



Position Paper
European Federation of Allergy and Airways Diseases Patients'
Associations¹

Proposal for regulation of the European Parliament and of the
Council on the provision of food information to consumers
2008/0028 (COD)

For the attention of the European Parliament, Council, the Commission,
responsible authorities in the member states and European Food Safety
Authority EFSA

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The only way to manage a food allergy or intolerance is to avoid the allergen to which one reacts. Food Allergy is a Food Safety issue, and must be considered with other Food Safety risks (eg microbiological, physical and chemical). Food sold without accurate labeling and clear identification of all ingredients should be considered 'unsafe'.

¹ EFA represents through its' [member associations](#) the people with food allergy in Europe. EFA is a non-profit network of allergy, asthma and COPD patient organisations representing 32 member organizations in 20 countries, and over 400.000 patients. EFA aims to substantially reduce the frequency and severity of allergies, asthma and COPD, minimize their societal implications; improve health-related quality of life of patients; and ensure full citizenship of people with these conditions.

Food Allergies are a lifestyle burden for people concerned as well as for their families and people who share their food, as it requires extreme vigilance. Allergic reactions to food can be life threatening. Eating out in particular poses dangerous risks. Therefore the list of contents on all labels of food products purchased for consumption must always be carefully checked to avoid introducing an allergen in the diet of persons at risk from allergic reactions.

Background: the situation in Europe for people with food allergies

1-2% of adults and 5-8% of children live with IgE-mediated² food allergies.³ In addition, at least 1% of the population has celiac disease and up to 20% of the population has non-IgE-mediated food intolerances and need to avoid particular foods. The prevalence is an important gap in research.

The introduction of mandatory allergen labeling on pre-packed food has changed our lives. [The directive 2003/89/EC](#) was a step forward. The effect on public health has been immediate as can be seen in the statistics of anaphylactic shocks⁴ caused by « hidden allergens ». However feedback from EFA members and associated help-centers and fatal cases indicate that there are still problems to be addressed.

As a result, EFA very much welcomes this proposal but notes that some issues related to food allergies are not sufficiently taken into account. This paper presents the EFA position. The patient groups who gave input are listed at the end.

1. Quality of labeling for pre-packed food

Legibility of the label: Very often, the labeling is not easy to read. Nowadays, the letters of the ingredients list are often smaller than 1 mm ... while there is no newspapers or book using font size under 2 mm!

July 2008 : Dexter Skinner, 16 who suffered from a severe peanut allergy, died after biting into a chocolate bar. **Could you read this?**

September 2008: Deja Hay, a seven-year-old boy who is allergic to cow's milk died after drinking a carton of pineapple and coconut juice. Skimmed milk was listed among the ingredients, but he didn't expect

December 2007 : Stephanie Faulkner, 14, was out for a meal with her best friend but suffered a severe anaphylactic shock and died after she ate a chicken tikka masala at a Bangladeshi restaurant. The menu did not mention nuts.

EFA urges the European Parliament and the Council of the European Union to ensure that the 3mm font size and provisions on the contrast between writing and background as proposed by the Commission are kept.

"I take my glasses with me, because everything – all ingredients are written obviously in extremely tiny print, and my eyesight is such these days that I can't read it. "

A person with food allergy

Change in the recipe: There is nothing in the Commission proposal on warnings of introduction of one of the 14 mandatory allergens in a new recipe of an existing product. It is of particular concern since it has led to serious accidents as consumers do not expect danger coming from a product that has been eaten without problems in the past. In this case,

² IgE mediated means allergic

³ The prevalence, cost and basis of food allergy across Europe. ENC Mills, AR Mackie, P Burney, K Beyer, L Frewer, C Madsen, E Botjes, RWR Creve, R van Ree. Allergy 2007; 62: 717–722

⁴Anaphylactic shock is a life-threatening allergic reaction, i.e. to food.

mentioning the allergen in the ingredient is not sufficient. Best practice guidance suggests the use of a 'New Recipe' flash on the front of the packet. This could be a legal requirement.

EFA demands that changes in the recipe be clearly mentioned on the labeling by a “new recipe” statement or a notice “contains, in addition, the name of the allergens” on the main side of the package.

2. Labelling for non pre-packed food – 7 out of 10 severe reactions happen when people eat out

In most countries non-pre-packed food (sold in bakeries, butcher's shops, snack bars, restaurants and canteens) is not covered by regulation. There is no information available to protect people against an allergen they need to avoid.

Therefore we welcome new provisions included by the Commission concerning allergen information for non pre-packed food in its proposal, which acknowledge that 7 out of 10 severe allergic reactions happen when people eat out⁵. However there are shortcomings in this proposal concerning this issue.

The proposal states that information “should be provided” but doesn't indicate how. The Parliament Rapporteur Renate Sommer proposes that the information should be available by any means, not necessary a label.

