1. DEVELOPMENT OF ALLERGEN MANAGEMENT THRESHOLDS

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1.1 Introduction

This paper will cover a number of areas including what the Food Standards Agency has been doing in the area of allergen management, the consequences of poor allergen management, trying to draw some lessons from the incidents that have happened in the last 12 months, and what the Agency is planning to do in terms of taking forward the problem of how we determine the management threshold levels. Definition of allergen management thresholds is what the food industry is waiting for in order to be able to inform their advisory labelling decisions. Analytical methods will also be mentioned briefly.

So, as we all probably know, there is EU legislation that requires the labelling of a number of specified allergenic foods when they are used as deliberate ingredients in pre-packed foods. And this requirement, apart from sulphites, is for labelling of the deliberate ingredients, whatever the level of use, so that even the very minor ingredient at a very low level has to be labelled if it is deliberately added. However, the legislation doesn’t cover the issue of allergen cross contamination, and so the situation could arise where there are higher levels of an allergen present as a result of cross contamination, which is not covered by the law and therefore may not be represented on the label of the food, whereas lower levels of an allergen which have been added deliberately as part of the product formulation do have to be labelled. In some countries the issue of cross contamination has been addressed, and if there is significant cross contamination with an allergen or allergens, then the allergens concerned can be included on the label as the last ingredient listing, but that is not permitted under EU Law. Ingredient labelling only includes an ingredient added deliberately as part of the product formulation, rather than if it is present as a cross contaminant.
1.2 Food Standards Agency Guidance Documents

The Food Standards Agency produced Best Practice Guidance on Allergen Management and Advisory Labelling in 2006 (1). This was produced once the legislation was in place covering the labelling of allergens as deliberate ingredients. The guidance was produced very much as a collaborative effort; the Food Standards Agency worked with a number of different stakeholders; the manufacturers, the retailers, the allergy support organisations, and also the enforcement bodies. This approach contributed to the success of the document because it covers a wide perspective, and is practical and helpful. The main Guidance document gives a decision tree approach to take people through allergen management. This publication is intended to help Trading Standards enforcement officers and the larger food businesses. A leaflet entitled ‘Allergy – what to consider when labelling food’ (2) was also produced for the smaller food businesses, which covered in outline form both the labelling requirements and the issue of allergen cross contamination. The guidance was disseminated through the stakeholders that were involved in drafting the document; so it went through the trade bodies to the industry, and through LACORS to the enforcement officers. In addition, the Agency has always provided training for enforcement officers, and so the guidance was promoted by that route to the enforcers because that was felt to be a good way to reach the smaller businesses.

This Guidance has been updated recently, because at the time it was produced, Lupin and Molluscs were not on the list of allergens that had to be labelled, and the update reflects these additions to the list of allergens for mandatory labelling.

The food industry asked the Food Standards Agency to help in the provision of clear guidance to be used across all food sectors, and this resulted in the production of these Guidance documents. The food industry was very aware of the risks from cross contamination with food allergens, and wanted to provide meaningful and helpful information to allergic consumers. At that time in 2005 there was no legislation or authoritative guidance on how to manage allergen cross contamination; the industry had different guidance documents, but there was nothing available in a cohesive form. Some guidance addressed one allergen, some addressed a few allergens. There was no consolidated picture. The food industry had no consistent approach to managing allergens, and no guidance when making decisions on when to put allergen advisory labelling on pack. Another issue relates to appropriate analytical methods for detecting and measuring the presence of allergens; if the presence of allergens in foods is going to be controlled, there need to be the analytical methods available to measure them. Analytical methods will be discussed at the end of this paper.
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1.3 Warning Labelling

The Food Standards Agency was receiving a lot of information from consumers who were very confused by the advisory labelling that they were seeing on products. The different words and phrases that appear on different products were found to be confusing. Consumers also over-interpret the messages given; if labelling information is used that says there is a risk of cross contamination because nuts are also handled in the factory, the consumers will try to determine a level of risk that they think that phrase conveys. If consumers see a statement on pack that says ‘made on the same production equipment’, they also think that’s a risk, and they will try and assign a level of risk to that. It’s very clear that the labelling describes how the risk arises. However, the wording used doesn’t really say anything to quantify the level of risk, but consumers judge the risk based on their own interpretation of the wording, and so they’re making decisions based on the different phrases that are being used. There’s also consumer concern that the labels covering the possible presence of allergens in foods are over-used, and obviously they restrict choice if consumers avoid all foods carrying warning labels. What we tend to see, particularly in teenagers, which is a group that the FSA have studied, is that they think the warning is used in order to protect the food business, and is not there to protect the consumer, and the warning is ignored because the impression is that the warnings don’t mean anything. And so this leads to risk taking behaviours amongst this particular population group.

