

Labelling of potential allergens in food

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Abstract

In order to avoid food that they cannot tolerate, consumers suffering from food allergy or intolerance need sufficient and correct, information about food products. Labelling requirements are not satisfactory in this regard. Registration of adverse reactions in Sweden show that out of 77 cases, 51 were a result of inadequate labelling, six cases were fatal and several others required hospitalization. International recommendations for the labelling of food (Codex Alimentarius, a joint WHO/FAO organization) do not require specification of ingredients in composite ingredients if the composite ingredient constitutes less than 25% of the food (25% rule). Some ingredients are declared by category names. Ingredients such as milk, eggs, nuts, peanuts, fish, cereals, etc., will not appear on the label in these cases. Amendments are being discussed with a view to providing allergic consumers with more adequate information. A lowered specification limit for declaring ingredients in composite ingredients is suggested, combined with the establishment of a list of certain specific potent allergenic ingredients that should always be specified if present. Although many measures are needed to improve the situation for the allergic consumer, appropriate labelling of each product is fundamental. Adequate labelling is an important prerequisite for secondary prevention, a necessary basis for other measures and in addition will increase knowledge, awareness and caution in food production. © 1997 Elsevier Science B.V.

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1. Introduction

Being able to avoid foods that give rise to symptoms is paramount for people suffering from allergy or intolerance. In order to identify such foods, the consumers need information of the nature and composition of these foods.

The modern food market is characterised by a wide variety of products, a huge number of possible ingredients, new and novel products and components and untraditional composition of traditional foods and dishes. The consumer needs sufficient and correct information regarding the nature and composition of each product. This information is important to the consumer in general and vital to the allergic consumer.

There are several regulatory challenges in this area: (1) mandatory labelling should provide the best possible information; (2) regulation and control systems

should prevent unintended addition of allergenic substances (contamination); and (3) control should ensure compliance with regulations for processing and labelling. Last, but not least, consumers, producers and food handlers need appropriate information.

2. Adverse reactions to food

Since 1989, the National Food Administration in Sweden has registered foods that have caused adverse reactions (Malmheden Yman, 1995a,b; Malmheden Yman and Edberg, 1995). The results are summarised below. A few similar results exist from the other Nordic countries, but the investigations are not as extensive and systematical as in Sweden.

The cases of adverse reactions to food have been reported by physicians, dieticians, consumers or manufacturers. During this period, 77 consumers suffering from allergy, coeliac disease or lactose intolerance have

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experienced hypersensitivity reactions. The offending foods were in all cases compound products; that is, food composed of more than one ingredient. Typical foods involved were chocolate, candies, ice cream, hamburgers, meatballs, sausages, bread, cookies and pasta products. About 85% of the foods were prepackaged.

Investigation has shown that the presence of the offending ingredients were in most cases hidden to the consumer. In 13 cases it was a result of contamination during the production process and in 51 cases it was a result of inadequate labelling. In 13 cases the ingredient appeared on the label, but was not recognised and thus, was inadvertently consumed.

Using immunological methods, the following offending allergens were identified: hazelnut (5), walnut (1), pine nut (1), almond (3), apricot (1), sesame seed (2), sunflower seed (1), egg (8), milk (18), lactose (3), gluten (7), soy protein (10), pea protein (3) and peanut (14)¹.

In six cases the dose of allergen leading to reaction could be estimated. A total of 6 mg of hazelnut in a chocolate, 50 mg of corylin (hazelnut) in a cookie, milk corresponding to 10 mg casein and egg corresponding to 10 and 190 mg ovalbumin, respectively, caused reactions requiring medication. A meal of sausage containing the amount of cow's milk equivalent to approximately 60 mg casein resulted in fatal anaphylaxis.

In six of the cases the food intake resulted in fatal anaphylaxis. The victims were children and youngsters 9–17 years of age (four females and two males), all suffering from asthma. The causative allergens were milk protein in sausage, soy protein in hamburgers, kebab skewers, meatballs, peanut flakes on bread and hazelnut in chocolate.

