

# 5

## Labelling of allergenic foods of concern in Europe

Sue Hattersley and Chun-Han Chan, Food Standards Agency, UK

**Abstract:** People with food allergies need to know what is in the food that they buy, in order to make safe and informed food choices. The legislation covering requirements for declaring specified allergenic ingredients used in food sold pre-packed within the European Union is described, together with best practice guidance produced by the UK Food Standards Agency (FSA) covering the provision of allergen information for foods sold non-prepacked. Further guidance from the FSA covering the management of food allergen cross-contamination, as well as new legislation covering the composition and labelling of foods for people with gluten intolerance is also explained.

**Key words:** allergen legislation, labelling information, guidance, Europe.

### 5.1 Introduction

People with food allergies need to have clear information about the ingredients used in the foods they buy so that they can successfully avoid the foods that they know they are sensitive to. Whilst avoidance of single foods that are allergenic is relatively straightforward, the increasingly complicated nature of the food supply chain means that the food allergic consumer is faced with an ever more difficult task when trying to choose foods that are safe to eat, both when buying pre-packed foods at a retail level or when eating out. For example, for an egg allergic person, avoiding eating whole eggs may be straightforward, but effectively avoiding egg used as an ingredient in a complex food (such as a glaze on top of a fruit pie) can be more challenging.

Food allergic people can react to very small amounts of the allergen they are sensitive to, sometimes to amounts as low as a few milligrams. Furthermore, the symptoms seen when an allergic reaction is triggered can range from relatively mild symptoms, such as rash, through to severe life-threatening symptoms such as swelling in the throat, difficulties breathing, collapse and anaphylactic shock. It is therefore critical that such people have accurate information about the use of allergic ingredients in a food, however low the level of use and about possible cross-contamination events during production.

There are a very large number of foods (up to 200) that have been reported to trigger allergic reactions in people around the world, but a much smaller number of foods are associated with the majority of reactions reported. The Codex Alimentarius Standard originally listed eight allergenic foods (or groups of allergenic foods) that were considered to be of the greatest public health concern (Codex Alimentarius Commission, 1985). These were:

- cereals containing gluten;
- crustaceans;
- eggs and egg products;
- fish and fish products;
- peanuts, soybeans and products of these;
- milk and milk products;
- tree nuts and nut products;
- sulphites in concentrations of 10 mg/kg or more.

It is not surprising that the most common allergenic foods will vary in different countries given the different dietary patterns. For example, the allergenic foods that have to be declared in Japan (Ministry of Health, Labour & Welfare, 2005) include buckwheat, as well as eggs, milk, peanuts and wheat (but not barley, rye or oats), but buckwheat is not included in the specified lists in the European Union (EU) or USA (EC, 2003, 2007; USFDA, 2004). However, other factors may also have an impact, for example, allergies to many fruits and vegetables are linked to pollen allergy. This type of allergy is due to similarities between the proteins present, as with the case of allergy to apple being strongly linked to birch pollen allergy, and therefore the pattern of allergies will vary depending on the flora in different countries (Vieths *et al.*, 2002; Fernández-Rivas *et al.*, 2008).

## **5.2 Drivers behind the development of specific EU allergen labelling legislation**

In EU Member States, there has long been a requirement for labelling of ingredients used in pre-packed foods. However, the general food labelling Directive (2000/13/EC) (EC, 2000) contained a number of exemptions which meant that some ingredients were not required to be labelled.

One main exemption related to the components of compound ingredients, which themselves made up less than 25% of the final food, which did not need to

be separately identified. Whilst there may be an argument that the general population did not need to have information on all the individual components of that compound ingredient, clearly for the allergic consumer it is very important to know whether wheat is present in a sausage used in a casserole or celery is present in a vegetable stock used to make a soup.

It is also important for the allergic consumer that ingredients are clearly described, so that they can determine whether the flour used to thicken a sauce is wheat flour, which would pose a risk for the wheat allergic or gluten intolerant consumer, or maize (corn) flour, which would not pose a risk, or whether the oil used in a salad dressing was made from walnut oil rather than olive oil.

It was recognised therefore, that there were situations under the general ingredients labelling legislative requirements in Directive 2000/13/EC, where the allergic consumer would not necessarily receive sufficient information. The European Commission and the Member States agreed that this deficit should be addressed by developing specific requirements that would require the clear declaration of the use of allergenic ingredients in pre-packed foods in all circumstances. This requirement for the clear declaration of allergenic food ingredients was provided by Directive 2003/89/EC (EC, 2003) which came into effect in November 2005. This legislation amended the parent Directive 2000/13/EC governing general food labelling, and therefore covers only the deliberate use of the ingredient and relates only to foods sold pre-packed.

