White Paper

Quantitative Allergen Risk Assessment The Way Forward

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Introduction
Recent guidelines published by FoodDrinkEurope (FDE) acknowledge that allergen management continues to present a big challenge for food manufacturers, and endorse the ‘quantitative’ risk assessment approach to allergen management. But how does quantitative risk assessment help in practice, and how does it differ from/augment a purely HACCP-based approach to this crucial aspect of food safety?

Allergens in context
Allergen labelling regulations differ hugely around the world, and can present major problems for manufacturers. The fact that allergen-related issues – usually around mislabelling / mispackaging and inadequate training issues - now account for approximately 50% of all recalls in the US and more than 60% in the UK is an indication that some food manufacturers are still struggling to fully get to grips with the ‘allergen issues’.

It is clear that practical tools are needed that will assist manufacturers in managing allergens, and in avoiding some of the errors that lead to recalls.

Getting it right
Essentially, allergen management is about providing certainty that a product label accurately describes the food that is packaged inside. If that apparently simple requirement can be met at all times, then there ought to be no problems.

However, it is not so easy to meet this requirement in practice. For example, one must understand how ingredients are produced, and recognise the potential for cross-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 always used for the right product. Ultimately this links back to good knowledge of ingredients and process and the provision of adequate training for all staff involved with the manufacture of food.

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 risk assessment module of the FoodDrinkEurope Guidance, based on the RSSL risk assessment toolkit, is the latest industry advice to endorse this approach.

Pure risk assessment is defined 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 allergens tend to be categorised as chemical hazards and as such it tends to treat all allergens as being the same when clearly, they are not. Even in the absence of internationally agreed established minimum threshold limits, it is obvious that some allergens are more hazardous than others, either because statistically, they affect more people or because they elicit an allergic response at much lower levels.

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 arise from labelling and packaging errors. The most prevalent problem and hence the biggest danger to consumers is not that half a milligram of liquid egg 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 2 (Voluntary Incidental Trace Allergen Labelling) system is routinely used to determine whether advisory labelling (‘may-contain’ statements) should be used on finished products. Two outcomes emerge from the risk assessment process requiring labels to bear no statements, or precautionary ‘may-contain’ statements.

Risk assessment in practice
Clearly, the specifics of any risk assessment programme will vary according to the specifics of the food production facility. Understanding and applying the risk assessment criteria of the FoodDrinkEurope guidance may not always be straightforward. Not surprisingly, training is also strongly endorsed by the guidance, not just for those charged with carrying out the risk assessment but for all staff affected by it. Essentially, that means all employees involved with the manufacture of food, at any point of the process.

Practically based training, rather than classroom theory also makes a lot of sense. Walking through the factory, and teaching the principles of risk assessment in the context of what actually goes on, (rather than what the standard operating procedures, if correctly followed, suggest should be happening) is the best way to teach improved behaviours, as well as to correct obvious errors.

That said, it does not hurt to have some theoretical appreciation of the basic principles of risk assessment, and to recognise where it ‘fits’ alongside other potentially more familiar safety systems such as HACCP. It is also worth noting that risk assessment linked to hazard characterisation provides documentary evidence in support of sensible labelling statements, and 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 of 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. At this point, a producer will start to realise how much, or how little, they really know about their ingredients, how they are produced, and how they might affect the allergenic status of their own products.

Following this step, it will also be possible to highlight specific areas in the manufacturing process where cross-contact with allergens could occur, and to evaluate the likelihood of cross-contact. The aim here is to assign a numerical value to this likelihood 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, the proximity of storage is not the issue. More relevant will be a consideration of where ingredients are weighed, or how process equipment is shared or which members of 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 ingredient in question, but also on a consideration of the particular circumstances in which it is used. As an obvious example, one can easily appreciate that for an allergic consumer, undeclared whole pieces of almond used as a highly visible garnish on a
cake represent a different level of hazard from undeclared almond paste present in Marzipan used to decorate the cake.

The hazard rating will permit the assessor to determine whether appropriate control measures, such as cleaning practices (which will need to have been validated), 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 (usually proteins, sometimes DNA) 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 that have been properly validated, 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**
The FoodDrinkEurope guidance on allergen management is a useful addition to the food manufacturer's information resources, but simply reading the document won't get the job done! Nor indeed, will the checklists and procedural advice given within the document of themselves permit the inexperienced user to carry out a satisfactory risk assessment.

Training will still be required, and expert advice will still be needed in many situations, but the guidance should at least help manufacturers evaluate the quality of advice they are receiving.

It is clear that the food industry is in need of an improved approach to allergen management. A risk rather than hazard based approach, 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.