

European Union Forum

Information provision for allergic consumers – where are we going with food allergen labelling?

As the current treatment for food allergy involves dietary exclusion of the problem food, information for food-allergic consumers provided on food labels about the nature of allergenic ingredients is important to the management of their condition. The members of an EU-funded networking project, InformAll, focusing on developing strategies for the provision of credible, reliable sources of information for food allergy sufferers, regulators and the food industry, have been considering these matters with respect to food labelling. This paper presents an overview of the genesis of the new EU directive on food labelling, its relevance to food-allergic consumers and the problems that might arise if precautionary labelling becomes more widespread in response to concerns regarding inadvertent allergen contamination in foods. International efforts to define threshold levels of allergens able to trigger a reaction coupled with validated allergen detection methods are essential if the food industry is to implement effective hazard control procedures and address the problems of cross-contact allergens without devaluing the information provided to consumers on food labels.

**E. N. C. Mills¹, E. Valovirta²,
C. Madsen³, S. L. Taylor⁴, S. Vieths⁵,
E. Anklam⁶, S. Baumgartner⁷,
P. Koch⁸, R. W. R. Crevel⁹, L. Frewer¹⁰**

¹Institute of Food Research, Norwich, UK; ²European Federation of Allergy and Airways Diseases Patients' Associations, Brussels, Belgium; ³Danish Food and Veterinary Research, Søborg, Denmark; ⁴University of Nebraska, Lincoln, NE, USA; ⁵Paul Ehrlich Institute, Langen, Germany; ⁶European Commission, Directorate General Joint Research Centre, Institute for Reference Materials and Measurements, Geel, Belgium; ⁷IFA-Tulln, Konrad Lorenzstrasse 20, Tulln, Austria; ⁸SQTS-Swiss Quality Testing Services, Dietikon, Switzerland; ⁹SEAC, Unilever Colworth, Sharnbrook, UK; ¹⁰Department of Marketing and Consumer Behaviour, Wageningen University and Research Centre, Wageningen, The Netherlands

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Dr Clare Mills
Institute of Food Research
Norwich Research Park
Norwich NR4 7UA
UK

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Food allergy has been estimated to affect around 1–2% of the adult population, and up to 8% of children less than 3 years of age (1) and because there is no proactive treatment all that can currently be offered to individuals suffering from classical IgE-mediated food allergy is to 'avoid completely all foods containing the offending allergen' (2), coupled with emergency management of reactions for those with severe allergies. Such advice is also extended to sufferers of food intolerance conditions such as Coeliac's disease, for which food avoidance is also the only treatment currently available. Implementing such advice means that food-allergic consumers, together with their families and carers, must adopt a lifestyle of constant vigilance (life-long for many) to ensure that food they buy and eat is free from problematic allergens. This is not easy to achieve in practice and has been made worse by the fact that in many countries legislation has not required complete labelling of ingredients contained in processed food-

stuffs. As a result accidental consumption of problem foods (sometimes fatal) has resulted from 'hidden' allergens (3–5). Provision of good quality food allergen labelling is paramount for allergic consumers, their families and carers, to manage their condition effectively. In response to this need, the EU has funded a networking project, InformAll (<http://www.informall.eu.com>), with the aim of developing communication strategies for food allergy, promoting the provision of visible, credible sources of information appropriate to different stakeholders. One of the first aspects that the partnership has been considering is the labelling of allergens in foods.

What the allergic consumers want

As food-allergic consumers rely on food labels to implement the food avoidance they need all the ingredients in a

food to be declared on the label in a clear, understandable and a easy-to-read manner (6). The position of patient groups such as the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is that food-allergic and hypersensitive patients have the right to know which foods contain allergic ingredients. They have demanded that

1. Ingredients and substances recognized as causing allergies must be listed and labelled without exception and with clear reference to their common name.
2. The list of ingredients and substances recognized as causing allergies should be updated on the basis of new scientific evidence about food allergies and allergens.
3. There should be limitations imposed regarding the flexibility with which ingredients which constitute a minor part of the finished product, are labelled.
4. Exceptions from the need for labelling of compound ingredients (i.e. ingredients which comprise a number of different components commonly used in food products, like milk chocolate) are strictly limited.