It was agreed that the allergenic foods identified by the Codex Committee should be taken as the basis for discussion between European Union (EU) Member States and the European Commission, when the need for specific legislation on the declaration of the use of allergenic ingredients started to be considered. On the basis of scientific evidence that identified that a further three allergenic foods (sesame seeds, mustard and celery) were a public health concern in at least some EU Member States, these were added to the list of allergens to be covered by specific EU labelling requirements (EC, 2003, EFSA 2004). Subsequently, a further two allergenic foods (molluscs and lupin), were added to the EU list by Directive 2006/142/EC (EC, 2006a) on the grounds that there was evidence that these were a public health concern in EU Member States (EFSA, 2005, 2006; Radcliffe *et al.*, 2005; EC, 2006b). The current EU list of specified allergenic foods is:

- cereals containing gluten (wheat, barley, rye, oats, spelt, kamut, or their hybridised strains);
- crustaceans;
- eggs;
- fish;
- peanuts;
- soybeans;
- milk (including lactose);
- nuts (almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, macadamia nut and Queensland nut);

- celery;
- mustard;
- sesame seeds;
- sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as SO<sub>2</sub>;
- lupin;
- molluscs.

It is possible that further allergenic foods could be added to the EU list in the future if there was sufficient scientific justification. An emerging new risk may arise from changes in dietary patterns, for example the introduction of a new food into the diet (such as kiwi fruit) (Lucas *et al.*, 2003, 2004; Lucas and Atkinson, 2008) or, potentially, to changes in the way food ingredients are used or processed before consumption, for example, if an extract of an allergenic food were to be used for technological purposes in a compound food where its use was unexpected.

### **5.3 Exemptions for certain processed ingredients derived from the specified allergenic foods**

During EU negotiations on Directive 2003/89/EC, it was recognised that some ingredients derived from the specified allergenic foods would, in practice, not present an allergenic risk, due to the significant processing they undergo. It was considered that it would not be helpful for allergic consumers if such ingredients were subject to allergen labelling requirements, as this would unnecessarily restrict their food choices. In addition, it might mislead allergic consumers who inadvertently eat such products into believing that their allergy was resolving. It was therefore agreed that industry should be able to submit scientific dossiers of information to support the exemption of certain ingredients derived from the specified allergenic foods from the allergen labelling requirements. The dossiers submitted were evaluated by the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies, and the Panel's opinions can be seen on the EFSA website: [http://www.efsa.europa.eu/EFSA/ScientificPanels/NDA/efsa\\_locale-1178620753812\\_Opinions465.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/NDA/efsa_locale-1178620753812_Opinions465.htm).

A number of dossiers were submitted and subsequently evaluated by EFSA before the deadline of November 2005 for the coming into force of the allergen labelling requirements, and some exemptions were agreed on a temporary basis, pending the submission of further supporting dossiers. These exemptions, which were set out in Directive 2005/26/EC (EC, 2005), were for a two year period. Subsequently, following evaluation of the further dossiers by EFSA, a number of permanent exemptions were set out in Directive 2007/68/EC (EC, 2007). This Directive sets out the list of all allergenic ingredients that must be declared on labels and exemptions to those declarations – see Table 5.1. This Directive came into force in November 2007 but it included a transition period lasting until 31 May 2009 to allow the food industry time to change their labelling to comply with the new provisions.

**Table 5.1** Schedule of all allergenic ingredients that must be declared on labels and exemptions to those declarations (from Directive 2007/68/EC)

Allergenic ingredient	Exemptions
Cereals containing gluten (wheat, barley, rye, oats, spelt, kamut or their hybridised strains)	<ul style="list-style-type: none"> <li>• Wheat-based glucose syrups including dextrose</li> <li>• Wheat-based maltodextrins</li> <li>• Glucose syrups based on barley</li> <li>• Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages</li> </ul>
Crustaceans	None
Eggs	None
Fish	<ul style="list-style-type: none"> <li>• Fish gelatine used as a carrier for vitamin or carotenoid preparations</li> <li>• Fish gelatine or isinglass used as a fining agent in beer and wine</li> </ul>
Peanuts	None
Soybeans	<ul style="list-style-type: none"> <li>• Fully refined soybean oil and fat</li> <li>• Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources</li> <li>• Vegetable oils derived phytosterols and phytosterol esters from soybean sources</li> <li>• Plant stanol ester produced from vegetable oil sterols from soybean sources</li> </ul>
Milk (including lactose)	<ul style="list-style-type: none"> <li>• Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages</li> <li>• lactitol</li> </ul>
Nuts (almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts and Queensland nuts)	<ul style="list-style-type: none"> <li>• Nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages</li> </ul>
Celery	None
Mustard	None
Sesame seeds	None
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as SO <sub>2</sub>	
Lupin	None
Molluscs	None

Subsequently Directive 2007/68/EC was amended by Commission Regulation 415/2009 to extend the transition period for changing the labelling for any allergenic ingredients derived from egg and milk used as fining agents in wines

until 31 December 2010, to coordinate with other changes that needed to be made to labelling of wines under Council Regulation EC 479/2008 (EC, 2008a, 2009a).