Several other cases involved serious reactions requiring intensive care or hospitalisation. Recently, a ready-made dish, 'Cevapcici with rice', marketed as free from egg, milk, fish, gluten and nuts, caused an anaphylactic reaction in a 20-year old female, suffering from egg allergy. The cevapcici was found to contain 0.02% ovalbumin. Potato flakes added to the minced meat also contained hen's egg whites, which did not appear on the label.

Recently, cheese produced in Denmark caused a reaction in another egg allergic woman. Lysozyme was found in the cheese. Egg lysozyme is added for aging purposes and is frequently used in Denmark.

Lately, products containing peanuts have caused severe reactions and even deaths in Sweden. Peanut flakes used as decoration on bread were mislabelled as almonds. This caused the death of a 14-year-old boy sensitive to peanuts but not to almonds. Peanuts appearing on labels under the names 'Pinex' or 'Peanex'

have also caused severe allergic reactions. These names are trade names for processed peanut flakes and should be declared in a more descriptive fashion.

A pasta marketed as gluten free caused an intolerance reaction, vomiting on three occasions, in a boy with coeliac disease. In a girl with wheat/rye allergy, this pasta resulted in an allergic reaction and an attack of asthma on two occasions. An analysis of the pasta revealed it to contain 1% gluten. This is a remarkably high figure if caused by contamination. Gluten free products should contain no detectable levels of gluten if made from maize or rice, for example.

A cake mix, claiming to be gluten free and without egg, milk and soy protein, caused eczema in a woman while handling the mix. Analysis of the mix revealed 0.16% ovalbumin, 0.15% casein (milk protein), traces of soy and 0.3% gluten. The product contained all the proteins it claimed to be without.

Sesame seed appearing on the label as 'spice' or 'herbs' in a pasta sauce caused an allergic reaction in a boy sensitive to nuts, almonds, kiwi and sesame seeds.

A package of noodles imported to Sweden was labelled 'noodles with satay spice'. It caused severe reactions in two girls sensitive to peanuts. An analysis of the mix with the English label 'satay mein paste' contained approximately 50% homogenised peanuts. The term 'satay mein paste' appeared on the label only as 'spices' after translation into Swedish.

In the ingredients list of biscuits containing nougat cream filling, no information about the nougat cream ingredients was given. The nougat contained about 10% hazelnut.

Others report similar results (Steinman, 1996). Unexpected contents of allergenic components in food give rise to serious, even fatal, reactions. Contamination and erroneous labelling are the causes in some cases while misunderstanding the listed information occur in others. However, insufficient labelling, resulting from inadequate or unclear regulations, seems to be the most important.

3. Current labelling regulations and potential problems for consumers with food allergy/intolerance

International rules for labelling pre-packaged foods have existed since 1969. Codex Alimentarius, the joint WHO/FAO organisation for standardisation of foods, then issued a world wide standard for the labelling of pre-packaged foodstuffs (FAO/WHO, 1987). The standard serves as a basis for national regulations in many countries, but is not obligatory for the Codex members.

These international recommendations have exemptions making labels unsatisfactory for people suffering from reactions to certain foods. It is important to note that the main principles are satisfactory, however, the cause of the problem is the accepted deviations.

¹ Numbers refer to the number of cases.

In general, labelling should be sufficiently informative to consumers enabling them to make informed choices. Consumers should be provided with an understanding of the nature of the food, be able to distinguish it from other products and be able to make comparisons. Descriptions should not be false, deceptive or misleading.

The standard recommends certain mandatory information: name of the food, list of ingredients, net content, name and address of the manufacturer, packer, etc., date marking and storage instructions.

In some cases other details may be required: country of origin, quantitative labelling of ingredients, etc.

To an allergic person, the list of ingredients would be the most important feature. The term ingredient is defined as substances used in the manufacture or preparation of food. Ingredients should be declared by a 'descriptive term which is not misleading or confusing to the consumer'. The standard requires all ingredients, including food additives, to be declared in descending order of ingoing weight, however, there are exceptions to this general principle.

