8

Handling food allergens in retail and manufacturing

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8.1 Introduction

Food allergies can be uncomfortable, severe or potentially fatal to those who suffer them, depending on the nature of the reaction. The most common advice to sufferers is to avoid consumption of the trigger food in the diet. On the surface this seems a relatively simple and straightforward means of avoiding reactions. However, the fact that some individuals can react to minute amounts of the trigger food combined with the fact that the most common triggers of food allergies (milk, egg, wheat and nuts) can be widespread throughout a host of different foods means that avoiding allergens can be a time-consuming process.

All food manufacturers have an overriding legal responsibility to ensure that their products are safe and fit for the purpose intended. They must also comply with the relevant labelling legislation. The first step is to identify the key allergens. These are the allergens that are the most common causes of food allergies. Following this, a comprehensive evaluation of ingredients, storage, products and processes needs to be undertaken to understand in detail those products that contain these key allergens. Peanuts and nuts are considered as a special case in manufacturing and retail as they currently seem to be the major cause of anaphylaxis in the UK, a severe and potentially fatal food allergy. Peanuts themselves appear to be the most potent allergen and are the main cause of severe reactions.[1] They seem to initiate reactions in some peanut allergics at very low levels. Other nuts are also implicated in anaphylactic reactions and these include hazelnuts, almonds, brazils, cashews, pecans and walnuts. Additional controls at all levels are often introduced to ensure that the presence of even trace amounts of certain allergens in a product is communicated to sufferers.

Although both the retail and catering environments operate on a smaller scale than food manufacture, the principles involved in the handling of allergens are identical to that in large-scale food manufacture. The areas of concern when handling allergens and the actions that can be taken apply equally to large-scale manufacture as to smaller operations. However, one major difference is that food sold unpackaged, for instance in delicatessens and bakeries, is not sold with a detailed ingredients list. The handling of allergens in such cases mirrors that in the catering sector and is discussed in this chapter.

The main communication tool that the industry has is the ingredients list provided on the majority of products. It is important that ingredients lists are thorough, accurate and legible, and this is the duty of every manufacturer. However, this is not always straightforward and some of the issues surrounding this will be discussed in detail in this chapter.

8.2 Identification of allergens

The main challenge to the food industry is to provide accurate and up-to-date information at all times so that sufferers of allergies can select foods with confidence.

The first step in identifying a strategy for managing allergens in the food industry is to highlight the key allergens to be controlled. These do vary from country to country, but certain allergens are seen as important in most countries. Other key allergens may vary and can be added to the list to suit the specific country; for instance in France celery is viewed as an important allergen.

Suggested key allergens are as follows:

- Milk
- Wheat
- Eggs
- Soya
- Peanuts
- Tree nuts
- Shellfish
- Sesame.

Nut oils are an area worthy of comment. Research suggests that refined, bleached, deodorised nut oils do not initiate allergic reactions,[2] even in those who are anaphylactic to nuts. Unrefined, cold pressed or virgin nut oils are chosen specifically for their distinctive flavour. These oils are not refined and contain small amounts of protein from the original nut. The same research study showed that unrefined oils were able to cause reactions in individuals who have suffered previous anaphylaxis, but that generally the reactions were not as severe as those experienced when nuts were eaten. The small amount of protein that is present in unrefined oils is removed through the process of refining, bleaching and deodorising, rendering the oils suitable for allergy sufferers.

Once key allergens have been identified, all steps in the manufacturing process need to be cross-checked to ascertain whether there are any allergens present in the product, or indeed whether there is any chance of cross-contamination with any allergens during the manufacturing process.

8.3 Good Manufacturing Practice

Good Manufacturing Practice (GMP) in the food industry is the series of controls used during production that are aimed at ensuring that all products are consistently manufactured to a quality appropriate to their intended use. GMP aims to produce safe and wholesome food through well-controlled operations that avoid waste and any type of contamination. It should be applied throughout the whole production and supply chain and covers areas such as raw material sourcing, hygienic design of buildings and equipment, production processes, food handling, storage and transport conditions, safety procedures, cleaning procedures and personnel hygiene. The ability to demonstrate the principles and measures involved in GMP and the actions that are taken at a particular manufacturing site are essential to show that all reasonable steps are taken to prevent errors and indeed offences from potentially occurring. The manufacturer of a food product must comply with the relevant legal requirements, including product composition, labelling, safety and hygiene. GMP is an overall system for control and maintenance of quality. In its broadest sense it shows that quality is the responsibility not only of the factory, or group of factories, but also of suppliers, contract manufacturers and all business partners. The principles outlined in GMP have been developed for large-scale food industries, but they apply equally well to retail and catering environments, albeit on smaller scales.

Ideally, production facilities that handle ingredients containing key allergens will be specifically designed and built to enable complete segregation between products containing key allergens and those that are free from those allergens. A factory that produces food containing allergens should ideally have the following properties:

- Dedicated equipment
- Screened-off manufacturing/packing areas
- Dedicated workwear and washing facilities
- Cleaning regimes and pre-use inspections
- Segregated storage areas
- Air flow management/negative air pressure in nut areas.