The precise needs of allergic consumer depend on the nature of their condition, those with life-threatening IgE-mediated allergies being quite different from those with conditions such as Coeliac's disease. For the latter, continual consumption of low levels of gluten is debilitating, but occasional inadvertent exposure to wheat products but are not generally life-threatening, unlike those with severe IgE-mediated allergies for whom even the occasional exposure can be fatal. However, these distinctions are becoming increasingly blurred as IgE-mediated allergies, Coeliac's disease and other, sometimes much less well-defined food intolerances, are bunched together for regulatory purposes, making meeting the different needs of these groups a complex process.

How regulators are responding

In the past, the views and needs of the allergic consumer were not a consideration for regulators formulating food-labelling rules. Instead their priority was to ensure that the consumer was properly informed regarding the quality and nature of the food ingredients present in manufactured foods. Producers adding milk ingredients such as casein or whey protein to a prepared food have to declare it as such and not milk; an example of such a label is shown in Fig. 1A. However, the nature of ingredients listed on the label is not as important for the milk-allergic consumer as their being able to readily identify the presence of milk *per se*. In the past the '25% rule' has not applied to food additives, and has meant that if a manufacturer includes salami at less than 25% of the weight of a food, such as pizza, only the additives in the salami would have to be declared on the label and not the salami ingredients themselves (meat, fat, milk powder,

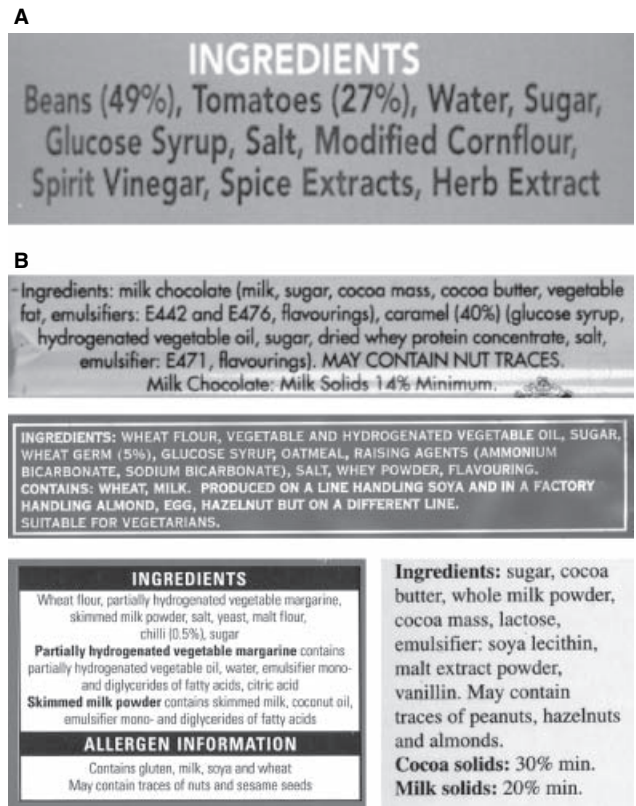


Figure 1. Examples of allergen labelling. (A) This label refers to the milk protein ingredient 'whey powder'. As 'milk' is not specifically mentioned someone with cow's milk allergy needs to know that 'whey powder' is something they have to avoid. (B) This selection of labels includes examples of precautionary 'may contain' labelling, together with more explicit labels where information as to the nature of the nuts and the reasons for the possible presence of allergenic ingredients are included.

etc.). The consumers wish to be better informed, coupled with increasingly complex food production methods means that comprehensive labelling of the composition of foodstuffs is now necessary.

