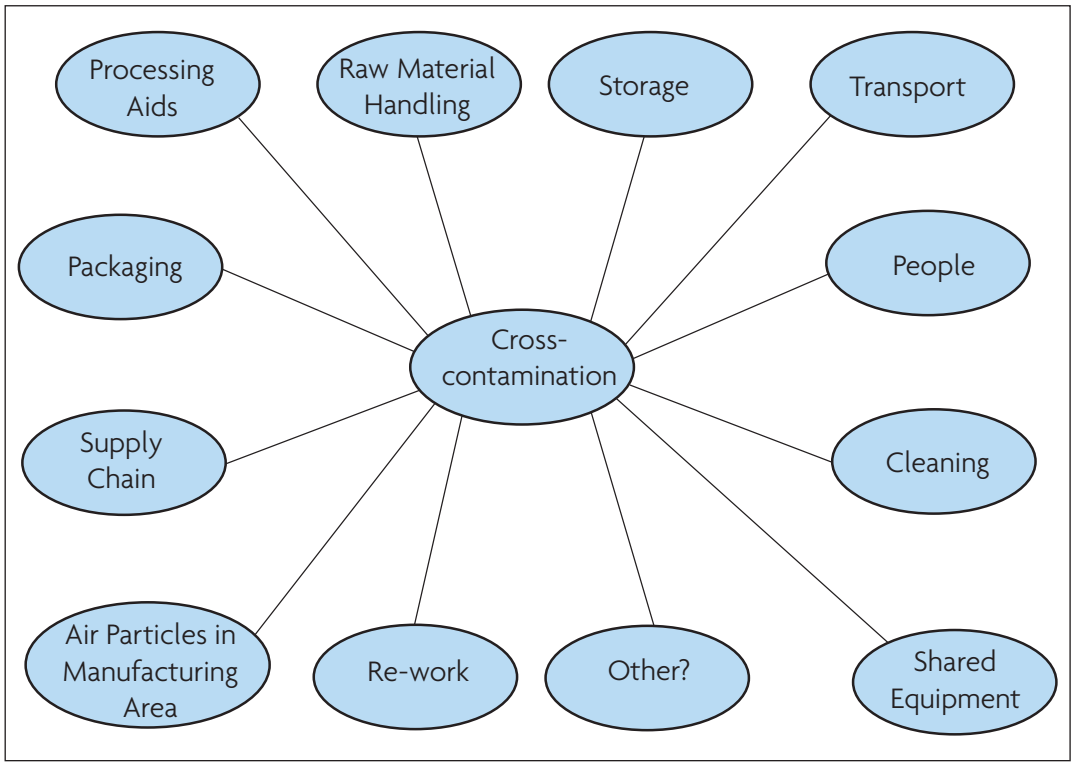
- whether there are particular **subgroups of the population** likely to be at particular risk, such as babies and young children (although allergy to egg and milk is relatively common in babies and young children, the allergy is often outgrown by the time the child reaches school age) or those who restrict 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 refined nut oils which are highly processed ingredients, is likely to pose a lower risk than cross-contamination with either whole, or pieces of, nut. Also, if the product has been processed, it may not have any protein present and therefore will not present an allergen cross-contamination risk. It should be noted that some processed products that contain little or no protein have not been submitted for temporary exemption from the requirements of Directive 2003/89/EC but do not represent a risk; and

- the **physical nature of the particular ingredients being used and the geography of the manufacturing environment**. The physical form of the allergen is important, for example a liquid and a powder represent different types of risk. 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 (for example, by physical barriers, distance, timing or cleaning) between the products in which it is deliberately used and those where it is not.

The second step in the risk assessment process will identify the probability of unintentional presence of allergens, by thinking about how cross-contamination could happen and how likely it is to happen (see figure 2).

Figure 2: Potential sources of cross-contamination



The outcome of the initial risk assessment will be either:

Probable A likely chance of risks occurring.

Remote Risks are unlikely to arise but are still possible. Low probability risks should not be ignored and should be managed and eliminated where appropriate.

3.2 Allergen Risk Management

Where a risk has been identified (as either probable or remote), attempts can be made to reduce the unintentional presence of allergens in the product as far as possible.

Whether manufacturing individual ingredients or complex food products, consistency in risk assessment and application of risk management measures is needed.

The 'visually and physically clean' standard can in principle be applied to each stage in the supply chain.

For example, primary agricultural produce with risk of cross-contamination in the field could be assessed using a visual inspection standard where representative samples are confirmed as 'visually and physically clean' from contaminating allergenic materials.

3.2.1 General Principles

Allergens should be managed to avoid their unintentional presence in products wherever possible. This management involves evaluation of the likelihood of allergen cross-contamination associated with every step of the food production process, from sourcing raw materials through to marketing of a finished product.

Food businesses generally already have Good Manufacturing Practice (GMP) in place. These require a commitment and discipline to ensure products meet food safety, quality and legal requirements, using appropriate manufacturing operations, including effective food safety systems (using hazard analysis principles) and quality assurance systems. Existing GMP controls will assist with allergen management, for example avoiding cross-contamination by segregation, cleaning, using separate utensils etc. However, it should be noted that unlike microbiological risks, heating does not necessarily destroy food allergens and may actually increase their potency, for example roasting peanuts.

The introduction of allergen management into a food business can be seen as an extension of existing food safety management rather than a completely new system.