However, in practice many manufacturing plants are generally used for the production of more than one product, and often one of the products contains a key allergen. Where dedicated equipment is not available for one particular product that contains key allergens, additional controls need to be introduced to control the presence of allergens and prevent contamination of other products with key allergens.

8.3.1 Allergens and GMP

The control of allergens in the food industry clearly falls under the remit of GMP, as key allergens in products should be labelled as any errors or omissions have the potential to cause serious safety problems for those who suffer allergic reactions. The areas of product composition, labelling and safety are particularly relevant to the control of allergens in the manufacturing process and these will be discussed in detail throughout this chapter. A number of criteria must be considered to state that a given product is free from a particular allergen.

To claim that a product is free from a particular allergen it must:

- not contain the allergen as an ingredient;
- not contain any rework or any other material that contains the allergen;
- not carry any risk of cross-contamination with the allergen through manufacture or packing on a plant where other products containing the allergen are processed.

8.3.2 Hazard Analysis and Critical Control Point (HACCP) studies

HACCP studies are detailed procedures which are undertaken to evaluate possible safety hazards, to eliminate them where possible or to find ways of keeping them under control, and are an important part of any Good Manufacturing Practice plan. These studies are not mandatory but are a useful tool in food manufacture to demonstrate diligent care during production. HACCP studies involve the identification of Critical Control Points (CCPs) in a manufacturing process using a systematic and standard approach to hazard analysis. CCPs are those specific parts of a manufacturing process where there is a risk of contamination of a product occurring and where a specific control needs to be introduced to minimise the risk. They range from critical points in the storage of raw materials to prevent cross-contamination, to the cleaning of a particular part of a plant following production, to the use or disposal of any waste that may be produced. CCPs can be related to microbial contamination, but in this case will be discussed in relation to contamination with allergens. Once CCPs have been identified, the risks need to be detailed and the procedures developed to minimise the risks of contamination. Training, reporting and documentation of the actions taken are also part of any HACCP study, to ensure consistency in quality control for every production run.

These studies are invaluable in the control of allergens in the manufacturing environment as they give a clear indication of the risk of allergens being present in a specific product, particularly through potential cross-contamination from or to other products. Although not mandatory, HACCP studies should be undertaken on each production line and are a critical part of any Good Manufacturing Practice procedures used in a manufacturing site.

8.3.3 HACCP in practice

Each step in a manufacturing procedure needs to be assessed from an HACCP angle. Consequently any manufacturing process will have many such assessments covering various aspects of the production chain. Critical control points that relate to the handling of common allergens cover all areas of manufacturing, including storage, production, packing, transport and employee safety.

In all cases, the HACCP study must include the identification of the CCP, providing a clear outline of the potential hazard, details of the control measures in place, identification of the person responsible for the control measures, the action required to ensure the controls are met and finally any corrective action should a problem occur. The HACCP study needs to be undertaken in a systematic and thorough manner. Each step in the process of manufacture, from receipt of ingredients to packing of the finished product, must be assessed. Table 8.1 shows one example of a systematic approach to an HACCP study.

Each HACCP study gives a detailed review of a specific step in the manufacturing process. An example of an HACCP study is given in Fig. 8.1, showing the handling of nuts in a production facility. The particular step involved is the disposal of packaging in which nuts are delivered to the factory. There is a risk that this packaging could be reused and could transfer traces of nuts to other ingredients.

This specific example shows the detail required for each critical control point in the HACCP study. A completed HACCP study provides an extremely thorough review of the entire manufacturing procedure and gives very detailed advice to the operators of the production line to control any risks that could arise. HACCP studies provide a very useful tool for quality control.

HACCP studies must be undertaken for each production line and must be recorded in detail. It is important that instructions and training are provided to all operators, outlining the steps that need to be taken to control any risks. In the case of completely new lines, new products being manufactured on an existing line, or major line modifications, the HACCP study must be repeated as even small changes to procedures can introduce new CCPs. The HACCP study must take into account the real-life characteristics of any line to provide accurate information and appropriate controls.

An essential part of all HACCP studies is a clear training programme to ensure that all staff who work in a particular area are fully aware of the

Table 8.1 Systematic approach to HACCP studies, related to allergen control

1 Process step details	What is the nature of the process involved?
2 Hazard Description	Is there a risk of contamination with allergens?
3 Control measures	What procedures will control this risk?
4 Modifications	Can changes control the risk – what are they?
5 Is it a Critical Control Point that needs documenting and controlling?	

HACCP – Nuts Critical Control Point No. 8 Disposal of packaging	
Hazard	Contamination of other lines if nut packing materials are used for other purposes, e.g. storing other raw materials
Controls	Prevent use of packaging for other purposes to ensure no cross-contamination to other ingredients
Person Responsible	Mixer operator
Action Required	Dispose of all nut packaging materials once used
Corrective Action	If nut packaging materials are observed in use for other purposes report to LINE MANAGER immediately

Fig. 8.1 Example HACCP study.

background to the HACCP studies and the actions that must be taken. Briefing about allergies should be included in all induction sessions and regular updates will ensure that staff continue to be well informed. It is particularly important that information is given to all those who work in an area that handles nuts and peanuts, and all staff understand the importance of the quality controls.