## **5.4 Other allergen information that manufacturers can choose to put on food packaging**

### **5.4.1 Allergy boxes or statements**

In addition to the statutory requirements to label the use of allergenic ingredients in pre-packed foods, many food manufacturers in European countries also voluntarily provide additional information on food packaging to help food allergic consumers to make safe and informed food choices. This can take the form of ‘allergy advice’ boxes or statements that highlight the allergenic ingredients used in the product, using phrases such as ‘contains egg, milk and peanuts’. Such statements may also declare possible allergenic cross-contaminants (see Section 5.4.2). Whilst the use of such allergy statements or boxes can be used as a shortcut by allergic consumers, they are not controlled by legislation (although clearly they should not be misleading) and they should therefore not be relied upon in isolation from the ingredients list.

In addition, the use of two pieces of information on the packaging relating to allergenic ingredients does increase the chances of errors and inconsistencies in the labelling. In the UK, there have been a number of food incidents where foods have had to be withdrawn from the market as the allergens listed in an allergy statement did not match those declared in the ingredients list. In particular, it is very important that food manufacturers who choose to include such statements on a product, ensure that all the allergenic ingredients declared in the ingredients list are included in the allergen statement, as it is accepted that, despite advice to the contrary, many allergic consumers will just use such as statement as their primary source of information.

### **5.4.2 Allergen cross-contamination warnings**

Allergen labelling legislation in the EU covers only the deliberate use of an ingredient in a pre-packed product. However, for the allergic consumer, there may be a health risk if a food product contains a significant level of an allergen as a result of accidental cross-contamination at some point in the food chain. Whilst food manufacturers can put in place a number of checks and processes to try to control the risk of the accidental presence of an allergenic food ingredient in a product, it is not always possible to completely avoid such a risk, particularly in premises that make a wide range of products, with multiple ingredients.

In such situations, many food manufacturers will opt to use some form of advisory labelling to alert allergic consumers to such risks, using phrases such ‘*may contain nuts*’, ‘*made in a factory that also uses nut ingredients*’ or ‘*not suitable for someone with a nut allergy*’. Whilst the intention of such warnings is

to help allergic consumers to make safe food choices, over recent years the use of such warnings has become widespread and, for certain food products (such as biscuits, breakfast cereals and confectionery), it can be difficult to find products without such warnings (FSA, 2002). Currently there is no internationally agreed action level for cross-contamination with allergenic foods below which advisory labelling is not appropriate. Therefore manufacturers may choose to label *any* risk of allergen cross-contamination, however low or remote. In addition, improvements in allergen analytical detection methodologies have also meant that the presence of lower and lower levels of allergen can now be detected, which may also be a factor in the increasing use of allergen advisory labelling.

There is evidence from consumer research (FSA, 2005) that many food allergic consumers consider such allergen advisory warnings to be overused and therefore they are often ignored. In addition, the variety of phrases used by different food businesses can also confuse food allergic consumers who may interpret the different phrases as meaning different levels of risk. There is evidence (Hefle *et al.*, 2007) that demonstrates that 'May Contain' statements seem to be a more effective deterrent than 'shared facility' statements, with 'shared equipment' statements having an intermediate effectiveness. However, products with 'shared facility' statements were more likely to have detectable levels of cross-contamination. Food businesses are also placed in a difficult position as the ability of analytical methods to detect the presence of an unwanted food allergen continues to improve in sensitivity. The results of such tests need to be assessed in terms of what they mean in relation to risk to the allergic consumer. At present, there is little quantitative guidance available to food businesses on the management of food allergens or to inform their decision-making regarding the need for allergen advisory warnings for individual food products.

#### **5.4.3 Development of best practice guidance on allergen management and advisory labelling issued by the UK Food Standards Agency in 2006**

In the UK, there was general agreement between food allergic consumer support organisations and food businesses that the excessive use of allergen cross-contamination advisory warnings devalued the impact of such warnings and also unnecessarily restricted the choices available to food allergic consumers. The Food Standards Agency (FSA) was approached with a view to producing a single guidance document bringing together existing best practice advice on allergen management. The FSA worked with stakeholders including food manufacturers and retailers, as well as allergic consumer support organisations and food law enforcement bodies, to develop its best practice guidance on allergen management and advisory labelling guidance, which was published and was made freely available on-line in July 2006 (<http://www.food.gov.uk/safereating/allergyintol/guide/>). The aim of the guidance was to set out consolidated best practice advice on allergen management that would lead to the adoption of a risk-based approach for the use of allergen warning labels, thereby maintaining food safety and also helping to maximise consumer choice. The main guidance document was

accompanied by a leaflet aimed at small and micro-businesses (<http://www.food.gov.uk/multimedia/pdfs/publication/allergyjamjar0109.pdf>) that set out the key allergy-related issues to be considered when labelling food.

