Food allergens – manufacturing issues

by Chris Hodge, Advanced Food Safety Ltd, Jubilee House, 5 Broad O'Th Lane, Shevington, Wigan, Lancashire WN6 8EA, UK.

It is now nearly two years since the introduction in November 2005 of the mandatory labelling of 12 specified food allergens. This was to meet the requirements of European Directive 2003/89/EC legislation which was nationally implemented via UK labelling regulations.

The requirement to label allergens was in response to the rising issue of food safety concerns from allergic consumers across Europe. The exact numbers of allergenic individuals in the UK is imprecise, due to a number of factors, including, a general lack of patient diagnosis to specific allergens by clinicians. However, as shown in Table 1 it is estimated that over 1.5 million of the UK population is affected in some way.

These statistics emphasise the responsibilities of food manufacturers in ensuring that all allergens present are accurately labelled, so as not to present a food safety risk to allergen intolerant individuals. It also emphasises the need to ensure the technical accuracy of any advisory 'may contain' statements, in order to maximise choice for those consumers with a specific allergenic condition.

Recent research by UK's Food Solutions Organisation, representing SMEs in the food and catering industry, showed that only 50% of the food businesses surveyed were aware of the allergen legal labelling requirements. This is especially concerning as on a European dimension the 12 million businesses represented in the SME category are said to handle or produce 80% of food consumed.

Product recalls

In the last two years there have been numerous product recalls due to foods being incorrectly labelled with allergen information. The number of recalls and products involved in 2007 is likely to be up on the numbers recorded in 2006. This is of great concern to the food regulators and consumers, who would be right to question the food industry's ability to effectively manage the food safety issues involved. Each recall is hugely disruptive to the company involved, which together with the associated costs and potential loss of Brand confidence could have a long term business impact.

Although recalls may occur as the result of an occasional deviation from the usual meticulous standards to which manufacturers operate, much is to be learned from the root cause analysis. The results of the analysis for the major recalls in 2006 are:

- 56% of recalls (10) – incorrect allergen labelling information.
- 28% of recalls (5) – allergen cross contamination in manufacturing processes.
- 16% of recalls (3) – wrong label or packaging applied.

Food manufacturers must therefore re-evaluate their strategies for effectively managing the processes involved to ensure the right label with the correct information is applied to the right product every time.

The first evaluation should involve allergen management awareness. This activity should involve the whole organisation to ensure any deficiencies in allergen management knowledge are identified and rectified via training.

Our warehouse man in the picture above typifies the extremes of allergen management awareness in the range of food handling facilities – from those facilities which are simply involved with ingredient storage and distribution for processing elsewhere to those facilities with on-site manufacturing processes.

Hopefully our warehouse man reflects confidence in the knowledge that the allergens on the pallet are totally under control. All subsequent processes as identified by risk assessment will be carefully managed including the appropriate segregation requirements.

The other extreme is the 'ignorance is bliss' scenario. The warehouse man has little or no knowledge of the potential food safety consequences which may arise from less than strict allergen control in usage. In this situation, there is generally a low awareness of allergen management techniques throughout the organisation, which can result in certain allergens being selectively managed for importance. In these circumstances risk assessment processes are usually lacking in identifying the end to end processes necessary to manage all the food safety issues involved.

Table 1. UK estimates of UK food allergy.

	Rounded numbers 2006
Total population:	**60 million**
Population below 15 yrs	12.1 million
Population above 15 yrs	47.9 million
2% adults allergic	0.96 million
5% children allergic	0.6 million

Total number of allergic individuals — 1.56 million. Based on National Statistics data.

Allergen risk assessment

Application of a thorough allergen risk assessment programme is key to successful allergen management activities. The process is HACCP based to identify all the allergens involved in your product recipes and potentially all sources of cross contamination throughout the supply chain.

Such studies will follow the usual principles of HACCP in utilising specialists within the team who have intimate knowledge of the production processes involved to identify all allergen hazard sources.

Allergens identified for management either as ingredients for labelling or potentially present as cross contaminants should then be managed via pre-requisite control programmes linked to the HACCP plan. Examples of such programmes are:

- The use of validated cleaning procedures to confirm cleaning efficiency without the need to test either final rinse water, for example, in CIP systems or 'start up' product after each change over cleaning cycle.
- Supplier control programmes (vendor questionnaire/supplier audit) to understand the likely level of cross contamination from these sources.

Such programmes remove the burden of managing allergen presence (or absence as appropriate), by the operation of CCP product test monitoring.

The need for expensive, repetitive and on occasions ineffectual product testing is, thereby, eliminated whilst the level of control is improved.

There will be occasions when

Continued on page 22

Continued from page 21
product end point testing will be required, however, such as the confirmation of any allergen claims such as, 'free from'.

Change control procedures

Drilling down into the individual details behind the product recall statistics, it is considered that approximately three quarters (72%) of the 2006 recalls could have been avoided by rigorous application of change control procedures.

Observation of quality system management activities at numerous food manufacturing sites of all sizes throughout Europe has identified that the operation of change control as a formal procedure is in the minority. The essentials of change control are simple to implement. The process should be applied whenever business activity changes from one state to another. Typical examples of state change are:

- Change of an ingredient supplier: need to be certain that ingredient attributes are 'like for like'.
- Change of product label information, such as, on the implementation of a new product.
- Change of manufacturing plant layout: that any new risks as a consequence are fully managed.

Each change should be managed by identifying the risks inherent in the change by formally risk assessing the processes involved. The degree of formality in performing the risk assessment will be dependent upon the nature and duration of the change. Short term or temporary changes, will be much less formally risk assessed than the activities required in assessing long term and permanent changes.

Control procedures will then be implemented to manage the aspects identified by risk assessment, documented and trained out to those involved. The process is concluded by formally reviewing the effectiveness of the implemented system to successfully manage the change.

Labelling guidance

Implementation of European Directive 2003/89/EC into UK national legislation made no requirement for 'may contain' allergen labelling.

Neither were threshold levels established in legislation to define at what level allergens must be labelled, except for sulphite at levels greater than 10ppm or 10mgm/litre as consumed.

This has resulted in numerous implementation issues for manufacturers in deciding whether 'may contain' labelling was appropriate for their recipes and ingredients.

We are aware that DG Sanco – (European Commission Health and Consumer Protection Directorate General) are currently reviewing the EU Labelling Directive 2000/13/EC.

As part of this review DG Sanco will be looking to see how or whether the labelling rules covering the incidental presence of allergens can be remedied.

The major issue is the lack of scientific and medical agreement globally on 'how much is too much' of a particular allergen for a susceptible individual.

Research has shown that the eliciting dose at which an allergen reaction may occur can range from less than one milligram to low milligram levels dependent upon such factors as:

- The patient's physiological condition (whether exercising or not).
- The fat content of the food matrix which can affect where allergen absorption can occur.
- Acidity of the food matrix in establishing accurate analytical data on allergen levels present.

Once agreement can be reached on the clinical levels at which a reaction occurs, there will need to be a 'society decision' in deciding what level of risk is acceptable for the European population as a whole when setting threshold levels by allergen.

In the meanwhile, FSA have done much to support the technical activities involved in the decision making process of whether or not to apply precautionary product labelling.

After consultation with a wide group of stakeholders including food manufacturers, retailers, health professionals, caterers and consumer support organisations, the FSA published the Orange guide: Guidance on allergen management and consumer information, July 2006.

As professional handlers of food we have responsibilities to allergen sufferers in providing allergen safe food – every time. n

FaxNOW +44 257 254 888
✉ info@food-safety.co.uk