8.4 Control of allergens throughout the supply chain

8.4.1 Cross-contamination

Cross-contamination is the risk of small particles of one ingredient being transferred from a product where they are added to another product where that ingredient is not present. Although it is a term that sounds negative, from a food industry point of view it simply represents the risk of small amounts of certain ingredients being present in a product to which they were not initially added. This can occur when two or more slightly different products are manufactured or packed on the same line and have different ingredients, such as cereal products with different additions or different flavours of chocolate bars. Cross-contamination of ingredients or products can occur at the level of the raw material supplier (who may process many raw materials), during transport or storage of raw materials or, indeed, during manufacture or packing of the finished product.

In relation to allergens, cross-contamination is a real risk that must be controlled or acknowledged on the label. In most cases it is only minute amounts of an allergen that are transferred from one product to another. However, it is clear that very sensitive individuals can react to extremely small quantities of allergens, so cross-contamination of any nature must be handled properly.

HACCP studies, as detailed earlier, are used to identify any risks of cross-contamination, which can occur at any point within the supply chain. Where a risk exists there are two options, namely control of the risk or use of the appropriate labelling on the product. Peanuts and nuts are particularly common agents involved in cross-contamination and the statement 'May contain nut traces' can be seen on a number of products. The use of the 'may contain …' statement is not a substitute for Good Manufacturing Practice and appropriate controls, and it should only be used where a real risk of cross-contamination exists. The most common product lines to carry 'may contain' statements are chocolate products, as chocolate is usually produced on a continuous process, and although cleaning of lines is undertaken between products a full cleansing is usually performed less frequently, as water and chocolate do not mix. Other areas that pose risks are those where dry ingredients are used and dust may be present in the atmosphere, as in breakfast cereal production.

Cross-contamination is not restricted to large-scale food manufacturing environments. The risk is equally problematic in bakery shops, small confectioners and out-of-home eating establishments. The use of tongs, scoops, dishes and trays is often common to a number of products in these areas. Think of purchasing a doughnut from a small bakery where the doughnut will be placed into a bag to take away using tongs. There is a risk that those tongs were last used to handle a Danish pastry that may have had nuts liberally sprinkled over the top or a cake with an egg-based icing. Even these minute quantities of allergens can pose a risk for very sensitive individuals. The control of allergens in these circumstances and the communication to the ultimate consumer is much more difficult.

All aspects of the supply chain must be evaluated for presence or risk of contamination with key allergens. This includes purchasing of raw or semi-finished materials, transport of these materials, storage within the production unit, production, packing and distribution. At each stage full HACCP evaluations of all equipment used, processes and risks need to be undertaken and documented to provide information on the suitability of the product for sufferers of different allergies. A full evaluation of a production line may involve many HACCP studies.

8.4.2 Purchasing raw materials

All raw ingredients such as flour, milk, nuts and fruit, and compound ingredients such as processed cereals, chocolate, biscuits or toffee must be purchased against a detailed specification. This must include the nature of the product, the ingredients included in a compound ingredient, and any risks of cross-contamination that may occur in the production or packing of the ingredient that is purchased. Supplier Quality Assurance is a system whereby suppliers are audited to ensure that they meet the high quality standards demanded by food manufacturers; it places the responsibility of meeting the standards set by the manufacturer clearly within the remit of the supplier. The initial audit procedure

is a detailed analysis of the supplier and the operations that occur within their facilities. It is essential that it includes a detailed risk assessment relating to the presence of allergens and particularly the use of peanuts and nuts at the supplier's location. The presence of allergens in any raw material needs to be clearly acknowledged, even down to the level of carriers in flavours. Additionally, any real risk of cross-contamination from other materials that may be processed or packed in the same facility must be assessed in detail. HACCP studies can be used to identify any CCPs in the supplier's procedures. Where a real risk of cross-contamination with allergens exists, it must be highlighted on the specification to ensure that information is fed through and eventually highlighted on the label. This is particularly relevant for compound ingredients such as chocolates and cereals. The suggestion that cross-contamination exists must be ascertained following a detailed review and is not a substitute for Good Manufacturing Practice, nor should it be used to discharge any liability should a problem occur.

8.4.3 Distribution of raw and semi-finished materials

The distribution of raw materials from their site of packing or production to the factory where they are used also represents an additional risk area for cross-contamination. The transport of allergen-containing ingredients needs to be undertaken with care to ensure that traces of these are not transferred to other raw materials. They should be transported and stored in fully sealed containers to reduce any risk of spillage, and clearly labelled so as not to be confused with other ingredients. Any risks of cross-contamination need to be identified and noted so they can be marked on the label of the finished product. Colour coding of packaging is a useful way of segregating and identifying allergen-containing ingredients. A standard colour can be used for the packaging and containers in which the ingredient is stored and for the equipment associated with the production of products containing that ingredient (such as trays, moulds, dishes and brushes). A colour coding system must be robust to ensure that confusion does not arise. A standard colour should be chosen for use through the supply chain and this should be applied and adhered to rigidly. Induction sessions to new employees must include detailed instructions on any colour coding procedure.