The FSA Guidance document encourages manufacturers and retailers to think about the risks of allergen cross contamination, where they might occur at any point along the food chain, whether they can be reduced or eliminated, and whether they can be managed down to a level where the risk is remote. This is encouraging the food industry to assess their production facilities and product specifications for risk, to see if they can manage that risk, and then only if that cross contamination can not be controlled down to a minimal level, to communicate that risk to the consumers. The correct procedure should be to go through the risk assessment and the allergen management stages first, and only then if there is still a risk of cross contamination with an allergen, that risk should be communicated to the consumers by means of warning labelling.

1.4 Allergen Management Thresholds

While the Guidance gives advice on best practice in allergen management and the appropriate use of warning labelling, what it doesn’t do is quantify the amounts of allergens on which to base risk assessments. At the time that the Guidance was produced in 2006, it was hoped that figures could be given for the amounts of allergens required to trigger an allergic reaction, or at least an indication of management threshold levels for allergens could be included, but when the information available on allergen thresholds in the literature was studied in more detail, the science really wasn’t available at that time to be able to set management
levels in food to inform labelling decisions. This was partly because a lot of the information that had been published on clinical thresholds in individual patients was being produced by studies with different study designs, and with different criteria, and so it was very difficult to pull all the literature together and come to a definitive level for thresholds for the various allergens. There are now a lot of allergen challenge studies being conducted using very standard protocols and standard materials, and so we are a step or two closer to consensus on what clinical thresholds are. The next step is to translate this information from the clinical thresholds in people, through to management levels in food.

The lack of detection methods for some of the allergens is also an important issue in the allergen management area, and a key point is, that although there are detection kits available for a lot of the allergens, there are no standard reference materials. Many of the detection kits and the methods that they use are not independently validated, and this is a vital issue that needs to be addressed.

The Food Standards Agency does intend to revise its Guidance to provide quantitative information on allergen thresholds. While it would be preferable to be working on this in the next few years, it is becoming apparent that this may take longer than that for all the major food allergens.

1.5 Allergen-related Food Incidents

Allergen-related food incidents occur when allergen management goes wrong. The next section will cover what some of the common causes of allergen-related food incidents are, and the sorts of actions that businesses can take.

Looking back historically, the main cause of food allergy incidents, certainly in 2007, and perhaps at the beginning of 2008, was the wrong product being put in the wrong packet. So in situations where 2, 3, or 4 different varieties of something are being made, the packaging may not have been changed over for a new product run from the previous one, and at least at the beginning of the product run the wrong product is then in the packet, so the allergy information is completely wrong and the product needs to be withdrawn. Looking through the data for 2008 and 2009, although we did still see a significant number of cases where the product was in the wrong packet, I think this scenario is becoming less common, so businesses are getting their procedures right and getting the checks in place. There are still some incidents where there is inconsistent labelling; an allergen might be listed in the ingredients list, and while some allergens are declared in an allergy statement or box, in some cases not all of the allergens present are included in the box. This is a risk for the allergic consumer, because despite consumer education to always read the ingredients list, a lot of people use the allergy statement on products as a shortcut, and so if an allergen is missed off that statement then there’s a risk because the consumer will think that product is safe for them. There have been some cases in which multipacks have allergy labelling...
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on the outer packaging that is not consistent with the labelling on the individual products inside, and so again the consumer may just read what’s on the outside, which may be right or wrong.

Looking back, most of the incidents concern deliberate ingredients and incorrect labelling, but what we are beginning to see, certainly over the last year, is more incidents related to detection of significant levels of cross contamination and this probably reflects the impact of the mandatory allergen labelling legislation that has been in place since the end of 2005. Local authorities are now doing much more sampling to check product labelling, and so they are detecting allergens in products in which the allergen is not included on the label; it’s not a deliberate ingredient, but there are significant levels of cross contamination. A recent trend is with products that are described as ‘free from’ particular allergens where the allergen that the ‘free from’ statement relates to, can still be detected in the food. This is a particularly important issue, because obviously the allergic consumer has a high level of trust in ‘free from’ products to be suitable for them based on their particular allergy.

The FSA issued over 60 food allergy alerts in 2008, and to the middle of May 2009, there have already been 25 alerts, which is a similar level to 2008. The most common allergens involved were milk, soya, sulphites, wheat and gluten, and nuts. There were quite a lot of incidents in the last year where there were significant levels of milk cross contamination in plain chocolate products; at least half of the milk-related incidents involved milk in plain chocolate. Another trend emerging recently is in products containing dried fruit ingredients, particularly apricots, where the sulphite information is not being carried through from the ingredient through to the meal, the jam or the products that contain the apricots.