At the time the guidance was produced, there was no consensus on the levels of allergenic ingredients present in foods that were likely to provoke allergic reactions in consumers sensitive to those foods. Whilst the availability of commercial test kits for detecting the presence of a number of common food allergens continues to improve, there are as yet few independently validated allergen detection methods available to food businesses and enforcement bodies. This further complicates the situation for a food business trying to control allergen cross-contamination and make decisions on whether or not advisory warnings are appropriate.

The approach taken in the guidance was to set out general principles that can be used to manage allergen cross-contamination and includes a decision tree approach to inform decision-making on whether or not advisory labelling is appropriate (see Fig. 5.1). Such decisions should be based on an analysis of the risks of unintentional allergen cross-contamination across the supply chain from agricultural production of raw ingredients through to final food product that is sold to consumers. This risk analysis comprises an assessment of the nature of the risk, whether that risk can be managed, and how the risk should be communicated, as well as involving a review process.

The nature of the risk posed in a particular situation will depend on a number of factors, including:

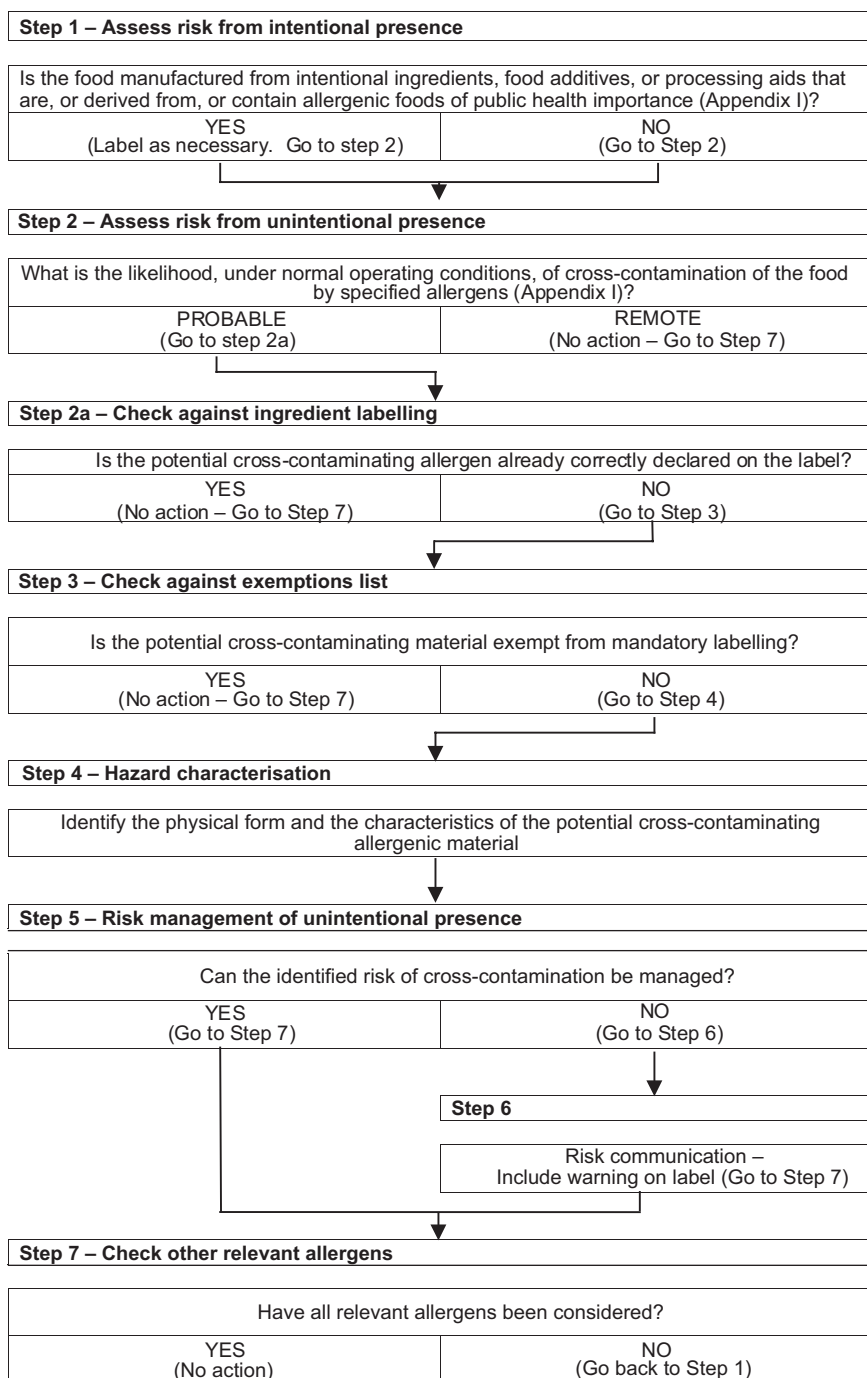
- the amount of the allergenic ingredient that could be present;
- the allergenicity of the particular ingredient involved (for example, refined nut oils will pose a lower risk than pieces of whole nut);
- the physical nature of the ingredients being used;
- the geography of the manufacturing environment.

