MNF Interview

with Claudia Hischenhuber,
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Allergen Management in the Food Industry – Potential and Limitations

Dr. Claudia Hischenhuber is Quality Advisor for Allergen Management in the Corporate Quality Management Department of Nestlé located in Vevey in Switzerland.

MNF:
The EU has recently amended its Labelling Directive 2000/13/EC by means of Directive 2003/89/EC. What are the key changes resulting from this amendment?

Hischenhuber:
Food allergy is now generally recognised as a significant public health problem. In order to be able to avoid the specific food allergen affecting him/her, the allergic consumer needs sufficient and correct information regarding the nature and composition of each product. Although almost any food has the potential to induce an allergic response in sensitive persons, there is scientific consensus that only a relatively small number of common foodstuffs account for the vast majority of severe allergic reactions. To ensure that the most important allergenic ingredients are always correctly labelled, it had been decided to make an amendment of the EU Labelling Directive. A list of common food allergens has been drawn up that encompasses those major allergenic foods as defined by Codex Alimentarius (Foods that might cause hypersensitivity) and three other food items recognised as important for the EU countries. These food items and – in principle – all products derived from these foods ("products thereof") have to be labelled even if they are present in a sub-ingredient in a very small amount. This allergen list is tabled in Annex IIIA of the Directive and includes: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts (*i.e.*, almonds, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut, and Macadamia nut or Queensland nut), celery, mustard, sesame, as well as sulphites at concentrations of at least 10 mg/kg or 10 mg/litre, expressed as SO_2. However, the new Directive does not address labelling of allergen cross-contact.

> *"As a general policy, we do not introduce an additional allergen in a factory if the allergenic ingredient does not give a well justified added value to the product"*

One of the most significant changes resulting from the amendment is the abolition of the so-called 25% rule, *i.e.*, it was not mandatory to label all the constituent parts of an ingredient that contributes less than 25% of the finished product. For example, up to now, a soya protein-containing sausage on a pizza could be labelled "sausage" without mentioning the allergenic ingredient. Generic terms such as "flavouring" are no longer allowed either, if a component of the flavour is derived from a major allergenic food. In addition, ingredients should have a clear reference to the respective allergen in their name (*e.g.,* lysozyme from egg). As these measures are clearly intended to provide better protection of the food allergic consumers, there is a question mark as to whether all "products thereof" are still able to induce allergic reactions, *e.g.*, highly refined soya oil, glucose syrup or glucose derived from wheat. In order to avoid confusion among the consumers as to which ingredients are safe for them, scientific dossiers could be submitted until the end of August in order to prove that they are unlikely to trigger allergic or other hypersensitivity reactions. Unfortunately, the issue of "products thereof" is very complex and it is not completely clear yet whether certain highly purified ingredients will have to be labelled as being derived from an allergen and whether such labelling will help the allergic consumer in making his food choice.

MNF:
Which of the allergenic foods listed in Annex IIIA are used in Nestlé factories?

Hischenhuber:
While my answer to the first question was rather long, I could now reply in one word: All. But, if you do not mind, I would like to add a short comment: The issues linked to the use of one or the other major allergenic food ingredient in our factories vary between product types. As a general policy, we do not introduce an additional allergen in a factory if the allergenic ingredient does not give a well justified added value to the product or if the product cannot be easily produced on another site already processing this allergen. To give some examples: we process peanut-containing products only in selected factories; in Europe we source whole hazelnuts from suppliers who have no peanut cross-contact risk in their factory and supply chain; and we eliminated soya-containing flavours in meat products and replaced them by other spices and flavouring agents without soya.

MNF:
What are the key elements of Nestlé's Allergen Management Policy?

Hischenhuber:
To ensure that a wide variety of foods are available for consumers with food allergies, the following policy applies to the manufacture and labelling of Nestlé food products: It is our responsibility to help consumers with food allergies avoid inadvertent ingestion of ingredients in Nestlé food products that can trigger an allergic reaction.In all cases, any major allergenic ingredient (as defined by Codex Alimentarius or the

respective local legislation) that is added to a food product must be declared on the product label. GMP (Good Manufacturing Practices) and HACCP (Hazard Analysis and Critical Control Points) should be applied, in so far as possible, to avoid cross-contact between products that do not contain a specific major allergen with those containing it. Furthermore, it is part of our supplier approval process to ensure that we receive the correct ingredient information from the supplier and that potential allergen cross-contact risks have been evaluated on the supplier's site.Where the HACCP and GMP approach cannot ensure the absence of any of the major allergens, they must be labeled in an appropriate way, such as "may contain traces of milk" or: "traces: egg, celery".