In response to such concerns, a paper was produced by the Nordic countries in 1993 and submitted to the Codex Alimentarius Commission Committee on Food Labelling (7) which suggested changing the international food labelling rules to help the allergic consumers. It recommended that the '25% rule' was replaced by a '5% rule' and that a list of major allergenic foods should be created for which labelling would always be mandatory despite the '5% rule'. This proposal was adopted by the Codex Alimentarius Commission as an amendment to the Codex General Standard for the Labelling of Prepackaged Foods (8). Consequently the EU has embarked on amending the food labelling directive (9) which abolishes the '25% rule' and requires manufacturers to declare any allergen present, or any product derived from such allergens. In the White Paper on Food Safety, the

European Commission announced its intention to propose an amendment to Directive 2000/13/EC on the labelling of foodstuffs and in doing so has recognized the need to provide consumers with better information about food allergens. Member States now have 1 year to turn the Directive into national law, manufacturers then having a further year to implement the directive. Thus consumers can expect to see changes in labelling by late 2005. The purpose of the legislation is to protect allergic consumers, and the concept of allergen labelling as such poses no problem for the food manufacturer, but its implementation raises a number of issues for regulators, the food industry and the allergic consumer.

The EU labelling Directive

The main provisions of the proposed amendment are:

- 1. Abolition of the 25% rule, which would consequently enshrine the principle of labelling of all ingredients (not just allergenic ones).
- 2. Maintenance of a limited number of derogation (exceptions) for some categories of compound ingredients.
- 3. A list of ingredients or substances causing most cases of food allergies or intolerance – in this case derogation (exception) is not allowed.
- 4. Practical procedures enabling manufacturers to have a certain degree of flexibility, making it easier for them to comply with the new labelling obligations imposed by the proposal.

In principle all ingredients in a product will now have to be listed, and although there will still be some exceptions these will not apply to a list of allergenic ingredients in Annex IIIa of the directive (Table 1). Some examples of what this means in practice are given below:

Table 1. Major allergenic foods listed in Annex IIIa of the EU draft Directive on labelling of foods

<i>Cereals</i> containing gluten (i.e. wheat, rye, barley, oats, spelt or their hybridized strains) and products thereof
<i>Crustaceans</i> and products thereof
<i>Eggs</i> and products thereof
<i>Fish</i> and products thereof
<i>Peanuts</i> and products thereof
<i>Soybeans</i> and products thereof
<i>Milk</i> and products thereof (including lactose)
<i>Nuts</i> (i.e. Almond, Hazelnut, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut) and products thereof
<i>Celery</i> and products thereof
<i>Mustard</i> and products thereof
<i>Sesame seeds</i> and products thereof
<i>Sulphur dioxide</i> and sulphites at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO ₂ .

- Sulphite added above 10 mg/kg will always appear on an ingredient label, even if it does not have a function in the finished product. As alcoholic beverages are no longer exempt sulphite used in their production will have to be declared.
- Egg white used as processing aid in wine production and lactose used as carrier substance for a flavour will now have to appear on the list of ingredients.
- Ingredients from Annex IIIa, such as milk or nuts, contained in compound foods such as chocolate must appear on the label.
- If the source of a vegetable oil or a flavour is listed in Annex IIIa it has to be specified on the label.
- In addition the categories ‘crystallized fruit’ and ‘vegetables’ may not be used any more, i.e. the actual mixture of vegetables has to be specified in the list of ingredients.

Ingredients made from the foods in Annex IIIa may be exempted if it can be proven that they do not cause unwanted reactions. In the longer term it is intended that the list in Annex IIIa should be revised and updated on the basis of the most recent scientific knowledge, the first revision taking place within 2 years from the publication of the Directive. A working group under the European Food Safety Authority has been asked to set up the criteria to be used for deleting products from the Annex IIIa list.

From regulations to label – allergen hazard management

For allergen labels on prepackaged foods to be useful to the allergic consumer they must be both credible and accurate. Consequently, manufacturers must have a detailed knowledge of the constituents of a product from each stage of the supply chain. For ‘simple’ ingredients (e.g. wheat flour, milk powder) added at the manufacturer’s factory, this poses few problems. However, ensuring that all the individual components of complex ingredients like chocolate are included requires good communication and co-operation with suppliers, sometimes from across the globe, throughout the supply chain. Robust inventory systems are being developed to manage the process, which include tracking changes in formulation of manufactured foods. The proposed regulations also impact on manufacturing practices, where different materials may be used to achieve the same ‘functionality’ in a given product. For example, different types of oils may be used in manufacturing margarine at any given point in time, depending on factors such as supply and cost.