It can’t be stressed enough that one of the key things to get right is to make sure that the right packaging is used for the right product. There have been incidences where the packaging either remains in the line at the end of the run and is transferred to the beginning of the next run, or perhaps the remaining packaging is put back in the packaging store, but it’s not put back in the right place, so this is a very common cause of incidents. It may not be the whole batch of product that is affected by the wrong packaging, it may only be a very small number of units at the beginning of the batch that are in the wrong packet, but generally it is impossible to be sure how many individual products are affected, so the whole batch has to be withdrawn. In the case of the apricots and the sulphites, it is obviously key to get accurate information from suppliers about what allergens are in the ingredients that are being brought in to the factory, and to make sure that that information is carried through to the final product. Obviously, there should be careful consideration of where cross contamination can happen, and systems put in place to reduce this risk. Businesses that are not sure about whether their allergen management practices are sufficient, should ask for advice from their local authority. The FSA have done a lot of training for the local authority...
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enforcement officers to help them understand allergen management practices. Enforcement officers can look at individual businesses and best advise them as to how they can manage allergens in their factory. Staff training is also a key issue; it may be that the person running the line knows what they’re doing, but if that person is off sick and somebody else comes in, they may not know that line or that practice, it is key that all staff are properly trained.

The FSA has trained enforcement officers in allergen management for a number of years, and last year launched an on-line training module on allergen management, which is freely available to anybody on the Agency’s website (3). Whilst this training was originally aimed at enforcement officers, it is something that, because it’s freely available, is a resource that is very valuable for small businesses as it can be used from the business in a short space of time. The training is interactive, and covers the factory setting, and aspects such as packaging or cleaning.

1.6 The Future

A significant issue that the Agency is working on to take this area forward, is to consider how we might be able to set the allergen management thresholds, or action levels for allergens, that are going to lead to more consistency in the advisory labelling decisions. The other area to be addressed is validating the analytical methods that would be needed to be able to make the threshold information work.

The issues currently are: a proliferation of ‘may contain’ advisory labels; uncertainty from the food industry and consumers; and a lack of legislation to address allergen cross contamination. A ‘risk based’ approach to controlling allergens and making decisions on the advisory labelling is needed.

From the business and the consumer perspective, the key question here is how to determine the management threshold levels for use by the industry to underpin the labelling decisions - how do we move from threshold data in individual people (taking into account the question of how representative those data might be) to levels in food that are going to be protective for the allergic population. The limit of detection could be applied, and in many cases that might provide sufficient protection, but the limit of detection is going to fall as test kit methodology improves, and is not actually related to the level of risk, so whilst it could be used, it isn’t a real scientifically based measurement to use in terms of risk to the consumer. If there aren’t quantitative management thresholds, there will inevitably be warning labelling on foods where they are perhaps not necessary, which will lead to restriction in choice for the consumer.

From the point of view of a regulator, it would be very helpful to have some threshold levels. The legislation might need to be reviewed, because if there are
very low levels of an ingredient present that has been added deliberately, that ingredient may actually not pose a risk to the allergic consumer at that level, but it is currently being declared, and so is restricting choice unnecessarily for consumers. The key thing at the moment is dealing with the food incidents involving detected levels of cross contamination. Judgements have to be made on when that level of contamination is sufficiently high that it is a risk to the allergic population, and without agreed quantitative thresholds, to some extent, that has to be a subjective judgement by the regulators, and obviously having threshold figures to work with would be an enormous help. More products are being claimed to be free from particular allergens, and at the moment that applies if the particular allergen can’t be detected. It would be helpful to have a quantitative measure for allergens that can be applied for foods that want to make those specific claims.

The goals of the FSA are to define levels for the main allergenic foods, below which their accidental presence in the food is deemed not to pose a significant risk at the public health level, and therefore doesn’t need to be labelled. Significant risk also needs to be quantified at a public health level. If this can be achieved, then it should lead to consistency among the different retailers and manufacturers over their decisions on when warning statements are used on foods, and this will then increase confidence for the allergic consumer, who will know what the labels mean, what that means in terms of risk for them, and it will help them choose foods more safely.

Working towards achieving these goals, in 2007 the FSA brought together international stakeholders; regulators as well as clinicians and patient groups and food industry from Europe, from America, Canada, Australia and New Zealand to try and look at whether there are methodologies available already that we can use in allergen risk assessment. There are lots of mathematical models that are used in risk assessment for chemicals in food and those methodologies were examined to establish whether they could work and be applied to food allergens. The methodologies were discussed at the workshop, together with their advantages and disadvantages and how such approaches might be taken forward. Information gaps and the research that is needed to take this issue forward were discussed, and this is summarised in a paper that was published at the beginning of 2009, which covers the presentations and the discussion at that workshop (4).