3.1. Composite ingredients

If the ingredient itself is a product of two or more ingredients and constitutes less than 25% of the food, the components of this composite ingredient need not be specified. For example, if there is less than 25% meatballs in a soup, only the term 'meatballs' may appear in the list of ingredients, specification of the ingredients in the meatballs is not required. In some countries meatballs may contain eggs, in other countries both eggs and milk, while some countries do not allow any of these ingredients in meatballs. The same applies to margarine, for example, which may be produced with or without milk. In both cases, only the term 'margarine' will be listed on the label. Chocolate, declared as such, may contain milk, even nuts or peanuts.

The declaration of composite ingredients is illustrated below.

Some of these examples are not complying strictly with the Codex standard, but are realistic illustrations of the practical implications, the 25% rule being difficult to understand and open to interpretation.

According to the Codex General Standard, the rule shall only be applied to standardised products. In many countries e.g. EU, the 25% rule is also being applied to products which are produced according to custom or tradition without the composition necessarily being specified in a standard, which in practice means most composite ingredients.

According to international trade agreements countries should accept products which are in accordance with other countries' standards or traditions. The names of these foods may be listed as ingredients without specification. Usually, consumers will not be

aware of the standards or customs of other countries, nor will it be easy to obtain the relevant information. As an example, mayonnaise, which is produced with eggs in some countries and without eggs in others, may cause an unpleasant and even fatal misunderstanding if egg is not listed among the ingredients.

The 25% rule leads to the paradoxical situation that a substance added to a food in small amounts as an ingredient must be declared, whereas the same substance can be present as a component of a compound ingredient in much larger amounts in another product, without being specified.

3.2. Class names

The Codex standard provides for the declaration of certain ingredients by class or category name instead of specific name. Several of these names may 'hide' ingredients which may induce reactions in hypersensitive people. The terms starch or vegetable/animal oil or fat may be listed without any indication of the source. If present in amounts of 2% or less, mixtures of spices and herbs may be declared as 'spice(es)' or 'herb(s)'. Specification of individual fruits in mixtures of crystallised fruit is not required if the total amount is less than 10%. The EU also allows vegetable mixtures present in a total amount of 10% or less to be declared as 'vegetables' without further specification. Thus celery, peas, carrots and soybeans might not be listed on the labels of soups, stews, etc. Crystallised fruit in cakes, confectionery products or desserts might be mixtures of oranges, apples, cherries, apricots, etc., without this fact appearing in the declaration.

Some examples of the 25% rule and the use of class names are outlined as follows:

Sorbet with filling and coating

Ingredients may be listed as: water, sugar, tangerine concentrate, chocolate, nougat

Ingredients in nougat not declared: almonds or hazelnuts

Ingredients in chocolate not declared: milk

Biscuits

Among the listed ingredients is 'cake crumbs'

Ingredients in cake crumbs not declared: wheat gluten, almonds, hazelnuts, peanuts, egg

Spaghetti dish

Among listed ingredients: tomato sauce, meatballs, spaghetti

Ingredients in meatballs not declared: milk, individual spices and herbs

Ingredients in spaghetti not declared: wheat, egg

Vegetable soup

Among listed ingredients: margarine, vegetables, herbs, spices

Ingredients in margarine not declared: milk

Vegetables not declared: carrots, peas, celery

Not specified: individual herbs and spices

3.3. Food additives

Additives with a technological function in the final product shall always be declared, even if they are part of raw materials or composite ingredients. Food additives in raw materials with no technological function in the finished product will not appear in the list of ingredients. This rule is often referred to as the 'carry-over rule'.

Apparently, some food additives may trigger hypersensitivity reactions at levels below that required to exert a technological function, e.g. sulphites.

4. Proposed amendments

In regards to ensuring that sufficient information is provided to people suffering from food allergy and intolerance that will enable them to avoid products they cannot tolerate, it seems quite clear that the exemptions to rules for declaration of ingredients in the general labelling standard are unsatisfactory. Other important issues, such as the terms used in the labelling, is a matter of compliance and control, and not caused by the rules themselves.