Several factors need to be addressed to ensure appropriate management systems are developed – how much of an allergenic food needs to be detected, what component in the food must be monitored, and its behaviour during food processing. This information is crucial for

development and validation of appropriate analytical procedures to monitor ingredients, equipment clean-down and finished foods by manufacturers and regulators alike. However, research is still needed in order to define threshold doses which elicit allergic reactions and hence set limits for levels of allergens in foods in relation to their labelling. Such information is also required to establish the detection limits for allergen analysis methods, which take due account of the effect of food processing on both allergenicity and detectability.

How much? The role of thresholds

Allergists recognize that exposure to small quantities of allergenic food can elicit adverse reactions in individuals with IgE-mediated food allergies (10, 11). A threshold dose is defined as the lowest observed adverse effect level (LOAEL), an amount of a specific food that would elicit mild, objective symptoms in highly sensitive individuals (12). Double-blind, placebo-controlled food challenges (DBPCFCs) conducted with low doses of specific allergenic foods demonstrate rather clearly that finite threshold doses exist below which allergic consumers will not react (11). Individuals with IgE-mediated food allergies appear to vary rather widely in their degree of sensitivity to specific allergenic foods. For example, in DBPCFCs with peanut-allergic individuals, individuals threshold doses ranged from 2 to > 50 mg (12). Threshold doses for peanut, egg, and cows' milk appear to be in the low milligram range or higher for individuals with allergies to those specific foods (11). However, these data were often obtained using different protocols making the estimation of a threshold dose rather difficult. More data are needed on low-dose challenges of individuals with specific food allergies using a consistently applied clinical protocol to obtain better estimates of threshold doses for various foods. This is one of the goals of the Food Allergy Research and Resource Programme (FARRP), based in the USA but working internationally with clinicians and the food industry to establish objective information on thresholds for all the major allergenic foods that will have to be labelled.

While low doses of allergenic foods clearly can present some risk to allergic consumers, the imposition of a zero tolerance level for the offending foods places unachievable burdens on the food industry for numerous reasons that have been described previously (11). The food industry manufactures many different food products within the same processing facility. Several hundred different products can be manufactured within a single building. In such situations, trace residues of a specific food could come into contact with another food being manufactured in the same facility. Furthermore, the food industry often uses shared equipment to manufacture related food products, e.g. ice cream and sorbet or chocolate confections with differing ingredients. Without

reliable information on threshold doses, it is very difficult for the food industry to economically implement prudent sanitation practices for shared equipment or facilities. Such information is important if researchers are to provide manufacturers with the appropriate means to monitor cross-contact allergens through, for example, clean-down procedures for common processing equipment.

What to analyse for

Almost all allergens are proteinaceous in nature and highly sensitive analytical methods have been developed using either immunoassays or PCR-based methods to detect traces of allergenic foods resulting from such common industry practices (14–16). A number of methods have been developed for analysis of many major allergenic foods listed in Annex IIIa of the draft labelling directive, some of which are commercially available in kit-form. The detection and especially the quantification of allergens in processed food products can be very difficult, as they are often present in trace amounts, or are masked by the food matrix. This is illustrated by recent results from the work programme of the European Commission's Joint Research Centre (JRC). Peanuts available in the food sector are derived from various sources, and were processed in various ways, such as dry and oil roasting. Processing in this way resulted in significant variation in the detectability of peanuts in corn flour, when analysed for by ELISA using three different peanut allergen kits (Fig. 1). For one kit processing made no difference to the peanut immunoreactivity, whilst roasting decreased the immunoreactivity by around 30%. Significant differences in kit performance were also observed with overreporting of peanut by between two- and threefold in two of the three kits analysed.