EFA demands that the labeling of allergens or availability of this information one way or the other but preferably in written form wherever food is sold (catering, sold loose) be mandatory in non pre-packed food. It is essential to guarantee that people with food allergies have access to information that will protect them and may save their life.

3. “May contain” labeling - precautionary labeling (pre-packed or non-pre-packed!) - serious reactions, and even deaths, have been caused by foods with “may contain” labelling:

This type of labeling has been introduced by the food industry on a voluntary basis. Some allergens are part of the recipe while others may be present in the prepared food by cross contamination. As this term “may contain” is not legally defined, each producer has his own interpretation. Therefore the food allergic consumers are not able to judge if there is a risk involved, especially if they find this mentioned on labels for products that have previously been consumed without problems.

A recent study has shown that parents of allergic children perceive risk and react differently depending on the wording used to warn that the product may

80% of parents with food allergic children would not let their children eat a product where it reads:

- 'Not suitable for nut allergy sufferers' or
- 'May contain nuts'

Only 50% if it is mentioned:

- 'This product does not contain any nuts but it is made in a factory that uses nuts'
- 'Cannot guarantee nut free'
- 'May contain traces of nuts'

⁵http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/labelling_citizens_summary_310108_final_cab.pdf

contain allergen, despite the fact that there is may not be any difference between what is meant as they are not defined⁶. In other words, without a legal and common definition, people with food allergy are misled.

According to feedback from people with food allergy in Belgium and France to our member associations, they think that it is a legal requirement to use precautionary labeling.

Our associations are aware and have examples that serious reactions, and even deaths, have been caused by “may contain” labels. These labels indicate a doubt or give the option for the reader to opt for the doubt factor. Young people (in particular) are tempted to ignore these messages. In cases where there is in fact a real cross contamination of the product, this can lead to a severe reaction or death.

Parliament Rapporteur Renate Sommer proposes in her draft report on the current Commission proposal a solution to indicate the risk for cross contamination in non pre-packed food: a legal sign, indicating that *“information on the ingredients is available, but that cross contamination cannot be avoided”*, and we are concerned that this would remove the food supplier’s obligation to comply with the law to supply ‘safe food’ and to alert customers to any risks associated with the food on sale. It would not resolve the current ‘may contain’ labelling dilemmas faced by high risk consumers. This later warning would also delete the responsibility of the enterprise for good practice and in fact confirm by law the current wild practice on the use of “may contain”.

For cross contamination, and for may contain labelling, the Swiss legislation sets the following rule :

“Unintentional impurities” can only be declared with a level more than 1g/kg of allergen (for all mandatory allergens except cereals and sulphites which have different thresholds)

This declaration should only be authorized if the company can prove that cross contamination cannot be avoided despite the respect of all rules of good practice in manufacture.

http://www.admin.ch/ch/f/rs/c817_022_21.html (in de, fr or it)

“I’m always scared to ask. I feel I’m a nuisance. It’s a bit embarrassing.”
An English University student about restaurants and takeaways.

Swedish food sector guidelines 2005 give the following definition and guidance on the use of **precautionary labelling**:

“May contain” labelling should only be used as a last resort when the risk for contamination by each allergen in a specific production-line is:

1. **Uncontrollable**, i.e. the ability to ensure the entire process is considered impossible, e.g. due to manufacturing in part occurring in systems that cannot be cleaned with water.
2. **Sporadic**, e.g. if the allergen is detected sporadically after product changes.
3. **Documented** through cleaning controls, test results, or substantiated consumer reaction

EFA urges the European Commission to put in place a definition of “may contain” precautionary labelling for the European market, and ensure that it can not be used unless:

- All reasonable **precautions** have been taken in the production
- **Good practices** are in use
- The workers have received awareness and practical **workplace training** on food allergy, as they do for managing microbiological and other food safety risks

⁶ [Parents' attitudes when purchasing products for children with nut allergy: a UK perspective. Noimark L; Gardner J; Warner JO. Pediatr Allergy Immunol. 2009 Aug; 20\(5\):500-4. Epub 2009 Jun 17.](#)

On the long term, **precautionary labeling should be abolished and threshold levels need to be defined** in order to have the lowest risk possible for people living with food allergies. As it is impossible to have a zero risk, this could be '95%' of people who are most allergic do not react to this dose'. **When there is a realistic danger, and the allergen is always present in the product, it should be mentioned in the ingredients list.**

4. Establishment of a safety chain for people with food allergies – people with food allergy need to be vigilant but industry must do their part

In our developed society, we cannot accept that some people are faced with danger simply by eating everyday food. That is why each person working at every stage of the production, delivery, manufacture, sale and service of food should always be able to check the ingredients used, as well as any possible contaminants. Each "food business operator" must be aware of the risks involved by food allergy in the same way as they understand the risks involved in poor cleanliness.

