



Risk Assessment and Allergen Management

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Introduction

The issue of allergen management continues to present a big challenge for food producers, not least because allergen labelling regulations differ so widely around the world. The differences create uncertainty about how best to manage allergens, and may go some way to explaining the fact that allergen-related issues now account for approximately 50% of all recalls in the US and more than 60% in the UK.

It is clear that many food manufacturers require practical tools that will assist them in managing allergens, and in avoiding some of the labelling and packaging errors that lead to recalls.

One market, many standards

It is not always easy for food manufacturers to decide their own approach to allergens. Different customers and different markets will impose their own requirements, but whilst these requirements may differ, they are unlikely to be in conflict. Essentially, allergen management is about providing certainty that a product label accurately describes the food that is packaged inside.

There are several facets to providing this certainty. For example, one must understand how ingredients are produced and recognise the potential for contamination prior to receipt at one's own facility. One must control storage, handling and processing of these ingredients to avoid the risk of cross contamination within the production site. Finally one must be sure that packaging is designed properly so as not to present conflicting information, and that the right packaging is used for the right product.

Risk assessment

Risk assessment forms the basis of the best, most practical and most useful approach to allergen management, both from the perspective of handling/processing ingredients and of deciding appropriate labelling messages. Not surprisingly, risk assessment is required by all the international standards for food production that have been approved by the Global Food Safety Initiative.

The Health & Safety Executive defines risk assessment as the semi-quantitative – or in exceptional cases quantitative – estimation of whether a potential hazard is likely to occur in practice. It is normally expressed as a risk factor or score, arrived at by multiplying a score relating to the severity of the hazard by a score indicating the likelihood of the hazard occurring. So to cite some obvious examples, the risk score of being hit by a car is high if you are standing in the outside lane of the motorway, and low if you are standing on the beach. The risk score of stepping on a venomous stonefish might be high if on an Australian beach, and low on a British beach.

In the context of food allergens, a 'low' risk situation is considered as requiring no particular intervention, and certainly no advisory labelling that a product 'may contain' allergens. However, situations identified as medium or high risk should be investigated further and risk control/management procedures followed.



Although a pure HACCP approach has a role to play in allergen risk assessment, it is fair to say that it has largely proved to be an inadequate system for allergen management. The problem with HACCP is that it tends to treat all allergens as being equivalent. However, it is no more sensible to suggest equivalency between allergens as to suggest that a blow to the head with a cushion is equivalent to a blow to the head with a mallet. Even in the absence of established minimum limits, it is clear that some allergens are more hazardous than others.

A reliance on HACCP has also resulted in food manufacturers focusing on the management/prevention of inconsequential and unlikely (and hence low-risk) cross contamination incidents, whereas all the evidence suggests that the vast majority of recalls are from labelling and packaging errors. The most prevalent problem and the biggest danger to consumers is not that half a milligram of egg powder comes into contact with 100 litres of an egg free product. It is that the wrong product is put into the wrong box, or the wrong label is put on the right product. The big risk is not from cross contamination of ingredients per se, but of mislabelling/mispackaging.

This is not to say that cross contamination is irrelevant or trivial. However, once control measures have been put in place, (ingredient and equipment segregation, validated cleaning etc), then risk assessment linked to hazard characterization is the tool that will determine where the real vulnerabilities are and where most effort should be focused.

In Australia and New Zealand, the VITAL (Voluntary Incidental Trace Allergen Labelling) system is routinely used to determine whether advisory labelling ('may-contain') should be used on finished products. Three outcomes emerge from the risk assessment process requiring labels to bear no statements (Level 1 or green), precautionary 'may-contain' statements (Level 2 or yellow) and 'allergens-present' statements (Level 3 or red).

Risk assessment in practice

Clearly, the specifics of any risk assessment programme will vary according to the specifics of the food production facility. However, the basic principles are universally applicable. Not only does risk assessment linked to hazard characterisation provide documentary evidence in support of sensible labelling statements, but it is also the precursor to developing a consistent approach to allergen management and improving ingredient sourcing and handling right across a company.

The process begins with defining the scope the risk assessment, and documenting it so that it is clear which aspects of the operation have been considered.

The next step involves constructing a series of allergen maps, which will help in identifying the key areas in manufacturing where cross-contact between allergen containing and non-allergen containing ingredients and products can occur. All ingredients, materials, processes and flow of people should be considered in this step, as should the use of rework. Thereafter, it will be possible to highlight specific areas in the manufacturing process where cross contact with allergens could occur.

The next step is to evaluate the likelihood of cross-contact, and to assign it a numerical value for the purposes of calculation. This value will be somewhat arbitrary, but must be based on a sound appreciation of the probabilities. Clearly, at one moment in time, it might seem logical to suggest the probability is higher for two ingredients stored close together than two stored far apart. However, if they are stored in sealed containers, proximity of storage is not the issue. The issue maybe where ingredients are weighed, or how process equipment is shared or which staff are detailed to handle which ingredients. Allergen mapping will highlight the risky contact points, and also provide an opportunity to instigate new control measures, if needed.



Following probability assessment, a process of hazard evaluation then needs to be carried out. Again, the process of rating a hazard as high, medium or low is somewhat arbitrary, and not every food producer will have the allergens expertise to apply such a rating system with any confidence. Suffice to say it must be based not only on the particular ingredient in question, but also on a consideration of the particular circumstances in which it is used.

The hazard rating will permit the assessor to determine whether appropriate control measures, such as cleaning practices, are currently in place or need to be implemented. Here there is no need for arbitrary assessment. The effectiveness of control measures can be scientifically evaluated by a competent laboratory, with reliable analytical techniques available for detecting and quantifying allergens in finished product and on contact surfaces of equipment and utensils.

Even where the control measures can be shown to be effective, on-going verification will still be needed, perhaps via routine sampling and testing, or regular audit.

Daily monitoring of the effectiveness of control measures, using simple to apply, 'real-time' tests will help to ensure they are working well, and will enable corrective action to be taken in a timely manner. These checks might include visual inspections or other rapid assessment measures, such as laboratory testing.

The final stage of the risk assessment involves deciding if advisory labelling is needed. Rather than relying on often meaningless 'may contain' statements to act as a legal protection, it should be every manufacturer's ambition (some would argue responsibility) to provide a firmer assurance that allergens are not present in products, even in cases where allergens are processed on site.

A properly conducted risk assessment should provide ample evidence to permit manufacturers to label products with confidence, and not to resort to 'may contain' statements when they are clearly not needed.

Conclusion

There have been many examples of products appearing on supermarket shelves with confusing and conflicting messages about allergen content. Consumers are justifiably mystified when a product that already clearly contains ingredient X also carries a 'may contain X' statement, or when a product that clearly should not contain ingredient X 'cannot be guaranteed to be X-free'.

Clearly, the industry is in need of an improved approach to allergen management. Risk assessment, rather than hazard analysis, offers a better way of reaching judgements about how best to handle allergenic ingredients and how best to label products that are made in facilities where risks of cross contamination do exist, but can be shown to be minimal and under control.