3.2.2 Manufacturing

The key aspects of food and drink manufacturing businesses to be considered in the management of allergens are illustrated in figure 3, which are then discussed in more detail in the following sections.

Figure 3: Key areas for consideration

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 management of allergens should also be available and/or posted wherever they need to be observed in pursuit of the company's management policy. Additionally, it is important to ensure awareness of these procedures on the part of both workers and visitors by posting in the reception and production areas at least a summary of the critical aspects. Training and awareness procedures should include:

- Recognising which ingredients are the allergens of concern and why.
- Identifying potential allergen cross-contamination situations.
- Hand washing.
- Clothing requirements including laundering.
- Re-work procedures.

- Waste management procedures.
- Cleaning procedures.
- Dedicated equipment if available.
- People movement around the site, for example, people changing production line or site, trips to the canteen and visitors.
- Equipment movement around the site, for example, maintenance tools, food trays, etc.

Manufacturers should be aware of people moving freely between production lines and plants, potentially transferring allergens on their clothing or hands. There may also be an allergen cross-contamination hazard in communal areas such as canteens and locker rooms.

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 if appropriate, for assessing those ingredients used by their suppliers or co-packers. Any change in supplier should be accompanied by the appropriate checks.

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 asking suppliers to provide the required information. Manufacturers should ensure that materials are ordered against a clear specification and that they ask appropriate questions of their suppliers.

A business may wish to ask its suppliers whether an ingredient contains any food allergens either as:

a) a major component (for example, textured vegetable protein from soya),

b) a minor component (for example, as a food additive or processing aid which has been derived from an allergenic source like amylase from wheat), or

c) due to food allergen cross-contamination (for example, chickpea flour from a mill which also mills wheat).

Raw material suppliers (and their agents) should be aware of the hazards arising from contamination by food allergens and conform to the manufacturers' purchase specification. However, commodity raw material

suppliers should only use allergen warning statements on products after they have carried out an assessment of the risk of cross-contamination, otherwise it may cause unnecessary advisory warning labelling on finished products.

Ingredients should be fully described in specifications, for example not using general terms such as 'vegetable' oils and fats where those allergens listed in Annex IIIa 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 on cleaning on page 22). Allergenic raw materials should be stored in clearly identified areas where possible, for example, 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 only be used for storage of other raw materials after appropriate cleaning.

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.

In summary, practices should ensure that the allergen status of all ingredients (including flavourings, additives, carriers and processing aids), as well as other materials that might come into contact with the food such as baking release agents, are 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.

☑ Check implications of any change of ingredient supplier.

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 particularly in small and micro businesses. 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 production area.
- 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 managing re-work, ensuring that residual material containing an allergen is not re-worked into a product not containing the allergen.
- By separating the air supply, where this is practical.

Shared Equipment
It is recommended that, where practically possible, consideration is given to the dedication of equipment within production facilities. For example, weighing equipment, scoops and utensils could be dedicated and the weighed product placed in dedicated, lidded and labelled containers. Consideration could be given to colour coding equipment, although this may not be practical where a number of allergens are being handled, and/or colour coding is used already for other purposes, such as the identification of cooked or raw ingredients, or vegetarian products.

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

Physical Separation
Physical separation should be considered for 'high risk' ingredients (such as milk in baby foods) and the implications of changes to the layout of the food production area 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.

Airborne Particles in Manufacturing Area
It is recommended that, wherever practically possible, consideration should be given to the implications of air movement. For example, where nut products and nut free products are produced in the same production area it may be possible to dedicate air conditioning/extraction fan systems 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 production runs consideration should be given to scheduling those products not containing the allergenic ingredient first. Additionally, long runs of allergenic products should be undertaken wherever possible, to minimise changeovers and these should be followed by a major clean down.

Storage
Consideration should be given to the temporary labelling of work in progress. This is, for instance, a half-finished product that is held-over. Care should be taken that the product is not mistaken for another product with a different set of allergens.

Similarly, care should be taken to label and store packaging materials that are unused at the end of a production run.

Co-products are misshapes and broken products, which for quality reasons are not acceptable as finished product but could still be consumed by employees or sold through factory shops. Such products should be subject to the normal allergen labelling controls.

Re-work
Re-work that contains allergenic ingredients should be re-worked only into products that contain that allergen, for example chocolate that contains nuts or nut fillings should only be re-worked into other nut-containing chocolates. Re-work should be clearly identified in order that it may be tracked in the manufacturing process.

Oils used for cooking allergenic foods (for example, shellfish, fish and breaded or battered products) should not be used subsequently for cooking products not containing that allergen.

In summary

☑ Is it possible to have dedicated production lines or areas?

☑ Is it possible to erect physical barriers between production lines or areas?

☑ Is it possible to dedicate utensils and equipment?

☑ Is it possible to clean between production runs?

☑ Is it possible to schedule production runs to minimise possible cross-contamination?

- ☑ Is re-work managed?
- ☑ Is it possible to manage airflow?
- ☑ Are held-over products suitably labelled?
- ☑ Is there a procedure for removing packaging and labelling it before returning it to the stores?

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 where appropriate. A 'visually and physically clean' standard is not just a casual visual inspection of the production line or area, it also requires that all of the trouble spots are sought out and inspected. 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, for example, via residue/environmental swab testing (see Appendix IV on testing). Equipment may need to be dismantled and manually cleaned to ensure hard to clean areas are free from allergen residues. Particular food materials (for example, powders, seeds, pastes and particulates) present significant cleaning problems and any relevant industry guidance, where this has been developed, should be followed. Adequate procedures should 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 (for example, by use of compressed air cleaning), or an area which has already been cleaned (for example, clean dry mix areas from the top down).