The responsibility for providing information – the right for information: We agree with the principle that it is the food suppliers' responsibility to keep product information and be ready to inform their customers about allergens at each step in the distribution chain, as mentioned in the proposal. The labeling of and information on ingredients and possible allergen contaminants for non pre-packed food is essential information for people suffering from food allergies and intolerances. Some European countries have already made this information compulsory.

It's not our fault that the food industry is so complicated and even the simplest products have tens of ingredients. We have a right for information and to choose our food without risk of getting sick because of allergens.

The full ingredient list including the 14 main allergens should be collected and managed at each stage of the food preparation process, where a product or a package is changed, either by packaging or addition of an ingredient so that people know what they eat and can choose the right product without the ingredients that they are allergic to. This means the producer of the raw material, the wholesaler who sells it to the shop or the catering establishment, the place where it is prepared, sold or served to the consumer.

EFA demands that every food business operator must be required by law to provide a complete and accurate ingredients list to another food business operator customer (including catering establishments) at the time the food is delivered.

Any subsequent changes in specification must be communicated to the catering establishment or final retailer.

The Swedish Asthma and Allergy Association has a **programme called Great, an Allergic Customer! for restaurants and catering**. As part of the programme, they receive training to manage and declare allergens. When they fulfill the criteria for best practice they can receive a certificate for good practice and 'endorsement' from the Association that people with food allergy are welcome! For example the MacDonalds chain restaurants in Sweden are certified.

<http://www.astmaoallergiforbundet.se/>

"They don't know what's in it. A lot of them are youngsters. They are not taught about special diets as part of their catering course."

Parents of allergic child

It is the responsibility of each producer, wholesaler, retailer or caterer to check the accuracy of what he or she receives and what sells, in order to be able to give the information requested by people with food allergies. **Training is the key as it has been for the success of managing other food safety risks eg hygiene.**

The wholesaler needs to be involved too: All this should apply to the “convenience” or “ready-made” products and ingredients bought from a wholesaler such as spices mixtures, ready made bread mix, ready made cake or pastry mix...

At any given moment in the production/supply chain, if the producer or wholesaler decides to mix several different products in one package, for example sesame seeds rolls with plain unseeded rolls, it should be mandatory that a new label is developed and applied.

In case where the product delivered to the catering establishment is not exactly the one that has been ordered or usually bought, it should be clearly indicated (e.g. a danger signal if one of the 14 allergens is used).

In each of the above examples, our associations have been aware of serious and sometimes fatal reactions due to a lack of accuracy or information from the wholesaler.

The Swiss association for people with allergy aha! published a practical guide for managing allergens in food sold loose after a discussion with different stakeholders. It gives the following recommendations:

1. **Principles that food sector personnel should follow to give reliable information** to the customers with food allergy
- 2 **Good practices through best practise examples**
3. **Check-list of actions** to be taken by food professionals.

<http://www.ahaswiss.ch/>

“We go to a holiday resort. They’ll cook everything with separate utensils, and they’ll even change the menu to accommodate us. So when places like that will accommodate our allergies, we tend to go with what we know, because we know we’re going to be safe there.”
A person with food allergy.

Managing food allergens must become a key component of all Food Safety Manuals, Guides and Training. All wholesalers need to be aware of severe allergies and alerted to what is required by the new regulations.

EFA asks for the establishment of European guidelines/legislation on the training of personnel in the food sector on managing food allergens.

Read the attached testimony: the life of a patient with severe food allergy: Growing-up and living with severe food allergies – I don’t want to be special, I just want to be safe

This position was prepared with input from EFA food allergy working group of members: Erna Botjes, Dutch Food Allergy Association, Netherlands, <http://www.voedselallergie.nl/>
Betina Hjort, Astma-Allergiforbundet, Denmark, <http://www.astma-allergi.dk/>
Marianne Jarl, Swedish Asthma and Allergy Association, <http://www.astmaoallergiforbundet.se/>
Giorgio Salerni, FEDERASMA, Italy <http://www.federasma.org/>
Georg Shäppi, aha! Swiss center for allergy, skin and asthma, <http://www.ahaswiss.ch/>
Suzanne van Rokeghem, Prevention des Allergies, Belgium <http://www.oasis-allergies.org/>
and AFPRAL, France, <http://www.afpral.asso.fr/>
Emilia Vassilopoulou, ANIKSI, Greece, <http://www.allergyped.gr/>

and Bernd Arents, Dutch Association for People with Atopic Dermatitis
www.stichtingvoedselallergie.nl VCME
Hazel Gowland, Food adviser, Anaphylaxis Campaign UK
<http://www.anaphylaxis.org.uk>