8.4.4 Storage of raw materials

Storage represents another risk area for cross-contamination. High-risk ingredients (from an allergy perspective) need to be stored with caution to prevent any cross-contamination occurring from spillages, poor labelling or even absent labelling. Ideally, high-risk ingredients, such as nuts and nut-containing ingredients in particular, should be stored in locked storage areas and be accessible only by authorised personnel when required for use in the production facility.

8.4.5 Scheduling

Production schedules give detailed information on the precise nature of a product to be manufactured on a given plant at a particular time, and the programme of products to be made over a given period. In many cases production lines are used for the manufacture of a number of products, including different flavours of one product or completely different products altogether. Schedules can be planned to reduce the risk of transfer of allergens from one product to another. Plants that are used to produce more than one product may be cleaned down after production of each product has been completed, with a full and thorough cleansing undertaken at regular intervals. Products that have a higher risk of microbial contamination, such as those containing fresh milk and raw meat, will be cleaned down thoroughly much more frequently. Effective management of production schedules will ensure that products containing allergens will be manufactured at the end of the programme before a full cleandown. Additionally, allergen-free products should be manufactured immediately after a full cleandown to minimise any risk of transfer of allergens to products that are manufactured later in the schedule.

8.4.6 Manufacturing

The control of allergens during manufacture and packing is a critical area. HACCP must be used at each stage of the manufacturing process itself to ascertain key areas of risk. Additionally, all equipment associated with plants that manufacture products containing allergens must be controlled to ensure there is no risk of transfer of allergens on brushes, spatulas and other items. A colour coding system is the best way of easily identifying equipment associated with a particular plant. One colour can be used for all items associated with that product such as trays, moulds, brushes and rework containers.

Manufacturing plants are often complex with many different parts that are capable of harbouring allergens. HACCP studies will identify the key areas of risk and appropriate controls can be introduced, as discussed earlier. It is essential that all staff are briefed on the importance of the controls introduced and take responsibility themselves for the quality control of the products they are manufacturing. Routine sensory evaluation undertaken on newly manufactured products is a useful tool to monitor quality control. Trained panels who are expert assessors on a particular product are an excellent resource to confirm that a given production run meets the specification for that product. They are also capable of identifying problems with a product and may pick up a problem associated with cross-contamination of allergens.

8.4.7 Rework

Rework is a term given to slightly defective or excess product or ingredients that are newly processed but not suitable for packaging immediately into finished product. It is first checked to ensure it is of a very high quality, and can be

reworked and added back to products. Lower quality waste is not added back to products but disposed of in an appropriate manner. Controls must be in place to ensure there is no cross-contamination of allergens when using rework. The simplest rule when handling rework is to put 'like into like' to prevent any risks. Additionally, rework must be clearly labelled for further internal use within the factory and controls must be in place to ensure it is used correctly. Rework is particularly an issue with regard to nut allergy as trace amounts of an allergen can easily be transferred.

8.4.8 Air movement

Handling dry allergens such as powders, nuts and dusts creates additional risks associated with the movement of air that may carry particles of allergens. Since a small number of sufferers react to extremely small amounts of allergens, care needs to be taken where there are excessive amounts of dust to ensure other products are not 'contaminated' with this dust. Air conditioning needs to be installed to prevent air containing dust particles being transferred to a separate part of the production facility and allergens being transferred with it.

In extremely dusty environments, such as nut roasting plants, additional care needs to be taken to prevent allergens being transferred on clothing from one part of the factory to another. On entering the high-risk area employees and visitors should be required to wear special protective clothing such as full body suits and hair cover. On leaving the specific area the protective clothing should be removed to prevent any transfer of allergens to another area of the factory.

8.4.9 Employees and visitors at manufacturing locations

In addition to the risks associated with products containing allergens, risks also arise to personnel who themselves are allergic to certain ingredients and who are employed at, or visit, specific manufacturing sites where these ingredients are used. All employees should complete a pre-employment questionnaire and medical to ascertain whether any suffer food allergies and particularly anaphylactic reactions. Those that do suffer should not be expected to work in areas where allergens to which they react are processed.

All visitors to a site where key allergens are used should be informed about the nature of products manufactured at that site and informed that if they are allergic to any ingredients used they are advised not to visit the manufacturing plant. Once again this is particularly relevant to the use of nuts and peanuts as reactions can be so severe. A suggested outline for a notice at the reception desk is provided in Fig. 8.2.

8.4.10 Canteen and restaurant facilities

The control of allergens extends from the production line itself to all areas of food provision within the manufacturing site. This includes canteen and

PLEASE READ BEFORE SIGNING IN

Welcome to our factory. This site uses peanuts and hazelnuts in some products. Peanut or hazelnut dust is present in the air within certain areas of the factory. If you suffer allergic reactions to either peanuts or hazelnuts we recommend that you do not enter these areas of the factory at all. Please speak to your contact at this site for information regarding areas where peanuts and hazelnuts are used. If you are in any doubt at all regarding your susceptibility to peanuts or hazelnuts we advise you to avoid these areas.