Fine powders that may become airborne may represent a greater cross-contamination risk than liquid or solid ingredients although other factors, such as the ability to clean down between production runs, may be important where shared equipment is used. The risks posed by cross-contamination that is at a low level and is homogeneous throughout a product run will be different to the risks of occasional cross-contamination with discrete particles such as pieces of nut or whole seeds.

Furthermore, the risks of cross-contamination may be high at the beginning of a batch when switching between products but be insignificant later in the batch run. The risk assessment will also need to take into account the marketing of the product, such that cross-contamination will pose a greater risk in products making claims to be 'free from' particular allergens, than in general food products.

If the business determines that there is a probable risk of allergen cross-contamination that cannot be eliminated or reduced, then that risk should be communicated to the consumer via advisory labelling. It is important that such advice is clearly communicated and that it is situated close to the ingredients list on the packaging, although there should be a clear distinction between the labelling





**Fig. 5.1** Allergen advisory labelling decision tree.

information provided about the deliberate inclusion of allergenic ingredients that are intentionally present in the food, and those which may be there unintentionally.

In the absence of internationally agreed allergen management levels in foods to use as a basis for decisions on whether or not advisory warning labels are appropriate, the guidance advises businesses to assess whether the risk of cross-contamination is probable or remote.

Work is currently underway in a number of fora to take forward the process of setting allergen management thresholds. A workshop in Madrid in 2007 discussed with international stakeholders whether it was possible to apply risk assessment methodologies used for chemical and toxicological risk assessment to the assessment of allergenic risks. Such approaches were considered to be useful, although a number of information gaps were identified that would need to be addressed before such approaches could be used (Madsen *et al.*, 2009).

## **5.5 Possible legislative developments in the future, including foods sold non-prepacked**

### **5.5.1 EU Review of food labelling legislation**

In January 2008, the EU published a proposal for a Food Information Regulation (EC, 2008b) that would bring together and update a range of existing legislative requirements into a single piece of legislation. This proposal is currently being negotiated by EU Member States, as well as being considered by the European Parliament. It is anticipated that existing allergen labelling requirements will be maintained in the new Regulation, but the possibility of an extension to the current requirements to include a new requirement to provide allergen information for foods that are sold non-prepacked, including in catering situations, is also being discussed. Such an extension in the requirements is justifiable as there is evidence to suggest (Pumphrey and Gowland, 2007) that food allergic consumers are more likely to have an allergic reaction when eating out than when eating food sold pre-packed. However, due regard must be given to the ability of businesses providing food that is not pre-packed to supply such information accurately and in a way that does not impose undue administrative burdens (see Section 5.5.2).

### **5.5.2 Development of best practice guidance on the provision of allergen information for foods sold non-prepacked issued by the UK Food Standards Agency in January 2008**

In general, food labelling legislation exempts foods sold non-packaged from the requirement to provide full ingredients listings (for example, Directive 2000/13/EC (EC, 2000)). However for the food allergic consumer, there is still a need for information about the ingredients in a food to enable a safe food choice to be made. As mentioned in Section 5.5.1 above, there is evidence (Pumphrey and Gowland, 2007) that, where a person with a known food allergy who is actively trying to

avoid the foods to which they react does have a further allergic reaction, this event is more commonly reported with foods that are sold unpackaged, including in catering establishments. There is a need to raise awareness in businesses selling food that is unpackaged about the needs of food allergic consumers and to provide advice to help them meet the needs of their customers.

Consumers with food allergies or food intolerances need to have information about the ingredients used in the foods they wish to purchase so that they can make safe food choices. Whilst many countries have legislation that requires the provision on such information on foods sold pre-packed, this generally does not cover foods that are sold unpackaged, including in catering establishments. This exemption arises from a consideration of the practical constraints faced by businesses selling unpackaged foods, many of whom are small or micro-businesses, as well as an acknowledgement that there is an opportunity in such transactions for the buyer to ask the person producing the food about the ingredients used.

The FSA considered that there was need for guidance for businesses selling food that is not pre-packaged, both retail and in the food service sector, to help them meet the needs of their food allergic consumers. This guidance was produced in collaboration with stakeholders from the retail sector, catering businesses and chefs, catering suppliers, food allergic consumers and enforcement bodies. It sets out a number of key messages, as well as describing examples of issues that can arise in different types of businesses providing unpackaged foods and ways that these can be addressed. The main guidance document (<http://www.food.gov.uk/multimedia/pdfs/loosefoodsguidance.pdf>), which is aimed at larger catering businesses and food law enforcement bodies, is accompanied by a leaflet (<http://www.food.gov.uk/multimedia/pdfs/publication/loosefoodsleaflet.pdf>) aimed at small and micro-businesses, as well as a poster (<http://www.food.gov.uk/multimedia/pdfs/publication/thinkallergy.pdf>) that can be used to facilitate staff training.

The guidance sets out three key messages for food businesses providing food that is not pre-packaged, relating to:

- effective communication, both between the customer and the business and also between the different functions within the business;
- training for staff;
- ensuring accurate information is available about the ingredients being used.