As well as dealing with the problems of the food matrix, methods must also be sensitive enough to specifically detect the allergens in those amounts that might trigger allergic reactions in sensitized individuals. It has been shown that a level of 100 µg of peanut proteins can trigger a mild reaction in a peanut-allergic person (13). Such a level of exposure could result from the consumption of 100 g chocolate or biscuits containing as little as 1 mg/kg of peanuts. On the basis of such information it is generally accepted that detection limits for analysis of allergens in different food products need to be in the range of 1–100 mg/kg, depending on the respective allergen and food product. In order to standardize analytical methodology available so far the European Committee for Standardization (CEN) has recently established a new working group on food allergens (CEN TC 275 WG 12). The working group concluded that there were no collaboratively trial tested (validated) methods so far available for the analysis of allergens in low ppm ranges. The JRC is responding to the CEN demands and is currently

validating five commercially available ELISA test kit methods for the detection of peanuts in dark chocolate and biscuits at very low levels (1 mg/kg). The comparison of the performance of ELISA- and PCR-based methods is also under investigation in the JRC. In addition, the US FDA is planning to carry out a collaborative trial study with various food matrices spiked with extracts from a peanut butter.

These efforts are complimented by the JRC efforts to validate methods for the detection of peanuts in dark chocolate and biscuits at very low levels (1 mg/kg). Using in-house and international validation studies (ring tests), five commercially available ELISA methods for detecting peanuts are currently under evaluation. Reference materials for allergens are also required in order to validate and calibrate analytical methodology. Given its importance as an allergenic food, a JRC priority is to develop a peanut reference material based on commonly used peanut varieties both for research and routine analysis. This peanut reference standard will also take into account specific demands from the food industry with respect to various nut roasting conditions.

In addition to conventional laboratory-based analysis there is an increasing demand for immunoassay techniques for use outside the laboratory, in places such as factory production lines and in the home, which deliver quick and reliable results without expensive laboratory equipment and reagents. The EU has been supporting the development of many of these analytical methods and the goal of one of these projects, Allergentest (<http://www.allergentest.info/>), has been the development of dip-stick or lateral flow device immunoassays for detecting peanut and hazelnut. Such assays can potentially deliver yes/no-decisions or semi-quantitative results in a very short analysis time (2–3 min). They have great potential in assisting the food industry in monitoring clean-down procedures on common processing lines and could be an important tool to help assist the industry in hazard control procedures to avoid cross-contact allergens.

Precautionary labelling and inadvertent allergens in foods

The new EU labelling regulations do not cover inadvertent inclusion of allergens in foods through the use of common processing equipment, or production lines which are in close proximity. Sometimes termed 'cross-contact', this may result in a 'nut-free' product containing traces of peanut and is a considerable problem for allergic consumers to live with and major challenge for the food industry to manage. A recent survey of foods in the USA showed that in 1999 around 40% of undeclared allergens in foods resulted from cross-contact, whilst 5% resulted from errors either by manufacturers themselves or through the supply chain (17). A more recent study suggests that undeclared peanut in chocolate was not so problematic but that around 31% of chocolate bars from

western Europe and 62% of those from Eastern Europe did contain undeclared peanut (18). Such studies indicate that undeclared allergens can be found in foods, it is not possible to tell if these levels of undeclared allergens are significant for allergic consumers without good quality information as to the thresholds which can trigger an allergic reaction.