Fig. 8.2 Typical factory advice sheet.

restaurant facilities as well as snack and coffee bars in factories and retail environments. All the controls outlined here for food manufacture apply equally well to food provision in a catering environment. Allergens should only be present in products where a sufferer would expect to find them, and information should be available for allergy sufferers to consult to assess whether a certain dish is suitable for their specific diet. If in doubt the allergy sufferer should be advised to avoid the dish and choose another option. The handling of allergens in the catering trade is discussed in more detail later in the chapter.

8.4.11 Confirmation of presence of allergens

Once all the above steps have taken place, food manufacturers are able to make a judgement based on all the evidence obtained as to whether a product contains or is free from a particular allergen. Information should be provided to allergy sufferers to enable them to select suitable foods for their diet. The provision of information to consumers on packaged food and food sold loose is discussed later in the chapter. In addition, a number of tests are available that can be used to analyse products for the presence of a given allergen. Generally a radio-immunoassay technique is used which checks samples of a product for specific proteins that have been previously identified as allergens. These tests can be useful, but in some instances results do need to be interpreted with care. Any analysis is only as accurate as the samples that are taken. The sampling of liquid or fluid foods gives a relatively reliable sample, as the food can be further blended to give an even distribution of all ingredients. The sampling of foods such as breakfast cereals, chocolate bars and other more complex foods poses a number of difficulties. A number of samples could be taken randomly from the food according to good practice, but there is a chance that the one small piece of allergen, be it a flake of nut or a grain of milk powder, could be missed. The results achieved would give a false negative, suggesting that a product is free from a particular allergen, as a random sampling technique did not actually pick up the small amount of allergen present. Such tests should not be used to give definitive information about the presence or absence of allergens in a product.

Their use complements the results obtained from a full HACCP study that should be undertaken on each product.

8.5 Other initiatives

Most food products sold through retail channels are packaged in such a way that ingredients lists on products provide an easy way for allergy sufferers to check the suitability of that product for their particular diet. Where products are sold without packaging or the packaging is removed before being presented to the consumer, the communication of the suitability of that product for allergy sufferers becomes more difficult. Both the catering trade and some areas of retail are areas where the communication of the suitability of products for allergy sufferers is extremely difficult, as foods are sold without labels showing the detail of the ingredients they contain. Allergy sufferers must take it upon themselves to check the suitability of any foods for their particular diet, and if in doubt at all about a particular product or dish they should avoid it.

The Ministry of Agriculture, Fisheries and Food has prepared a list of guidelines for catering establishments to raise awareness of the issue of food allergies and to help caterers provide information for sufferers. This is equally applicable to small retail environments. An extract from the recommendations is provided in Fig. 8.3.

8.6 Key aspects of legislation from a manufacturing view

Food legislation plays an important role in the development of a policy for the handling of allergens in food manufacturing. Manufacturers have a responsibility to provide safe food for consumers, and this includes safety from an allergy sufferer's view. The obvious legislation is that which directly relates to food, such as Food Labelling Regulations. However, in addition other areas of the law need to be considered and these include relevant consumer protection legislation and requirements arising from the European Product Liability and Product Safety Directives. Manufacturers need to consider the extent to which their position and that of their products will be influenced by a number of potential circumstances.

A significant number of people have unfortunately died or have been seriously ill as a direct result of an allergic reaction following the ingestion of foods which, unknown to them, contained small amounts of allergens to which they had an anaphylactic reaction. These cases have received widespread publicity. Responsible food manufacturers know that a number of foods and ingredients can give rise to rapid, life-threatening reactions in a small number of allergic individuals. The adverse publicity that might be received following an incident could be extremely damaging to the reputation of the product concerned and, indeed, the company's standing.

Advice to catering establishments

In case a customer asks you about the ingredients of a meal, you should aim to make sure that there is always someone on duty who knows or can find out the ingredients of all the foods you provide. If you are not sure whether there is a trace of a life-threatening ingredient in a meal then say so – never guess. If foods contain nuts, make sure this is reflected in the name or the menu description, for example, carrot and nut salad.

Foods to watch out for

Many establishments often use nuts and seeds to decorate cakes, ice creams, speciality breads or savoury dishes. Other less obvious sources of nuts and seeds are:

- marzipan which is made from almonds
- hummus which contains sesame seeds and halva which is made from sesame seeds
- sauces such as satay sauce which is made from peanuts
- products such as Waldorf Salad, salad dressings and flavourings

A customer suffering from severe food allergy will usually know about the foods they must avoid

What your staff can do to help customers

If you are asked by a customer you must

- Tell them what is in your food – exactly
- If you don't know don't guess – find out!

Remember!

Even tiny traces of these foods can kill.