It is accepted that the allergic consumer has a responsibility when eating food that is not pre-packaged, to ask for information about the ingredients used in the product in question. Businesses should have in place a recognised procedure for dealing with such requests and staff should all be aware of that procedure. This may involve referring queries to a senior member of staff but, if information is not available, staff should never guess, and in such situations should inform the customer that they are unable to provide the information requested. It is also important that there is effective communication within a food business between the people preparing the food and those serving customers. The final decision whether or not to eat the food rests with the consumer, based on the information they

receive. If it is not possible to provide allergen information about the standard products being provided, it may be possible for the business to provide alternative products not containing the allergen, such as meat cooked without the marinade or sauce or salads served without the garnishes or dressings.

All staff in businesses selling food that is not pre-packaged need to be trained to deal with requests from food allergic consumers. The type of training will vary for different types of business, but the poster developed by the FSA can be used as part of this process. Businesses also need to ensure that information about the ingredients they use can be accessed by staff and that this is kept up-to-date. Again the ways in which this is achieved will vary according the type and size of business involved. The FSA leaflet sets out seven key tips for businesses selling food that is not pre-packaged to help them help their food allergic customers.

- When someone asks you if a food contains a particular ingredient, always check every time – never guess. If you check but you’re still not sure, tell the customer so they can decide for themselves.
- If you are selling a food that contains one or more of the ingredients which can cause a problem, list them on the card, label or menu – and make sure the information is accurate.
- Keep up-to-date ingredients information for any ready-made foods that you use (for example, a filling you put in a sandwich). The ingredients might be on the label or invoice.
- When you are making food, make sure you know what is in all the ingredients you use, including cooking oils, dressings, toppings, sauces and garnishes.
- If you change the ingredients of a food, make sure you update your ingredients information and tell other staff about the change.
- If someone asks you to make some food for them that does not contain a particular ingredient, don’t say yes unless you can make sure that absolutely none of that ingredient will be in the food.
- If you’re making food for someone with an allergy, make sure work surfaces and equipment have been thoroughly cleaned. And wash your hands thoroughly before preparing that food.

## 5.6 Foods sold as ‘free from’

Almost all legislation governing the labelling of allergenic ingredients in foods relates to the labelling of ingredients that are deliberately incorporated into the food product and does not address claims that such an ingredient is not present. In the EU, there is the provision under the framework Directive on Foods for Particular Nutritional Uses (Council Directive 89/398/EEC) (EC, 1989) to make claims regarding the absence of gluten for foods for people with gluten intolerance (coeliac disease). For a number of years, food manufacturers within the EU, and elsewhere, could make use of the Codex Alimentarius Standard (Codex Alimentarius Commission, 1981) for foods for people with gluten intolerance, that

advised that foods could make the claim that they were 'gluten free' if such foods did not contain more than 200 ppm gluten. However, scientific evidence became available (Collin *et al.*, 2004, 2007; Gibert *et al.*, 2006; Catassi *et al.*, 2007) suggesting that the 200 ppm limit for gluten did not provide sufficient protection for all coeliac patients and a revised Codex Standard was published in 2008 (Codex Alimentarius Commission, 2008).

This revised Codex Standard was the basis of discussions between the European Commission and EU Member States that resulted in the publication of Regulation EC/41/2009 (EC, 2009b) in January 2009, setting compositional standards and labelling requirements for foods for people with gluten intolerance. This regulation requires that:

- foods which are specially prepared and/or processed to meet the special dietary needs of people intolerant to gluten can make the claim 'gluten free' as long as they do not contain more than 20 ppm gluten in the food as sold to the final consumer;
- foods for people with gluten intolerance that consist of, or contain, ingredients made from gluten containing cereals (such as wheat, barley or rye) that have been especially processed to reduce gluten, can be described as 'very low gluten' provided that the level of gluten in the food as sold to the final consumer does not exceed 100 ppm;
- foods for normal consumption can be described as 'gluten free' provided that the gluten content does not exceed 20 ppm in the food as sold to the final consumer.

However, there is no other legislation that sets out requirements for foods that make claims that they are free from other allergenic foods, other than the general food law provisions in Regulation No. 178/2002 (European Communities, 2002) that, *inter alia*, prohibits unsafe food being placed on the market and that requires that food labelling should not be misleading. If food businesses want to make such claims, they need to put in place procedures and checks to ensure that they are justified.

## 5.7 Conclusions

In many countries, including those within the European Union, there are statutory provisions that require allergenic foods in pre-packed food to be clearly labelled where they are used as deliberate ingredients. However, at present there are no provisions within the regulations on the management of the presence of allergenic foods as a result of cross-contamination. Nor are there currently any provisions covering allergenic ingredients used in foods sold non-prepacked.