Unfortunately, most manufacturing facilities and systems were built before the advent of allergen labelling and are difficult to adapt for optimal handling to avoid cross-contact making this even harder to manage in an effective way. These problems, coupled with the fact that some manufacturers lack the resources to implement appropriate control systems can result in manufacturers adopting 'precautionary labelling', rather than face possible legal action in the event of small amounts of undeclared allergen being discovered in their products. Examples of the types of label that allergic consumers have to deal with are shown in Fig. 2. In Australia and New Zealand precautionary 'may contain' statements are expressly allowed and is consequently widely encountered on packaged foods. Rather than helping the allergic consumer cope with their condition offers, such labelling means they have even more restricted food choices and makes every day activities such as shopping, difficult. In the eyes of many allergy sufferers, precautionary labelling is viewed as cover for suboptimal allergen control practices. There is also evidence that the widespread usage of 'may contain nuts' labels can be both a deterrent to shopping and a devaluation of the label itself (19), and there are concerns that other information of the same type from the same source, and possibly from related sources, could also become devalued by association. Indeed there is anecdotal evidence that allergic consumers may regularly ignore precautionary labels, putting themselves at a potential risk and further devaluing information provided on food labels.

A small qualitative study undertaken by the UK Food Standards Agency (19), found that the majority

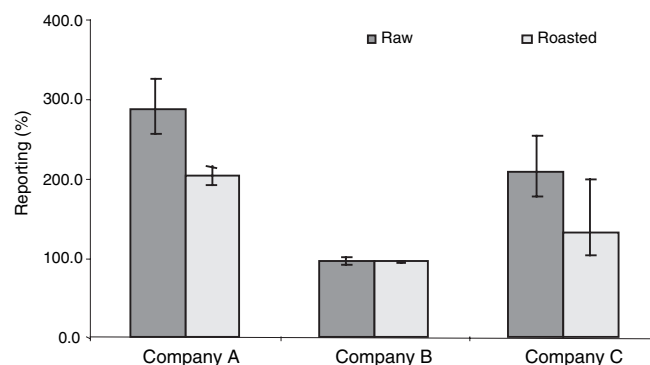


Figure 2. Recovery of peanut (raw and processed) spiked to corn flour at a level of 10 mg/kg by three different ELISA test kits.

of food-allergic consumers were 'risk takers' who took calculated risks when deciding to eat foods with 'may contain' labels with some who were 'total avoiders' and would avoid all contact with nuts, however remote the likelihood of exposure. Whilst all the allergic consumers needed ingredient information which was easy to find, read and understand, the 'risk-takers' wanted more meaningful information about allergen contamination which had proven difficult to completely control, to enable them to make their own choices with confidence. In contrast 'total avoiders' and those who shopped only occasionally on the behalf of allergic consumers wanted clear negative (not suitable for nut allergy sufferers) or positive (this product is nut-free) indications on the label, with the manufacturers taking responsibility for deciding which products are suitable for someone with a nut allergy.

The requirement for more information is at odds with providing food labels with clarity and is compounded by many labels appearing in multiple languages and in very small type, making them difficult to read. The ability of parents of food-allergic children to accurately *read* food labels is very poor (20), primarily because of the complexity and ambiguity of information provided. In some cases poor labelling practices may also lead to unnecessary restrictions to a child's diet. It may be useful to back-up information on labels with additional information (for example, information provided on a complementary website). However, further information is needed regarding the preferences of different end-users regarding the format that such information should take, and the type of additional information required to back-up what is provided on the label.

Whilst the ethos behind the new EU labelling directive is very much that of consumer protection, and it clearly goes a long way towards meeting the requirements of the allergic consumer groups, there is a danger that widespread use of precautionary labelling will negate these advances, especially in relation to undeclared cross-contact allergens. Allergic consumer groups, such as EFA, are beginning to call for the EU to regulate precautionary labelling. However, additional legislation may not be necessary in some countries as, for example, in the UK, manufacturers must practice 'due diligence' under more general legislation governing the safety of food. In addition to prepackaged food, such regulations also need to address foods sold loose, or from catering outlets which are not covered by the new directive and is urgently required. These represent a considerable risk to allergic consumers and are more likely to cause severe illness and death. Indeed, many fatal allergic reactions occur when allergic consumers are eating out (21). By developing (1) sensitive and reliable methods for monitoring allergens in foods and (2) reliable threshold information to guide the food industry proper sanitation practices can be implemented and the use of precautionary or advisory labelling statements could then be restricted to those products that are likely to present a genuine hazard to food-allergic consumers.

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