- Think before using nut and seed oils, salad dressings and seafood sauces
- Don't let nuts, seeds and shellfish touch food that shouldn't have those ingredients
- Clean your hands, work surfaces and utensils after handling nuts, shellfish and seeds
- Think before cooking with oils that have been used to cook other foods.

Fig. 8.3 Extract from MAFF guidelines: *Be Allergy Aware – Advice for Catering Establishments*.[3]

Manufacturers need to consider their legal obligations to inform purchasers of a product of the known or adventitious presence of allergens, even where this is not a specific requirement of current food labelling legislation. There are many additional points to consider from a manufacturer's view and these include some of the following. Is it appropriate that all relevant information should be given in the ingredients list or is an alternative location preferable? Where the presence of allergens is highlighted on labels the prominence of that message needs to be ascertained. There are not necessarily clear responses to these points available in law. It is clear that where an ingredient is knowingly added to a food, the Food Labelling Directive (79/112) requires that its presence should be declared on the ingredients list. However, there are exceptions to this Directive which are discussed in detail below.

8.6.1 Food safety legislation

Under the Food Safety Act 1990 all food manufacturers, caterers and retailers are required to ensure that the food they supply is safe (for the majority of people and when consumed in normal quantities) and is of the nature, substance and quality demanded. The General Product Safety Regulations 1994 (GPSR) will apply to food where there is no specific provision under the Food Safety Act (FSA) or any regulations made thereunder. As a result, information may need to be provided to consumers on any risks that a product might present regarding a number of factors, such as the effects of such a risk on a vulnerable group, for example allergic individuals.

A failure to comply with these requirements because of the unnotified, inadvertent presence of an allergen in a product through manufacture or cross-contamination, could give rise to a criminal offence being committed, even though no intention existed. There is, however, a due diligence defence available to manufacturers in the event of proceedings under both the FSA and the GPSR which would require the manufacturer to prove that he had taken all reasonable precautions and exercised all due diligence to prevent inclusion of an allergenic material. Manufacturers can reduce the risk of prosecution and contribute substantially to the establishment of a due diligence defence by implementing Good Manufacturing Practice and documenting all procedures taken as evidence of GMP processes, training and results, as detailed earlier.

8.7 Labelling and promotion

The majority of manufactured and packaged food products have to carry a full list of the ingredients they contain by law. The list shows the ingredients in descending order of weight in the finished product. There are currently no provisions made under either UK or EU food legislation which require potential allergens to be labelled. Whilst there is a general requirement that all ingredients added to a food must be declared on the ingredients list, in accordance with the

Food Labelling Regulations 1996, there are certain exceptions to this general rule. These relate to compound ingredients (an ingredient with a common name composed of multiple ingredients) which constitute less than 25% of the finished product, or to cases where the ingredient itself does not require an ingredients list if it were to be sold alone as a prepacked food (see exceptions below). Other exceptions to the Food Labelling Regulations include generic terms (e.g. fish can be used for any species of fish); 'carry-over' ingredients such as additives which do not have any technological function in the end product; additives used as processing aids; solvents/media for additives or flavourings; and those products which do not require ingredients lists at all such as food sold through catering outlets.

There are certain exceptions to the law. These include honey, condensed milk, dried milk products, coffee and coffee products, spreadable fats and chocolate. Each of these has its own regulations and needs to be considered individually.

8.7.1 The '25% rule'

This rule is contained in European Food Labelling Legislation. It states that compound ingredients (i.e. those that themselves contain a number of ingredients, e.g. toffee, biscuits, chocolate chips) that comprise less than 25% of the finished weight of the product need only be declared as the compound ingredient and not as the constituent ingredients that make up the product.

Manufacturers recognise the importance of providing information on the ingredients list to help sufferers of food allergies to select a suitable diet with confidence. To do this the list must accurately reflect the ingredients in the product, including those allergens that are present in minute amounts. Consequently, the majority of manufacturers voluntarily ignore the exceptions to the law and voluntarily label the presence of all allergens on the ingredients list. This includes carriers of ingredients, constituents of compound ingredients, and ingredients that may be present through cross-contamination that are on the list of key allergens.

8.7.2 A European view

Within the European Union various Member States are beginning to address the issue of labelling of allergens with various degrees of official recommendations. In France, the authorities have published a detailed review of the situation and recommended a number of ways in which industry, collectively, can significantly improve the information given to consumers. A restricted list of allergens is covered but the principal focus is on peanuts and similar derivatives, coupled with clearly defined changes to the legal framework for labelling. In Sweden, labelling legislation requires ingredients known to cause intolerance to be stated in the list of ingredients. Examples quoted include eggs, milk, gluten-containing grains, and legumes such as soyabeans, peas and peanuts. The

Swedish legislation also requires that when such ingredients are themselves present in compound foodstuffs, then any exemptions from ingredient declaration do not apply. In the UK, allergens do not have to be specifically labelled, though most manufacturers voluntarily provide information on the presence of peanuts and nuts where they are present.