The new regulatory threshold for gluten that will control the composition of foods to be labelled 'gluten free' is a step in providing adequate protection for food allergic consumers. However, the possibility of defining regulatory thresholds for other allergens needs to be explored further. It is clear that in order to provide better

food choices where ‘may contain’ labelled foods are concerned, the basis for making decisions on the declaration of the presence of allergens needs to be defined through establishing an allergenic management threshold. Developing workable and widely accepted allergen management thresholds requires further evidence to be used together with known clinical allergen thresholds to account for circumstances which can affect the threshold or severity of an allergic reaction. Until this is completed, it would be hard to establish any evidence-based management thresholds for controlling allergen contamination in food.

In the interim, the greatest risk to allergic consumers comes from the non-prepacked foods where currently the provision of information about the use of allergenic ingredients is not currently a legal requirement. The best practice guidance documents produced by the Food Standards Agency help food businesses to improve the management and communication of food allergens present in the foods that they sell.

## 5.8 References

- CATASSI C., FABIANI E., IACONO G., D’AGATE C., FRANCAVILLA R., BIAGI F., VOLTA U., ACCOMANDO S., PICARELLI A., DE VITIS I., PIANELLI G., GESUITA R., CARLE F., MANDOLESI A., BEARZII I. AND FASANO A. (2007), A prospective, double-blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. *The American Journal of Clinical Nutrition*, 85, 160–166.
- CODEX ALIMENTARIUS COMMISSION (1981), Codex Alimentarius Commission Standard for gluten-free foods CODEX STAN 118-1981. Rome: FAO/WHO. Available at: [http://www.codexalimentarius.net/web/standard\\_list.do](http://www.codexalimentarius.net/web/standard_list.do) [accessed July 2009].
- CODEX ALIMENTARIUS COMMISSION (1985), Codex Standard 1-1985. General Standard for the labelling of prepackaged foods. Rome: FAO/WHO. Available at: [http://www.codexalimentarius.net/download/standards/32/CXS\\_001e.pdf](http://www.codexalimentarius.net/download/standards/32/CXS_001e.pdf) [accessed July 2009].
- CODEX ALIMENTARIUS COMMISSION (2008), Codex standard for foods for special dietary use for persons intolerant to gluten. CODEX STAN 118-1979. Rome: FAO/WHO. Available at: [www.codexalimentarius.net/download/standards/291/cxs\\_118e.pdf](http://www.codexalimentarius.net/download/standards/291/cxs_118e.pdf) [accessed July 2009].
- COLLIN P., THORELL L., KAUKINEN K. AND MÄKI M. (2004), The safe threshold for gluten contamination in gluten-free products. Can trace amounts be accepted in the treatment of coeliac disease? *Alimentary Pharmacology & Therapeutics*, 19, 1277–1283.
- COLLIN P., MÄKI M. AND KAUKINEN K. (2007), Safe gluten threshold for patients with celiac disease: some patients are more tolerant than others. *The American Journal of Clinical Nutrition*, 86(1), 260.
- EC (EUROPEAN COMMISSION) (1989), Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. *Official Journal of the European Union*, L186, 27–32. Available from: <http://ec.europa.eu/food/food/labellingnutrition/nutritional/d89-398-ec.pdf> [accessed July 2009]
- EC (EUROPEAN COMMISSION) (2000), Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. *Official Journal of the European Communities*, L109, 29–42.
- EC (EUROPEAN COMMISSION) (2003), Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indic-