Any spillage that occurs 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 food allergen cross-contamination and can reduce the likelihood of needing costly product recalls.Ensure that cleaning equipment itself is cleaned after use to minimise the risk that it may carry and transfer allergen traces.

☑ Establish appropriate cleaning regime including laundering of protective clothing.

☑ Validate cleaning regimes.

☑ Monitor that cleaning is being done properly.

☑ Keep records of cleaning.

Packaging

Incorrect packaging and/or labelling is a major cause of allergen related product recalls. 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 automated label verification systems.

It is important that, following recipe changes or the introduction of a new allergen cross-contamination risk etc, the old packaging is not only withdrawn from use but is physically destroyed, so that it cannot be used in error.

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 multi-pack products and that allergen information appears on, or is visible through, both the inner and outer wrappers.

New Product Development and Reformulation

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 oil, for example sunflower oil, instead of butter. By using allergenic ingredients only when they are essential components of a food product, one element of the risk from unintentional allergenic cross-contamination will be minimised.

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

Extending Brands
If it is decided to extend a brand name into a different product sector (for example, 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. The approach to allergen labelling across a brand should be as consistent as possible.

Factory Trials and Consumer Testing
If 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 information should be clearly conveyed with products presented for wider test and marketing purposes.

However clearly they are labelled, care should be taken if sample products containing the major food allergens are distributed or offered where they can be taken by unsupervised children (for example through letterboxes, in stores or other public places).

Managing Changes
Any changes to one production process within the food production area or the 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 that 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.

Consumers may unknowingly consume allergen-containing products where changes have been made to the recipe of a familiar product and allergenic ingredients have been introduced. Any changes to the allergen status of a product (for example, recipe changes) need to be made obvious to the consumer, for example, by using prominent labelling flashes, 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'. It may also be possible to use other methods such as websites to inform consumers of recipe changes. 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. In addition, food manufacturers and retailers are strongly advised to provide updated information to consumer support organisations such as the Anaphylaxis Campaign and Coeliac UK as they have systems in place for informing their members about changes.

The processes described in detail above are summarised in the following figure.

Figure 4: Steps in the Decision Tree for Managing Allergens

STEP 1 RISK ASSESSMENT FROM INTENTIONAL PRESENCE

Is the food manufactured from any of the allergenic foods, or their derivatives, as specified in current UK legislation (as listed in Appendix I)?

YES — **List ingredient/additive/processing aid in ingredients declaration on pack.**
GO TO STEP 7

NO — **No need for on pack declaration of allergens in ingredient list.**
GO TO STEP 2

STEP 2 EXPOSURE ASSESSMENT

What is the likelihood, under normal operating conditions, of cross-contamination of the food by specified allergens from either the ingredients used in it or the manufacturing environment in which it is made/handled?

Definitions **PROBABLE** (Likely to occur)
REMOTE (Risk unlikely to arise)

NB. It is important in assessing the likelihood of allergen cross-contamination to consider all the possible sources (see figure 2) and also the physical form and characteristics of the allergen (as fully detailed in Step 4).

Is it **PROBABLE** that the ingredients in the manufactured food will be cross-contaminated with allergens during growing, harvesting, processing, handling or distribution or that the food is manufactured on a production line or equipment that comes into direct contact with allergen containing materials?

GO TO STEP 2a

Is there a **REMOTE** possibility that the ingredients in the manufactured food will be cross-contaminated with allergens during growing, harvesting, processing, handling or distribution or that the food is manufactured on a production line or with equipment that comes into direct contact with allergen-containing materials?

NO ADDITIONAL RISK MANAGEMENT OR ADVISORY WARNING LABEL REQUIRED.

GO TO STEP 7

STEP 2a CHECK AGAINST INGREDIENT LABELLING

Is the potential cross-contaminating allergenic food **already declared** on the label/ingredients list?

YES – NO ADDITIONAL RISK MANAGEMENT OR ADVISORY WARNING LABEL REQUIRED.

GO TO STEP 7

NO – GO TO STEP 3

STEP 3 CHECK AGAINST EXEMPTIONS LIST

Is the potentially cross-contaminating material exempt from mandatory labelling (for instance, an allergenic derivative officially exempt in legislation from mandatory labelling (see Appendix I))?

YES – NO ADDITIONAL RISK MANAGEMENT OR ADVISORY WARNING LABEL REQUIRED.

GO TO STEP 7

NO – GO TO STEP 4

STEP 4 HAZARD CHARACTERISATION

Identify physical form and characteristics of the potentially cross-contaminating allergenic material

Protein: Is the material highly refined (no protein present)?

Physical form: liquid/powder/particulate

Distribution of contamination: homogenous or particles (lumps, pieces, seeds).

GO TO STEP 5

STEP 5 RISK MANAGEMENT OF UNINTENTIONAL PRESENCE

Can this identified **risk** of cross-contamination be **reduced or eliminated**?

a) <u>For highly refined and/or processed materials with little or no allergenic protein</u>

As the allergenic protein is the trigger for adverse reactions in sensitive individuals, evidence of little or no allergenic protein present indicates effective protection against adverse reactions in sensitive individuals.