8.7.3 International trade

The progressive development of international trade is leading to an increasing number of products sold with multilingual labels produced in one, or perhaps two 'European' factories for sale in several countries simultaneously. This situation is no longer confined to large multinational manufacturers but also applies increasingly to major retailers who, in some cases, are now selling products with European labels. This creates a number of problems from a labelling stance. Firstly, where two factories produce the same product there may be a difference in the other products manufactured at both sites and consequently a potential difference in the allergens that could be transferred by cross-contamination. It is essential that the 'worst case' scenario is alluded to on the label. For instance, where manufacture is split between two sites and one line also produces nut-containing products where there is a real risk of cross-contamination, this should be alluded to on the labels of both. This ensures consistency of labelling and removes any risk of confusion or any inadvertent consumption of a product that may initiate an anaphylactic reaction. Secondly, it is known that awareness of, and sensitivities to, different allergens do vary throughout Europe. The voluntary labelling of particular allergens is specific to some countries, whilst for others this additional labelling is not deemed as important in their country. Potentially, the presence of an allergen could be mentioned in one language but not in another, and this is an issue that individual companies need to address. However, by far the majority of products sold in a given country provide the ingredients information in one language. Nevertheless, this raises a further issue that companies need to address. Imported products need to conform to the legislation and the voluntary labelling actions taken in the receiving country that sells the product, which may differ from that in the manufacturing country. This will ensure that consumers have information they need to select products for their diet and can choose products from a given company with confidence.

8.7.4 'May contain' statements

The statement 'may contain xxx traces' is used to show where there may be small amounts of the allergen present in the product, most likely as a result of cross-contamination. Currently it is most commonly used for peanuts and nuts. The statement must only be used where there is a real risk of cross-contamination and not as a catch-all to remove any liability. GMP and HACCP studies will identify real areas of risk and the need to use such a statement. Where it is used it needs to be clearly legible and in a place where consumers

Ingredients

Wheat flour, sugar, hydrogenated vegetable oils, cocoa powder, modified starch, dried egg, dried skimmed milk powder, raising agents (E500, E450(a)), salt, flavouring, water, chocolate (contains lecithin & vanilla), acetic acid.

May contain nut traces

Fig. 8.4 'May contain' statement.

would expect to find it. It has become common practice within the UK to place this statement at the end of the ingredients list and, where possible, in a typeface slightly larger than that used for the ingredients list and similar to that used for the word 'Ingredients'. Figure 8.4 shows an example.

The use of 'may contain' advisory labelling in respect of the potential, adventitious presence of a food allergen should be a last resort. Such labelling should never be used as a general insurance and a substitute for Good Manufacturing Practice.

8.7.5 Brand extensions

Many brand names are now used across a wide variety of products; for example, a chocolate bar brand may be used for a dessert, ice cream, drink, chocolate spread, Easter egg, and various shapes and sizes of chocolate bars. It is possible that individuals with a specific food allergy and for whom the original chocolate bar is acceptable may assume that the other products sold with the same brand name are also suitable for their diet. However, in most cases different products will contain different ingredients, be manufactured on different production lines, in different factories, using different technologies and may well contain different allergens from other products under the same brand. It must be stressed that each product needs to be assessed on its own merits by the consumer by checking the ingredients list on the label. The onus is certainly on the consumer to check the suitability of each product for their particular diet.

8.7.6 Promotional activities

The control of allergens in manufactured products extends beyond production and labelling to all promotional practices linked with that product. Those that need particular attention are those that relate to sampling of the product. Product sampling can follow a variety of routes, but the most common include:

- Wet sampling – the product is served from a central location in a ready to eat or drink format, for immediate consumption.
- Dry sampling – a product that needs preparation is distributed from a central location in a format that needs further preparation.

- Door drop – free samples of products are distributed via the postal system for trial at home.

It is essential that those who are sampling products are fully briefed as to the allergenic potential of that product. Wet sampling of products, or the sampling of products intended to be consumed immediately, needs to be undertaken with great care, as consumers receive the product without any packaging. Information must be available to advise consumers of the ingredients in the product, and notices outlining any key allergens assist sufferers of allergies in selecting whether to sample that product. These procedures apply to dry sampling also, but in these cases the product is often distributed in its outer packaging with a detailed ingredients list. Sampling to children can pose additional difficulties and should only be undertaken with parental consent for the child to take the product. This is particularly relevant with nut and peanut allergies, as the reactions can be severe to extremely small quantities of the allergen.

Door drop sampling does provide an efficient way of inviting a large number of people to try a product. It, too, has difficulties. In households where someone suffers anaphylactic shock to a particular ingredient, the entire household very often follows the same principles and becomes an egg-free, milk-free or nut-free zone, for example. In such households, great care is taken to select foods that are free from the particular allergen to minimise any risk of anaphylaxis occurring. This is particularly true in households with young children who are unable to read labels and unable to be responsible for the foods they choose. It is also the case in many households where there is a sufferer of peanut or nut allergy, as these foods can be more easily taken out of the diet of the whole family than foods such as milk, eggs or wheat. Delivering free samples of foods containing the allergen through the letterbox removes the choice to select suitable foods from the family. A young child could see the food product on the doorstep and consume some without parental knowledge. Consequently, it is recommended that door drop sampling is undertaken with great care and is avoided entirely for products that contain nuts and peanuts. There are alternative options, including distributing a coupon for the product enabling sufferers of allergies to choose whether to sample that product, or a reply-paid card which is returned if the household would like to request a sample of a particular product to be delivered. The latter two mechanisms put the choice directly in the hands of the householders and remove any risk of inadvertent consumption of a product by young children.

