

... Managing the risk posed by the unintended presence of allergens in food products ...

This paper, commissioned by the ILSI Europe Food Allergy Task Force and published in the peer-reviewed journal Food and Chemical Toxicology, discusses advances in the risk management of allergens which are unavoidably present in food products as a result of cross-contact. The latter may arise for a number of reasons, for instance the presence of residues in inaccessible shared equipment and airborne dust. The conclusion is that precautionary labelling based on quantitative action levels (i.e. maximum levels of unintended allergens above which precautionary labelling is deemed necessary) provides optimal protection for allergic consumers. This is the first paper of a three part series.

Food allergies are of global and growing importance to public health. They affect around 2-4% of the population. An allergy occurs when an allergen (a protein in a food, which in the majority of people will not produce an adverse reaction) sets off a chain of reproducible reactions involving the immune system. The symptoms vary from the very mild (e.g. hives, itching, dry mouth), to a serious, life-threatening reaction known as an anaphylaxis. There is no cure for food allergies; therefore, allergic consumers can only manage their condition by careful avoidance of the foods to which they are allergic. To do this effectively, allergic consumers are totally dependent on the availability, accuracy and quality of information provided on food products that they want to consume. Two types of labels are currently in use: Mandatory labelling and voluntary precautionary labelling.

Mandatory labelling

Under EU law, certain allergenic foods (celery, cereal containing gluten, crustaceans, egg, fish, lupin, milk, molluscs, mustard, peanut, sesame seed, soybean, sulphur dioxide/sulphites and tree nuts) must be declared on labels when they are used as an ingredient in pre-packed foodstuffs. Although many foods have the potential to induce an allergic response in sensitised individuals, these 14 foods/ingredients have been identified as highest priority in the EU.

Voluntary precautionary labelling

EU labelling legislation does not apply to allergens that are inadvertently present in foods (e.g. as a result of possible cross contact at some point in the food chain). Despite every effort taken by the food industry, it is virtually impossible to produce a zero risk product. Thus, to protect allergic consumers, food manufacturers voluntarily apply precautionary labelling such as “may contain...” or “prepared in a factory that uses...”. To date, there is no agreement on action levels (the concentration of an allergen in a product which would activate the need for a precautionary label). As a result precautionary labelling is applied when manufacturers determine that any risk may exist, however low or remote. As a result of widespread use, precautionary labelling is often ignored or mistrusted by allergic consumers, leading to risk-taking behaviour.

Despite these problems, it is recognised that if precautionary labels are consistent and based on sound science, they can be an effective means of informing consumers that an allergen may be inadvertently present in a food at a level which may pose a risk. While this was problematic in the past, growing amounts of data together with the development of risk assessment methodologies – in particular probabilistic modelling – now offers a potential solution.

In recent years, food challenge studies (these are studies conducted under medical supervision whereby the individual consumes a suspected food in gradually increasing amounts to see if allergic symptoms occur) have increased the availability of data on the minimum eliciting dose or MED. This is the lowest dose of a food allergen which initiates a reaction in an allergic individual. Although these data are collected at an individual level, data from numerous allergic consumers can be combined to estimate or model the distribution of MEDs in the allergic population. While the MED is a critical parameter in assessing the risk posed by the inadvertent presence of an allergen in a food, so is exposure to the allergen.

Exposure is related to both the level of allergen present in the food and the intake of the food (i.e. the amount consumed and the frequency of consumption). Across an entire population, considerable variability exists for each of these parameters. For example, there are natural differences between individuals with respect to MED, food intake, etc. An effective risk assessment must capture this variability by utilising all of the available data and it is now widely accepted that probabilistic modelling is the most appropriate approach. Probabilistic modelling enables calculation of the allergen management threshold, or reference dose which is the amount of allergenic food, in milligrams of protein, below which adverse reactions are unlikely. This can be translated into quantitative action levels, i.e. maximum levels of unintended allergens above which precautionary labelling is deemed necessary to protect consumers.

One of the biggest challenges is that the quantitative action level needs to be highly protective for the allergic population. For example, superficially it would appear that an action level based on a reference dose which protects 99% of the population is better than an action level based on a reference dose which protects 95% of the population. However, compliance with the former may not be economically or technologically feasible for the food industry and could result in an outcome which is completely opposite to that which is sought (i.e. an increase rather than a decrease in precautionary labelling). Therefore the choice of action level must also take into consideration the practicality of implementation by the food industry.

The authors conclude that precautionary labelling using quantitative action levels based on sound science will provide optimal protection to allergic consumers. This is now a realistic possibility considering the growing amount of data on minimum eliciting doses and the developments in risk assessment methodologies, in particular probabilistic modelling. However, adoption of any new precautionary labelling scheme requires agreement from all stakeholders. Furthermore, education of consumers and health professionals is paramount so that they understand the principles.

For further information please see:

Hattersley, S; Ward, R; Baka, A et al. (2014). Part I: Advances in the risk management of unintended presence of allergenic foods in manufactured food products – an overview. Food and Chemical Toxicology 67: 255-261

For a summary of the other papers in this series please see:

- 1. Managing the risk posed by the unintended presence of allergens in food products**
- 2. Development and evolution of risk assessment for food allergens**
- 3. Allergen management practices: Challenges for stakeholders**



Source: European Food Information Council