YES – NO RISK MANAGEMENT OR ADVISORY WARNING LABEL REQUIRED.

GO TO STEP 7

b) <u>For liquid or powdered materials with homogenous distribution</u>

Working to GMP and Good Agricultural Practice with HACCP controls, including a 'visually and physically clean' inspection (or allergen testing methods if preferred), combined with appropriate segregation measures should minimise the risk of cross-contamination.

YES – NO ADDITIONAL RISK MANAGEMENT OR ADVISORY WARNING LABEL REQUIRED.

GO TO STEP 7

c) <u>For particles or powdered materials with heterogeneous distribution</u>

It can be difficult to manage and ensure removal of particles or powdered materials from shared equipment/environment.

Therefore, unless:

- There is clear demonstrable evidence of a 'visually and physically clean' or equivalent standard, or
- Assessment of the end product as consumed indicates little or no allergenic protein remains, a risk of cross-contamination remains.

NO – ADVISORY WARNING LABEL REQUIRED

GO TO STEP 6

Cross-contamination by small pieces of allergenic foods such as peanuts, tree nuts and sesame seeds can be exceptionally difficult to manage and therefore may warrant additional consideration for use of advisory labelling.

STEP 6 RISK COMMUNICATION

Refer to section 3.3 Allergen risk communication.

GO TO STEP 7

STEP 7 CHECK OTHER RELEVANT ALLERGENS – REPEAT STEPS

Have **all relevant allergens** been considered? Is it certain that no other allergen could have cross-contaminated your product?

YES – NO FURTHER ACTION REQUIRED

NO – GO BACK TO STEP 1 AND REPEAT PROCESS UNTIL ALL RELEVANT ALLERGENS HAVE BEEN CONSIDERED

A number of theoretical worked examples using this process can be found in Appendix III.

3.3 Allergen Risk Communication

Following completion of the risk assessment (as set out in section 3.1) and elimination or reduction of the risks where possible, a decision on whether or not advisory labelling is appropriate then needs to be made.

This section gives advice on how to provide allergen cross-contamination information to the consumer.

3.3.1 Advisory Labelling

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.

Any advisory labelling should be in close proximity to the ingredients list. It is recommended that there is 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. List of ingredients should include only ingredients deliberately added to the product. The practice of including possible contaminants in the ingredients list (so called 'last ingredient listing') is illegal under Section 15(1)(a) of The Food Safety Act 1990 (Article 14(1)(a) of The Food Safety (Northern Ireland) Order 1991) 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.

The presence of deliberately added allergenic ingredients, and/or advice on the possible presence of allergen cross-contamination, may additionally be indicated by means of an allergy information/advice panel. These panels are not a legal requirement but, where such information is given, it is best practice to associate it clearly with the ingredients list. If such devices are employed, all allergenic foods or ingredients as defined by law and used in the food should be listed in such a box, panel or statement. If using a box headed, for example, 'Allergy Advice', make sure that there is a clear distinction between allergens that are deliberate ingredients and those that are possible cross-contaminants. An example of how this may be done is given below, but other formats for the box or statement may be used:

INGREDIENTS	CONTAINS
Wheatflour, Sugar, Vegetable Oil, Barley Malt Extract, Salt, Raising Agent: Sodium Bicarbonate, E503, E450, Glucose Syrup	Wheat, Barley, Gluten MAY CONTAIN Nuts

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. Warning labels should only be used where there is a demonstrable and significant risk of allergen cross-contamination, and they 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') may be confusing to consumers who do not have experience of food manufacturing conditions, separation techniques and cleaning procedures. Such consumers could therefore either ignore or incorrectly interpret such statements in terms of the risk of allergen cross-contamination that they represent. Consumer research conducted in 2002 demonstrated that most consumers wanted clear and consistent statements about what they could and could not eat, with the same phrases used by all manufacturers and retailers [5].

[5] Nut Allergy Labelling Report of Research into the Consumer Response, 2002. Creative Research/COI Communication

However, in a 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). Such consumers preferred to be presented with the facts, which would allow them to make their own decision on whether or not to eat the food. Some manufacturers agreed with this, not wishing to make medical judgements for individuals, while others preferred to make a suitability statement, believing that it is difficult to communicate the risk-based approach behind using an allergen advisory statement.

Either way, consumers need to be told about the potential risk in a simple, consistent way. It is suggested that a brief, factual phrase is used to communicate the risk and this will also be easily translatable into other languages. For example:

- *may contain X*
- *not suitable for someone with X allergy*

A number of illustrative examples of particular products and situations where advisory labelling is and is not appropriate are given in Appendix III.

Effective Labelling Messages

In the past advisory 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. 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. Similarly, where a product contains peanuts but may be cross-contaminated with tree nuts, it may be appropriate to use a phrase such as 'May Contain Other Nuts'.

If an allergenic food, or a derived ingredient, is listed in the ingredients list it is not necessary to additionally provide allergen advisory labelling 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 some of the ingredients used in the sauce may contain peanuts.

Advisory statements need to be easily visible and clearly legible. Fonts should be simple. See the FSA Clear Labelling Guidance (http://www.food.gov.uk/multimedia/pdfs/clearlabelling.pdf) for general advice.