In May 2009 a follow up workshop was held, which centred on defining a tolerable level of risk. Mathematical models can be used to do the risk assessment, but there are obviously some uncertainties in those data, and the safety factors that need to put in to these models to give a level of risk that is tolerable at a population level need to be determined.

Some of the information gaps that were identified established that there isn’t a clear picture of the exposure risks for allergic consumers, for example in the UK we have very good information from the national diet and nutrition studies about
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what non-allergic consumers are eating; the different types of foods, and how much of those foods. It is not known whether those intake data are applicable to the allergic consumer, who may have very different patterns of consumption depending on what allergens they are sensitive to. It is becoming clear from some of the modelling, that the likelihood of an allergic individual eating a type of food, rather than how much of the allergen is present in the food is perhaps one of the key determinants of whether there is a risk of someone having an allergic reaction. So for example, if milk allergic people don’t eat plain chocolate, then the milk contamination in the chocolate is not a risk because it’s not being consumed.

Understanding what governs the choices of allergic consumers and trying to get a better idea of what foods they are actually eating is key. Another factor that needs to be included in the modelling is the variability between different individuals. We know that there is a lot of variability between people in terms of their sensitivity, but also in the same individual there can be a quite significant degree of variation in the sensitivity to an allergen on different occasions. There are a number of external factors that can affect the severity of a reaction, for example if someone has exercised and consumes the allergen to which they are sensitive, they may have a more severe reaction. If they are asthmatic, and their asthma is poorly controlled, their reaction may be more severe on those occasions. Research is needed to try and understand the safety factors that we need to put into the models to allow for this variation, both between people, and within people on different occasions.

The aim of setting the tolerable level of risk for allergens is actually to improve the quality of life for the allergic consumer, because it’s clear from a lot of consumer research that it is the fear of having a reaction that is having the most significant effect on the quality of life of the allergic consumer. So if they can have more confidence in the labelling on the foods they are choosing, then this will have a significant impact on their quality of life.

In translating the clinical thresholds for allergens in a few individuals to the management levels for allergens in food, one of the issues to be considered is whether those people that are challenged are really representative of the consumers allergic to that particular food. It might be that the most sensitive people decide that they don’t want to be challenged so are excluded, but it could be that the more sensitive people are those that go to the clinics, and they are the subjects chosen for challenges, inferring that a lot of the less sensitive people never get to those clinics, making it difficult to know where the people being challenged actually sit in the spectrum of sensitivity. Therefore, the safety factors that should be applied must be carefully considered.

At the workshop held in May 2009, different stakeholders including consumer organisations, clinicians, as well as industry and regulators met to try and come to a consensus on what is a tolerable level of risk from all their different perspectives, and to think about the individual consumer, as well as at the public
health level. The fundamental question ‘what are we protecting against’ needs to be answered; obviously, management thresholds should aim to protect against severe anaphylactic reactions, but should they also be set at levels to prevent all the mild subjective reactions, such as a small amount of rash or lip tingling? Is it actually feasible to try and protect everybody against all the mild symptoms? Ideally management thresholds would be set at levels that would protect everyone with food allergy, but what proportion of the population is it feasible to protect? There was consensus at the 2009 workshop that zero risk does not exist; a minimal level of risk that is going to be tolerable to people should be the goal of this work.

1.7 Analysing for Allergens

When food incidents related to food allergens are reported, there are occasionally discrepancies between the analytical results for the allergen between what the food business has detected, and the results of testing by the enforcement authority. It may be that different kits are measuring different allergens, or that different kits work better in some food matrices than others. There are certainly issues surrounding the reproducibility of the analytical methods. Very frequently results are reported to the FSA from public analysts and local authorities as ‘the allergen is present’ or the ‘the allergen is there above 25 ppm’, rather than giving a quantitative result above 25 ppm. Some of the allergen test kits are quantifiable within certain ranges, and above that range the result is reported as above, making it impossible to know whether ‘above 25’ means 27 or 250 or more, and so the level of risk is very difficult to judge. Work needs to be done in improving the quantification of analytical methods and to develop robust analytical methods that are sensitive and specific for all the major food allergens. Ideally these methods would also be rapid, and suitable for use by the food industry in their processing and checking. The methods need to be validated using standard reference materials, which are recognised internationally and currently these do not exist. So there is another whole programme of work in this area that still needs to be taken forward.

1.8 References


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