- ation of the ingredients present in foodstuffs. *Official Journal of the European Union*, L308, 15–18.
- EC (EUROPEAN COMMISSION) (2005), Commission Directive 2005/26/EC of 21 March 2005 establishing a list of food ingredients or substances provisionally excluded from Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council. *Official Journal of the European Union*, L35, 33–34.
- EC (EUROPEAN COMMISSION) (2006a), Commission Directive 2006/142/EC of 22 December 2006 amending Annex IIIa of Directive 2000/13/EC of the European Parliament and of the Council listing the ingredients which must under all circumstances appear on the labelling of foodstuffs. *Official Journal of the European Union*, L368, 110–111.
- EC (EUROPEAN COMMISSION) (2006b), Standing Committee on the Food Chain and Animal Health. Section on General Food Law. Summary record of Meeting of 21 April 2006. Available at: [http://ec.europa.eu/food/committees/regulatory/scfcah/general\\_food/summary19\\_en.pdf](http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/summary19_en.pdf) [accessed July 2009].
- EC (EUROPEAN COMMISSION) (2007), Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. *Official Journal of the European Union*, L310, 11–14
- EC (EUROPEAN COMMISSION) (2008a) Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organisation of the market in wine, amending Regulations (EC) No 1493/1999, (EC) No 1782/2003, (EC) No 1290/2005, (EC) No 3/2008 and repealing Regulations (EEC) No 2392/86 and (EC) No 1493/1999. *Official Journal of the European Union*, L148, 1–61.
- EC (EUROPEAN COMMISSION) (2008b), Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers. Available at: [http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal\\_regulation\\_ep\\_council.pdf](http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/proposal_regulation_ep_council.pdf) [accessed July 2009].
- EC (EUROPEAN COMMISSION) (2009a), Commission Regulation (EC) No. 415/2009 of 20 May 2009 amending Directive 2007/68/EC amending Annex IIIa to Directive 2000/13/EC of the European Parliament of the Council as regards certain food ingredients. *Official Journal of the European Union*, L125, 52–53.
- EC (EUROPEAN COMMISSION) (2009b), Commission Regulation (EC) No. 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. *Official Journal of the European Union*, L16, 3–5.
- EC (EUROPEAN COMMISSION) (2002), Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *Official Journal of the European Communities*, L31, 1–24.
- EFSA (EUROPEAN FOOD SAFETY AUTHORITY) (2004), Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission relating to the evaluation of allergenic foods for labelling purposes. *The EFSA Journal*, 32, pp1–197.
- EFSA (EUROPEAN FOOD SAFETY AUTHORITY) (2005), Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the evaluation of lupin for labelling purposes (Request No. EFSA-Q-2005-086) (adopted 6 November 2005). *The EFSA Journal*, 302, 1–11.
- EFSA (EUROPEAN FOOD SAFETY AUTHORITY) (2006), Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies on a request from the Commission related to the evaluation of molluscs for labelling purposes (Request No. EFSA-Q-2005-84) (adopted 15 February 2006). *The EFSA Journal*, 327, 1–25.
- FERNÁNDEZ-RIVAS M., BENITO C., GONZÁLEZ-MANCEBO E. AND DE DURANA D. A. (2008), Allergies to fruits and vegetables. *Pediatric Allergy and Immunology*, 19(8), 675–681.
- FSA (FOOD STANDARDS AGENCY) (2002), 'May Contain' Labelling – *The Consumer's Perspective*. Crown Copyright 2002.

- FSA (FOOD STANDARDS AGENCY) (2005), *Qualitative Research into the Information Needs of Teenagers with Food Allergy and Intolerance*. Crown Copyright 2005.
- GIBERT A., ESPADALER M., ANGEL CANELA M., SÁNCHEZ A., VAQUÉ C. AND RAFECAS M. (2006), Consumption of gluten-free products: should the threshold value for trace amounts of gluten be at 20, 100 or 200ppm? *European Journal of Gastroenterology & Hepatology*, 18 (11), 1187–1195.
- HEFLE S.L., FURLONG T.J., NIEMANN L., LEMON-MULE H., SICHERER S. AND TAYLOR S.L. (2007), Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *Journal of Allergy and Clinical Immunology*, 120(1), 171–176.
- LUCAS J.S.A., LEWIS S.A. AND HOURIHANE J.O'B. (2003), Kiwi fruit allergy: A review. *Pediatric Allergy and Immunology*, 14, 420–428.
- LUCAS J.S.A., GRIMSHAW K.E.C., COLLINS K., WARNER J.O. AND HOURIHANE J.O'B. (2004), Kiwi fruit is a significant allergen and is associated with differing patterns of reactivity in children and adults. *Clinical & Experimental Allergy*, 34, 1115–1121.
- LUCAS J.S.A. AND ATKINSON R.G. (2008), What is a food allergy? *Clinical & Experimental Allergy*, 38(7), 1095–1099.
- MADSEN C.B., HATTERSLEY S., BUCK J., GENDEL S.M., HOUBEN G.F., HOURIHANE J.O., MACKIE A., MILLS E.N., NØRHEDE P., TAYLOR S.L. AND CREVEL R.W. (2009), Approaches to risk assessment in food allergy: report from a workshop “developing a framework for assessing the risk from allergenic foods”. *Food and Chemical Toxicology*, 47(2), 480–489.
- MINISTRY OF HEALTH, LABOUR AND WELFARE (2005), Food Sanitation Law. Law No. 233, December 24, 1947, last amendment Law No. 87, July 26 2005. Tokyo, Japan. Available at: <http://www.mhlw.go.jp/english/topics/qa/allergies/al.html> [accessed July 2009].
- PUMPHREY R.S. AND GOWLAND M.H. (2007), Further fatal reactions to foods in the United Kingdom 1999–2006. *The Journal of Allergy and Clinical Immunology*, 119(4), 1018–1019.
- RADCLIFFE M., SCADDING G. AND BROWN H.M. (2005), Lupin Flour Anaphylaxis. *The Lancet*, 365, 1360.
- USFDA (U.S. FOOD AND DRUG ADMINISTRATION) (2004), Food Labeling and Consumer Protection Act of 2004 (Title II of Public Law 108–282). Silver Springs, MD. Available at: <http://www.fda.gov/Food/LabelingNutrition/FoodAllergens/GuidancecomplianceRegulatoryInformation/ucm106187.htm> [accessed July 2009].
- VIETHS S., SCHEURER S. AND BALLMER-WEBER B. (2002), Current understanding of cross-reactivity of food allergens and pollen. *Annals of the New York Academy of Sciences*, 964, 47–68.