3.3.2 Allergen-free foods

A growing number of food manufacturers and retailers are providing ranges of substitute foods made without certain common allergenic foods, such as milk, egg or cereals containing gluten. In addition, some manufacturers choose to exclude certain allergens from a site. It should not be assumed that the lack of a need to use advisory allergen warnings entitles a product to make a 'Free From' or 'made in allergen X free factory' claim. Consumers are likely to actively seek such products if they need to avoid particular ingredients and it is essential that any such claims are based on specific, rigorous controls to ensure their validity.

If manufacturers produce lists of foods free from particular allergens, these should be regularly reviewed and updated.

An 'allergen-free' 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 occasions. However, when there is general agreement on the management action levels below which adverse reactions are unlikely to be triggered, appropriate limits for claiming that a product is free from a particular allergen can be set.

Standards for Gluten Free

Currently there are no established legal standards for any residual levels of allergens in products labelled as 'Free-from' those allergens. However, there are some international standards for gluten free products (see Appendix I).

3.4 Allergen Risk Review

Allergen Management Systems should be monitored and reviewed to provide assurance that they are working correctly. The most effective way of doing this is by carrying out routine checks on manufacturing operations including an audit or 'health check' of the system. 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 encompass compliance with GMP requirements, including:

☑ 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.

Customer complaints should be investigated and changes made where necessary.

The frequency of review will depend on the risk level of the operation. An annual review is likely to be reasonable in most circumstances. However, any of the following may trigger the need to conduct a review:

- Introduction of new ingredients, new recipes or new processes,
- Changes in scheduling, equipment, site, source of raw material, product storage, handling or manufacture,
- EFSA will be reviewing the list of allergens for mandatory ingredients listing, so new allergens may emerge that will need to be managed, or
- Any other changes which introduce significant risks.

For example, any changes to one process within a food production area, or introduction of a new product, can affect the risks of allergen cross-contamination of other products manufactured at the same site. 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.

Appendix I: Allergen Prevalence and Severity

This Appendix lists the allergens in Annex IIIa of 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.

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

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. Collaborative work to establish agreed management action levels for the most significant food allergens is currently underway.[6]

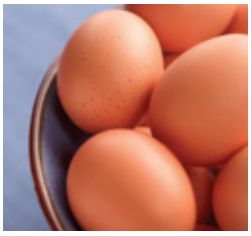
In the absence of thresholds, a qualitative approach to managing allergens should be applied and a number of factors considered. These factors are outlined in section 3.2. The following table should be used to feed into the risk assessment process.

[6] 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. ILSI Europe Newsletter, June 2005, pg.10-12.

Table of allergens

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut or their hybridised strains) [7]   	Coeliac disease or intolerance to gluten is a reaction to the protein gluten found in cereals like wheat, barley and rye. 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% of the UK population. Cereals can also cause food allergy, although this is not common in the general population. Cereal allergens can cross-react with pollen allergens.	• Flour • Starches • Bran • Rusk • Bread, breadcrumbs • Semolina • Cous cous • Hydrolysed vegetable protein (if made from wheat) *Note: Wheat based glucose syrups including dextrose†, glucose syrups based on barley, wheat based maltodextrins†, and cereals used in distillates for spirits are unlikely to trigger allergic reactions in allergic people or intolerance in those with coeliac disease. †Derivatives of these ingredients are also exempt.

[7] There is a Codex Alimentarius Standard for Gluten Free Products which is based on analysis of the nitrogen content of 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 that are made from ingredients that naturally do not contain gluten, where there is a proposal for a maximum of 20ppm (mg/kg). The 200ppm limit also applies to food that are mixes of gluten-containing and non-gluten containing cereals.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Crustaceans (includes all species of crustaceans, e.g. lobster, crab, prawns and langoustine)  	Allergy to crustacea is quite common. People who are sensitive can react to different types of crustacean, e.g. shrimps, prawns and lobsters. Crustacea often cause severe reactions, and some people can react to cooking vapours. Some people allergic to crustacea also react to molluscs.[8]	• Chitosan • Shrimp paste
Eggs 	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.	• Egg powder, dried egg or pasteurised egg • Albumin • Egg glaze • Mayonnaise *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.

[8] 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 has agreed to reconsider this issue.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Fish 	Fish allergy is more common in adults than in children but it can often be severe, and frequently causes anaphylaxis. All the major fish allergens cross-react in terms of their allergenicity and no fish is safe for fish allergic patients.	• Fish (all species) • Fish extracts • Fish sauce • Fish oils • Fish paste • Worcester sauce (some brands) • Omega-3 rich oils derived from fish. *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.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Peanut  	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. 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. Heat treatment, especially roasting, increases the allergenicity of peanuts.	• Unrefined, cold-pressed peanut oil (sometimes known as arachis oil) • Peanut butter • Peanut flour • Various peanut protein products • Satay sauce • 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 researchers[9], most peanut allergic consumers do not react to it).