There are differences in the way the Codex standard is implemented in various countries. The United States requires full ingredient declaration and has not implemented the 25% rule, as was the case earlier in several of the Nordic countries. Presently, Finland and Iceland have obligatory declaration of certain specific allergens. However, as mentioned the EU legislation includes the 25% rule, thereby extending the application considerably.

Amendments to the Codex labelling standard on these points are currently discussed. To meet the needs of consumers suffering from food allergy/intolerance, a working document was prepared in 1993 by Norway in co-operation with the other Nordic countries. This document discusses regulations for labelling and other possible measures in detail, concluding with a proposal to amend the standard (FAO/WHO, 1993).

Ideally, full and specific ingredient declaration would be the best. Realising that this might be difficult to achieve, a compromise was suggested: (a) lowering the percentage from 25 to 5%; combined with (b) setting up a list of certain specific ingredients always to be declared.

Since then, the proposal has been amended slightly based on discussions in Codex (FAO/WHO, 1993, 1994, 1996) and on the conclusions of a FAO expert consultation in November 1995 (FAO, 1995). The Scientific Committee for foods in the EU has issued a report on food allergy (European Commission, 1996). Although not discussing labelling aspects as such the report forms part of the basis for the discussions on labelling within the EU.

The present proposal is outlined below.

5. Proposed draft amendments to Codex general standard for the labelling of pre-packaged foods

(The proposed amendments are in italics.)

Section 4.1. The Name of the Food

The name shall indicate the true nature of the food and normally be specific and not generic.

Section 4.2. List of Ingredients

4.2.1. Except for single ingredient foods, a list of ingredients shall be declared on the label.

4.2.1.1. The list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term 'ingredient'.

4.2.1.2. All ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food.

4.2.1.3. Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient for which a name has been established in a Codex standard or in national legislation constitutes less than (5%) of the food, the ingredients, other than food additives which serve a technological function in the finished product *and ingredients known to cause allergic or intolerance reactions, need not be declared.*

The following foods and ingredients are known to cause hypersensitivity and shall always be declared as such:

Cereals containing gluten; i.e. wheat, rye, barley, oats, spelt or their hybridized strains and products of these; crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of

these; milk and milk products (lactose included); tree nuts and nut products; and sulphite in concentrations of 10 mg/kg or more.

Section 4.2.2.1. *Except for those ingredients listed in Section 4.2.1.3. and unless a general class name would be more informative*, the following class names may be used for the ingredients falling within these classes: (the remainder of section as is)

Section 4.2.3.2. A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. *The exemption does not apply to food additives and processing aids listed in Section 4.2.1.3.*

6. Comments to the proposed amendments

It should be emphasised that the propose is to improve the level of specification in the mandatory list of ingredients. The proposal is not a question of setting up a special system for labelling of allergens or to provide warnings on labels.

The exemption regarding composite ingredients was not included in the original standard and the 25% is arbitrary (FAO, 1995). It should also be noted that the 25% rule does not apply to certain other ingredients like food additives and that class names cannot be used for pork or beef fat. Whether the reason is due to fear/scepticism (food additives) or religious beliefs (pork and beef) the consumer's demand for more detailed information pertaining to certain ingredients is accepted.

The proposed change from 25 to 5% was considered the maximum reduction that had any hope of acceptance, a prediction confirmed by the strong opposition from certain countries to any changes in the 25% rule. The reduction will not protect extremely sensitive individuals; however, it is a step in the right direction. Since the proposed list of strong allergens does not include all substances that may cause reactions, lowering the limit for specification of ingredients is important to people reacting to other substances.

Since it was considered unrealistic to completely abandon the use of the 25% rule and class names, a list of common ingredients giving rise to severe reactions was proposed and modelled on the regulations in several of the Nordic countries. The selection of substances was based on the generally accepted literature and knowledge. The practicality of this approach was confirmed in 1995 by the FAO consultation. Severity and prevalence were considered the primary criteria. As prevalence data was limited and showed geographic variation, the Consultation "agreed that the practical

approach should be to list those foods which are generally recognised by experts to be frequent causes of severe systemic reactions".