8.8 Additional communication initiatives

The ingredients list on the label of a product is the most accurate way of assessing the suitability of a product for a sufferer of allergies. However, reading labels is a laborious and time-consuming process and makes shopping a lengthy ordeal. Most companies and retailers now produce lists of products free from

key allergens which make food selection much quicker and easier. The lists are available from the companies directly and are often on the Internet. Once again peanut and nut allergies are often handled as a special case, as they are the most common food causes of anaphylaxis. 'Free-from' lists are updated every six months to reflect any changes that may have occurred. Users of lists are also advised to check ingredients' lists, particularly where a 'new recipe' or 'new improved' flash indicates a recipe change. In the case of anaphylactic reactions information must always be accurate and up to date. Peanut and nut-free lists are often controlled closely and carry a 'Use by' date after which that list is invalid and recipients are asked to contact the company for an update. During the 'shelf life' of the list it is recommended that the names and addresses of all recipients are held. Should any changes occur to that list whilst it is 'live', all recipients can be contacted to advise them of the changes and will be issued with a new list and asked to discard the old one. The distribution of the list to third parties such as dietitians and doctors is not supported, as this removes control of the list from the company. If a change occurred to a list, the company would rely on the health professional remembering which patients had received the list from them to pass on the update. These detailed procedures ensure that the company has tight control over this list at all times and can do everything they can to help sufferers of allergies to select suitable foods with confidence.

8.8.1 Food intolerance databanks

Many countries throughout Europe have food intolerance databanks managed by a central group, with information provided by companies. They collate information from various food manufacturers and produce comprehensive lists of products free from the key allergens. In many cases the booklets they produce (milk free, egg free, etc.) are available to health professionals, especially dietitians, who are then able to work with sufferers of food allergy to help them select suitable foods and also meet their nutrition requirements. The lists provide useful compilations of products suitable for particular diets, but are not without their pitfalls. Often they are updated only on an annual basis and risk becoming out of date even whilst they are still being issued. Additionally, they are not suitable for information on nuts and peanuts, as such information can quickly become outdated and is more dangerous than useful, for the reasons outlined above.

8.9 Summary

The management of food allergens in the food industry is a complex and time-consuming process, but one that is essential. The main aim of an allergen-handling process is to be able to provide accurate information to sufferers to enable them to choose a suitable diet with confidence. The detailed knowledge of the allergens used in a particular product, on a specific production line and in the factory site is the first step in assisting sufferers.

The key steps in managing food in food manufacture are, firstly, to understand the constituents of all raw materials in detail, secondly to check all procedures used during the manufacture of the product for any risks of cross-contamination of allergens, and finally to provide accurate information to consumers of the product regarding the allergens the product contains. All steps need to be undertaken thoroughly to ensure that even trace amounts of allergens are detected. The processes involved in Good Manufacturing Practice and HACCP studies assist in this process.

It is well known that sufferers of anaphylactic shock can react to extremely small quantities of allergens and it is for these people in particular that information provided about the suitability of the product for particular diets must be accurate and up to date. The labelling of packaged food provides the best communication tool, and the onus must be on the sufferer to check the labels of products to ensure suitability for their diet. Manufacturers must take responsibility to ensure that the labelling accurately reflects the ingredients in the product and any allergens that may be present through cross-contamination during the manufacturing process.

The communication of the presence of allergens in food sold loose without ingredients lists and food sold through catering outlets will continue to be a critical area. Continually raising the awareness of allergen control in these areas is a key task to ensure that those who suffer food allergies are able to select foods and meals with confidence.

The control of allergens in future will continue to be an important aspect of quality control for all aspects of food manufacturing, including large-scale manufacture, smaller-scale operations and catering processes.

8.10 Sources of further information and advice

Anaphylaxis Campaign
PO Box 149, Fleet, Hampshire GU13 0FA

British Allergy Foundation
Deepdene House, 30 Bellegrove Road, Welling, Kent DA16 3PY

British Dietetic Association
7th Floor, Elizabeth House, 22 Suffolk Street, Queensway, Birmingham B1 1LS

British Nutrition Foundation
High Holborn House, 52–54 High Holborn, London WC1V 5RQ

Food and Drink Federation
Federation House, 6 Catherine Street, London WC2B 5JJ

Leatherhead Food Research Association
Randalls Road, Leatherhead, Surrey KT22 7RY

Further reading

Food and Drink Federation, *Food Allergens Advice Notes*, FDF, London, 1998.

Institute of Food Science and Technology, *Food and Drink Good Manufacturing Practice – A Guide to its Responsible Management*, IFST, London, 1998.

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8.11 References

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