[9] Hourihane J.O'B., Bedwani S.J., Dean T.P., Warner J.O. (1997a). Randomised double crossover challenge study of allergenicity of peanut oils in subjects allergic to peanuts. BMJ **314**: 1094-1087.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Soy(a)  	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. 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.	• Soya flour • Soya tofu • Soya protein isolates • Soya protein concentrates • Textured soya protein • Hydrolysed vegetable protein, if made from soya • Soya infant formula • Soy sauce • Lecithin (E322), if made from soya • Edamame beans *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.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Milk   	Cows' milk allergy is the most common food allergy in young children and affects 2 – 7% of babies under one year of age. About 87% of children grow out of milk allergy by age 3. There is a high degree of cross-reactivity between cows' milk and milk of other mammals such as sheep, goats and buffalo. Symptoms are often mild but milk can cause anaphylactic reactions in some individuals. 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.	• Whey • Caseinates • Milk powder • Lactose • Butter, cheese, cream, yoghurt, ghee *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.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Nuts  	Tree nuts (Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana)* – also known as cob nuts and filberts, Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoiesis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*)) 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.	• Nut butters • Praline (hazelnut) • Marzipan (almond) • Frangipane (almond) • Nut essences and flavourings • Nut oils (e.g. walnut oil in salad dressings) • Worcester sauce (some brands contain walnuts) *Note: Nuts used in distillates for spirits, and nuts (almonds and walnuts) used (as flavours) in spirits are unlikely to trigger allergic reactions.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Celery and Celeriac  	Celery is a 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, allergies to celery and celeriac are not common in the UK.	• Celery powder • Celery seeds • Celariac powder *Note: Celery leaf and seed oil and celery seed oleoresin are unlikely to trigger allergic reactions.
Mustard  	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.	• Mustard paste • Mustard seed • Mustard leaves • Mustard flour • Mustard powder *Note: Mustard oil, mustard seed oil and mustard seed oleoresin are unlikely to trigger allergic reactions.

Allergen	Prevalence and severity	Some derivatives and foods made with this allergen that can trigger allergic reactions
Sesame 	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.	• Sesame seeds • Sesame oil • Sesame paste • Tahini • Houmous • Halva • Furikake and Gomashio (oriental seasonings)
Sulphur dioxide and sulphites (above 10mg/kg or litre expressed as SO_2)	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.	• E220 Sulphur dioxide • E221 Sodium sulphite • E222 Sodium hydrogen sulphite • E223 Sodium metabisulphite • E224 Potassium metabisulphite • E226 Calcium sulphite • E227 Calcium hydrogen sulphite • E228 Potassium hydrogen sulphite Sulphur dioxide and sulphites are 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.

Note

*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

Appendix II: Legal Considerations of Allergen Cross-Contamination

There are both criminal and civil legal regimes relevant to the sale of foods containing allergens and the provision of 'allergen-free' lists[10]. 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 prepacked foods

The Food Labelling (Amendment) (England) (No. 2) Regulations 2004[11] 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 and the equivalent Regulations in Scotland and Wales, amend the Food Labelling Regulations 1996, (as amended)[12]. Sale of products that did not comply with the new rules were prohibited from 25 November 2005, but products that were labelled before that date could be sold while stocks lasted. The provisions in this legislation do not relate to foods sold loose or non-prepacked or those prepacked for direct sales (see guidance notes at www.food.gov.uk/multimedia/pdfs/labelamendguid25nov05.pdf).

The Food Labelling (Amendment) (England) (No. 2) Regulations 2005[13], which implements Directives 2005/26/EC and 2005/63/EC[14], exempts various ingredients derived from the listed allergenic foods from the labelling requirements of Directive 2003/89/EC. Separate but

[10] These legal provisions are correct at the date the document was drafted but may be subject to amendment.

[11] Scotland, Wales and Northern Ireland have equivalent Statutory Instruments to implement the Directive.

[12] Equivalent Regulations in Northern Ireland amend the Food Labelling Regulations (NI) 1996 (as amended).

[13] These Regulations are amended by [S.I. 2005/2969] The Food Labelling (Amendment) (England) (No. 2) Regulations 2005 and in N. Ireland by [S.R. No. 475/2005] Food Labelling (Amendment No. 2) Regulations (NI) 2005 and in Wales by [S.I. 2005/2835(W. 200)] The Food Labelling (Amendment) (Wales) (No. 2) Regulations 2005.

[14] The Food Labelling Amendment (Scotland) (No. 3) Regulations 2005 implement these Directives in Scotland.

parallellegislation applies in respect of Scotland and Northern Ireland and Wales, as indicated below. (See guidance notes at http://www.food.gov.uk/mulimedia/pdfs/labelguidederived.pdf and on the N. Ireland web page http://www.food.gov.uk/northernireland/niregulation/niguidancenotes/foodlabel).

The above Regulations do not cover accidental cross-contamination of a product with the listed allergenic foods or food ingredients. There is other law which may be applicable to possible allergen cross-contamination of foods that do not deliberately contain one of the EC listed foods, or their derivatives, with that allergenic food.

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

This provision applied from January 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 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) of this article are particularly relevant:

"3. In determining whether any food is unsafe, regard shall be had:

a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods."

"4. In determining whether any food is injurious to health, regard shall be had:

a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

b) to the probable cumulative toxic effects;

c) *to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers."*

Various criteria, have to be considered, 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 specifically intended for that category of persons (see Article 14(4)(c)). In the allergy context, this refers particularly to foods sold as 'free from' certain allergens or 'suitable for' people with particular health needs (for example, those people who have coeliac disease). (See section 3.3.2).

Article 16 of EC Regulation 178/2002 (General Food Law Regulation)

This article requires that the labelling, advertising and presentation of food, including the information made available, should not mislead consumers.

These articles are enforced in Great Britain by means of the General Food Regulations No. 3279/2004. Equivalent regulations apply in Northern Ireland[15].

Section 14 of the Food Safety Act 1990
(Article 13 of the Food Safety (NI) Order 1991)

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
(Article 14 of the Food Safety (NI) Order 1991)

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.