The Consultation further recommended that "food ingredients and additives derived from commonly allergenic foods should be listed on food labels with an indication of the original food source in addition to their regular name". Regarding composite ingredients, a reduction of the 25% rule was recommended, however, no new level was suggested due to lack of data. The Consultation felt that "the real protection to the consumer is the required listing of commonly allergenic foods and their products" (FAO, 1995).

It has been suggested that amendments to labelling requirements are of no use since they do not 'solve the problem'. In our opinion, it is important to realise that no single effort alone will be sufficient in itself and that full protection of the most sensitive consumers might be impossible to achieve. A set of the following measures is needed: information and education, product catalogues and databanks, improved production practices and control systems, etc. Labelling, however, is fundamental since this information follows each specific product. Although it is important not to impart a feeling of false security to the affected consumer, the situation can not be improved without adequate labelling. It is also an important prerequisite for secondary prevention.

7. Information by other means

Product information can be provided in other ways: databanks and product catalogues with detailed information on composition, lists of products not containing certain ingredients, information telephones, etc. Product information could also be made available in shops, through the use of catalogues, signs, notices, leaflets, etc.

Such measures are of great benefit to consumers and not the least to dieticians and other health personnel as an aid in dietary planning.

However, there will always be uncertainty as to whether the information is up-to-date. Product composition may be changed without corresponding updating of the information material. This is likely to be a problem, especially with imported products. The wide selection of products on the market further adds to the difficulty of ensuring that the information is always correct. Since reliance on wrong or incomplete information may have considerable adverse health implications, such disfunctional systems may, in fact, aggravate the situation for the consumers concerned. Information is unlikely to cover the whole range of products and it is unlikely to reach out to all consumers. Moreover, it is unlikely that the products included in the catalogues are constantly available to all consumers.

Data banks, product catalogues, etc., are useful supplements to information on the label and also make suitable foods more available, however, they cannot replace detailed labelling.

8. Contamination

During normal processing and distribution, products may be contaminated by substances carried over from previous productions, unintended additions, raw materials, dust, etc. The Swedish investigations, confirmed by many companies, shows that substantial amounts of allergenic 'contaminants' may be present. Such substances are not intended ingredients, thereby not considered covered by the labelling regulations and thus are not labelled. By applying the principles used in reducing microbiological risk to allergens, the problem can be significantly minimised. Producers should be informed of the potential severe and even fatal consequences of contamination with allergenic substances and provided guidance on how to use the internationally accepted system of critical control point analysis (HACCP) to allergenic ingredients.

Requirements for labelling are important in this respect. Producers will not be motivated to reduce the risk of contamination if the same allergenic substances are allowed as ingredients without being specified in the labelling.

9. Conclusion

Many measures are needed to improve the situation for the consumer suffering from food allergy/intolerance. However, it is difficult to see how the problems can be solved without appropriate labelling, which, in our opinion, is a necessary basis for many of the other measures. Detailed information following each product is essential. As an important side-effect, mandatory detailed labelling will increase knowledge, awareness and caution in food production.

Technical development, as well as the development of new products, increases the need for detailed information, as many products and ingredients are unknown to the consumer, and their presence in a particular product might be unexpected. Fat replacers based on egg and milk, hydrolysed fish protein as aroma in cakes, pea protein in sausages or soy protein in bread are just a few examples of untraditional uses of ingredients. Products sold under the same name might have different compositions.

World trade with food products will, on one hand, increase product diversity and, consequently, the need for sufficient information. On the other hand, regulations are harmonised on a global basis. According to the WTO agreement, products in accordance with Codex standards should be accepted in international trade.

Currently, there are many amendments and new aspects of labelling being discussed on a world basis. Irradiation, genetically modified food and country of origin are just a few. The arguments for more detailed information in these areas concern ethical, environmental and social issues. In this context, better labelling of foods, that are capable of causing serious illness or even fatalities in some consumers and reduced quality of life in many others, should be given high priority.

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