MNF:
How much is too much? Or in other words, have you defined any criteria for applying precautionary labelling (warning labels)?

Hischenhuber:
Yes, we have defined several criteria. I think it is not a scoop if I tell you that there are criteria which are quite easy to define, but it is still a major headache to define the threshold below which we can avoid labelling of potential protein traces! Generally speaking, if the HACCP study indicates a significant allergen hazard which cannot be controlled by segregation of processing lines or by cleaning, the control measure is precautionary labelling. One clear criterion for precautionary labelling is the potential presence of heterogeneously distributed allergenic material in the product. As an example: if a supplier of chopped almonds processes chopped hazelnuts on the same line and despite thorough cleaning procedures, it cannot be excluded that occasionally a hazelnut piece remains in the production line, then we know that there is a risk of finding a small piece of hazelnut in a product containing almond pieces. Although the likelihood is rather small, we cannot exclude that a person tolerating almonds but allergic to other nuts could eat the product with the hazelnut. Consequently, we will label that product to say that it may contain traces of other nuts. It is also important to highlight that in the case of heterogeneous distribution of the "contaminating" allergen, it is not useful to perform analytical tests of the product. We might not find any hazelnut traces in 50 samples and the 51st one will contain the small hazelnut piece which might trigger a serious reaction in a sensitive consumer.


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Another criterion is: effective cleaning of a shared line is not feasible. A typical example is the production of chocolate. Understandably, the consumers want to enjoy a wide variety of chocolates at an affordable price. For this reason, different types of chocolate mass have to go through pieces of equipment which are shared for different products. However, the chocolate mass cannot be cleaned out to an extent that all allergenic material would be taken away. Wet cleaning of such equipment would even jeopardize the microbiological food safety. For this reason, after changeover from one allergen-containing product to another, part of the new production batch can contain allergen traces of the previous product (*e.g.*, when changing from milk chocolate to dark chocolate, the dark chocolate may contain milk traces which are labelled accordingly).

As said in the beginning, there is still some way to go before a general consensus is reached on which are the minimum eliciting doses ("thresholds") for the major allergenic foods and on defining "how much is not too much" for the vast majority of the allergic patients, *i.e.*, which amount of allergen will certainly not trigger a serious reaction and will also most likely not trigger any reaction. Results of Double Blind Placebo Controlled Food Challenges combined with probabilistic risk assessment modelling approaches should help us to get better answers to these questions in the near future.

MNF:
To which extent do you use these precautionary labels such as "may contain traces ..."

Hischenhuber:
We are clearly committed to minimizing precautionary labelling and we do not replace GMP just by putting on the package a warning label! If we are building a new factory or if we are adjusting product portfolios of existing factories, we consider segregating products containing different major allergens as much as possible. We can also avoid precautionary labelling in certain cases through clever production scheduling, *e.g.* we manufacture the product containing a specific major allergen at the end of the week. After this production, a complete and especially effective, but very time-consuming cleaning of the whole installation is performed and the line is released for the new production after thorough visual inspection. Cleaning effectiveness has been validated beforehand and is monitored in regular intervals by analytical tests.

We have no corporate policy as to which wording should be applied to inform the consumer of potential traces; this is because consumer perception is quite different depending on the country and the culture. The essential point is that the label is easy to understand and that the allergic consumer is warned!

MNF:
Finally, a very general question: do you think that allergen risks are manageable?

Hischenhuber:
I am optimistic and I say, yes they are; but food industry and ultimately the consumer will benefit from more elaborated allergen risk assessment tools which support risk management decisions. The recent 3rd Threshold Conference in Mallorca, organized by FARRP (Food Allergy Research and Resource Program) and ILSI (International Life Science Institute) Europe, was another step forward towards achieving consensus on NOAELs (no observed adverse effect levels) for the major food allergens, those levels which should be safe for the vast majority of allergic consumers.

MNF:
Dr. Hischenhuber, thank you very much for this interview.

Interview by Stefan Vieths