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

Directive 89/398/EEC and subsequent Directives on foods for particular nutritional uses ('PARNUTS' foods)

Any foods that are sold for particular nutritional uses will also need to meet the requirements of the relevant legislation.

[15] General Food Regulations (NI) 2004 SR. No. 505/2004.

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 management 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[16], 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 Consumer Protection Act 1987 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 Consumer Protection Act 1987, a product unintentionally cross-contaminated with an allergen may 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

[16] A defective product is defined as one where the safety of the product is not such as persons generally are entitled to expect. Criteria include any instructions or warnings given with the product and what might reasonably be expected to be done with it.

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 Consumer Protection Act 1987 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: Worked 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. Manufacturers should work through these examples using the allergen advisory labelling decision tree (see figures 1 and 4). Each manufacturer will need to make their own assessment of the particular risks associated with the products that they produce.

Example 1. Production of oven chips with sunflower oil that was refined in premises also refining peanut oil

Step	Example
1	Oven chips contain refined sunflower oil as a deliberate ingredient. There are no deliberately added allergenic foods requiring labelling.
2	The supplier has declared that sunflower oil was refined in a food production area that also refines peanut oil. There is a probable risk of cross-contamination under normal operating conditions between the refined sunflower oil and refined peanut oil as they are made using shared equipment.
2a	Peanut is not already declared in the ingredients list.
3	Refined peanut oil is not exempt from allergen labelling when present as an intentionally added ingredient.
4	The potentially cross-contaminating allergenic material is a highly refined oil with little or no protein present.
5	Analysis confirms batches of peanut oil consistently do not contain peanut protein.
6	There is no need for an advisory warning label for peanut because the only probable risk of peanut exposure is highly refined peanut oil with little or no protein present.

Example 2. Production of two similar condiment sauces on the same line, one of which contains mustard oil

Step	Example
1	Horseradish sauce A does not contain any mustard ingredients.
2	A horseradish sauce containing mustard oil is produced on the same line as horseradish sauce A. Despite rigorous GMP, there is a probable risk of cross-contamination under normal operating conditions as the two horseradish sauces are made using shared equipment.
2a	Mustard is not already declared in the ingredients list.
3	Mustard oil is exempt from allergen labelling when present as an intentionally added ingredient.
4	Not applicable.
5	Not applicable.
6	There is no need for an advisory warning label for mustard because the only probable risk of mustard exposure is an ingredient/derivative already legally exempted from allergen labelling even when intentionally present.

Example 3. Production of tea cakes in the same bakery as burger buns with sesame seeds

Step	Example
1	Tea cakes do not contain any sesame seeds.
2	Teacakes are made using the same tins and oven as burger buns with sesame seeds. There is a probable risk of cross-contamination under normal operating conditions.
2a	Sesame is not already declared in the ingredients list.
3	Sesame seeds are not exempt from allergen labelling when present as an intentionally added ingredient.
4	Sesame seeds are small particles, which will be unevenly distributed and cross-contamination is difficult to manage.
5	Although teacake production is scheduled first followed by sesame seed burger buns, followed by a thorough clean at the end of the day, a visual inspection of teacake batches show that teacakes sometimes contain sesame seeds.
6	There is a need for an advisory warning label for sesame because GMP measures in place cannot control cross-contamination and are insufficient to manage the identified risk.

Example 4. Production of cheese flavoured potato crisps on same line as salted potato crisps

Step	Example
1	Salted potato crisps do not contain any cheese.
2	Salted potato crisps are made on the same line as cheese flavoured crisps. There is a probable risk of cross-contamination under normal operating conditions.
2a	Cheese (milk) is not already declared in the ingredients list.
3	Cheese (milk) is not exempt from allergen labelling when present as an intentionally added ingredient.
4	Cheese flavouring is a fine powder, which is evenly distributed.
5	Rigorous GMP measures are in place. Shared equipment is accessible for cleaning. Physical segregation measures are in place. Shared equipment is minimised. Salted potato crisp production is scheduled first, followed by cheese flavoured product. Salted potato crisp production can only re-start following a thorough clean, inspection and sign-off that equipment meets 'visually and physically clean' standard.
6	There is no need for an advisory warning label for cheese (milk) because GMP measures in place are clearly managing cross-contamination and are sufficient to manage the identified risk.

Example 5. Production of two pasta products on the same line, only one of which contains egg

Step	Example
1	Pasta A does not contain any egg ingredient.
2	It is made on the same line as pasta B containing egg.
2a	Egg is not already declared in the ingredients list of pasta A.
3	Egg is not exempt from allergen labelling when present as an intentionally added ingredient.
4	Egg is added to the pasta mix pre-extrusion as a powder which is evenly distributed. Extruded pasta shapes can be lodged in various locations post-extrusion.
5	Production of pasta B is scheduled after pasta A to minimise carry-over of egg-containing material. Due to the nature of the product, daily change-over 'wet cleaning' throughout the process is not possible except at the weekend shut down when the line is able to dry out. The line is rigorously visually inspected following daily changeover 'dry cleaning' routines to minimise any product retention.
6	As no further measures can be taken to reduce a) egg residues from the pre-extruded product flow, or b) probable risk of particulate product cross-contamination, there is a need for an advisory warning label for egg for pasta A.

Step 6. Production of coleslaw in an area where Waldorf Salad is also produced

Step	Example
1	The coleslaw recipe does not contain deliberately added allergenic ingredients. The mayonnaise used is a stabilised oil/water/vinegar emulsion.
2	A Waldorf salad containing walnuts and celery is produced in the same premises. The Waldorf salad is produced on the same line, at the end of the coleslaw production run, and it is followed by a wet wash down to a 'visually and physically clean' standard. There is a probable risk of cross-contamination under normal operating conditions since the two salads are made using shared equipment.
2a	Nuts and celery are not declared on ingredients list.
3	These ingredients are not exempted from labelling.
4	The potential cross-contaminating allergenic materials are walnut and celery pieces, which will be unevenly distributed, and therefore the cross-contamination maybe difficult to manage. Moreover, the configuration of the plant may be such that it will be impossible to thoroughly check all areas.
5	Walnuts: Rigorous GMP procedures are in place, the shared equipment is wet washed after every run to a 'visually and physically clean' standard, and physical segregation measures are in place. Small pieces of nuts are very difficult to manage throughout the plant and therefore it warrants additional consideration for use of advisory labelling for nuts (walnuts). Celery: The cross-contamination by pieces of celery is easier to manage. The wet wash is followed by an inspection and sign-off that the equipment meets the 'visually and physically clean' standard.
6	Walnuts: There is a need for an advisory label for nuts (walnuts) for the coleslaw. Celery: There is no need for an advisory warning label for celery.

Appendix IV: Allergen Testing Methods

Testing methods play an important part in the validation and ongoing verification of Allergen Management 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, and 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 ImmunoSorbent 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 where appropriate.

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 quantify 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 quantification.

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, particularly cleaning regimens.

In the manufacturing environment, where time and/or analytical capabilities may be limited, raw materials, environmental swabs or final products can be tested using rapid, simple 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 rapid tests for peanut have emerged.

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

Recent developments in the application of gluten testing have resulted in new, more sensitive methodology, developed by Professor Enrique Méndez, becoming available. This test, which has been temporarily endorsed by the CODEX Committee on Methodology, Analysis and Sampling (CCMAS) in April 2005, is scheduled for further discussion in November 2006.

Important

It is important to recognise that the development of analytical methods for detecting and quantifying levels of allergens in foods is still at an early stage. Although a number of methods have been developed to date, the EU has not yet agreed independently validated methods for all the allergens for which statutory ingredients labelling is required, nor are there recognised and readily available standard reference materials for food allergens (with the exception of peanut). In addition, commercial kits that are currently available may vary in sensitivity and specificity and their effectiveness across a wide range of food materials may vary.

Therefore, food producers, for the time being, can adopt a 'visually and physically clean' standard for assessing the risk of possible allergen cross-contamination. This requires a thorough visual inspection of the production line (following cleaning) and the final product.

Appendix V: Sources of Further Information

Anaphylaxis Campaign

PO Box 275
Farnborough
Hampshire
GU14 6SX
Tel: 01252 542029
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

Coeliac UK

Suites A-D
Octagon Court
High Wycombe
Buckinghamshire
HP11 2HS
Tel: 0149 443 7278
Helpline: 0870 444 8804
Fax: 01494 474349
www.coeliac.org.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

Food and Drink Federation

6 Catherine Street
London
WC2B 5JJ
Tel: 020 7836 2460
Fax: 020 7836 0580
www.fdf.org.uk

Food Standards Agency

Aviation House
125 Kingsway
London
WC2B 6NH
Tel: 020 7276 8000
Fax: 020 7276 8004
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

LACoRS

10 Albert Embankment
London
SE1 7SP
Tel: 020 7840 7200
Fax: 020 7735 9977
www.lacors.gov.uk

Appendix VI: Glossary/Abbreviations

Allergen

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

Anaphylaxis/Anaphylactic Shock

Acute form of allergy characterised by uticaria, 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.

Antigen

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

Arachis Oil

Peanut oil.

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

Consumer Testing

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

Co-products

Products which are removed from the normal production chain for quality reasons, but which may still be sold for human consumption.

Cross-Contamination

The unintentional presence of another substance in the final product. In the context of allergens, it usually refers to trace amounts of allergenic foods which, whilst not of themselves unwholesome, may be problematic for those suffering from particular allergies.

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.

Equivalent Standard

The evidence to demonstrate little or no material of allergenic significance. This would include considering test results and processing/dilution factors.

Food Allergy

A reproducible adverse reaction to a food or food ingredient that involves the immune system, for example, 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 – for example, lactose.

Hazard Analysis

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

HACCP

Hazard Analysis and Critical Control Points.

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.

Reference Material

An established material with defined properties that can be used to validate a measurement method and allow the calibration of results.

Refined Oil

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

Re-work

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

Threshold

For the purposes of this document the term refers to the amount needed to elicit an allergic reaction in a sensitive individual within a given population.

Unintentional Presence

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

Visually and Physically Clean

This is an inspection standard which is usually applied following appropriate cleaning where there is no visible presence or residue of cross-contaminating allergenic material. For example:

1) no visible particles of food on contact surfaces of shared equipment.

2) no wheat grains in a consignment of maize.

Waste

Materials that no longer have any use and which must be removed and kept separate without contacting anything within the food production chain so as to avoid cross-contamination.

Work in Progress

Part processed or semi-finished product, which is not wrapped, and therefore still at risk of cross-contamination with allergens when moved around a food production area or between premises.

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