SciCom

Scientific Committee of the FASFC

Advice 04-2018 on the FASFC analysis program with regard to food allergens

Background & Terms of reference

The control plan of the FASFC is based on analyses (sampling) and inspections, which are programmed according to a risk-based methodology developed within the agency. The analyses program is submitted periodically to the Scientific Committee for evaluation. This opinion concerns specifically the evaluation of the section "allergens" of the analysis program. More specifically, the Committee has been asked:

1. to evaluate possible trends based on analytical results obtained between 2012 and 2015,
2. to comment on (a) the pertinence of the choices and the application of the statistical approach, and (b) the relevance of the choices of the parameter/matrix combinations and the selected sampling sites, and
3. to clarify the modalities for establishing a multiannual vigilance program for sampling aimed at (a) the detection of allergens on the one hand and (b) the estimation of the prevalence of allergens, on the other hand.

Methodology

This opinion is mainly based on expert opinion and study of the control and inspection results of the FASFC.

Conclusions & Recommendations

Most samples analysed between 2012 and 2015 are compliant for the presence of allergens. Given that for the majority of samples a result below the quantification or the detection limit is given, no trends can be derived. However, it is not always clear whether the reported value relates to the detection or the quantification limit (i.e. “LOD” and “LOQ” respectively), and whether the units given in the database relate to the allergenic ingredient (e.g. milk), the total protein content of the allergenic ingredient, a specific protein (e.g. β-lactoglobulin) or DNA. In view of a possible, more profound treatment or interpretation of the analytical results, it is recommended to agree with the laboratories on a consistent and unequivocal reporting of the results, and to look, where appropriate, for standard conversion factors (e.g. conversion from the analytical result to total protein quantity of the allergenic ingredient). In order to be able to compare results with the allergenic reference doses applied by policy, results should be available in terms of protein concentration of the allergen in question (SciCom advice 24-2017).

The approach applied for programming the analyses of hazards in the food chain and as such of allergens, is based on three criteria; (i) the harmful effect, i.e. the severity of the allergic reaction of the allergens to be controlled, (ii) the occurrence of the allergens in the group of products to be controlled, and (iii) the contribution of this group of products to be controlled to the total contamination of the food chain. The main remark regarding the current implementation of this approach for the analysis program with regard to allergens concerns the fact that unlike most other parameters to be monitored and included in the analysis program of the FASFC, allergens are considered as one group and not as separate parameters.

Furthermore, the Committee recommends to consider the incidence of the allergic reaction (i.e. the number of cases of, for instance, anaphylaxis in a population for a certain period), the prevalence of the food allergy (i.e. the number of allergic persons in a population for a certain period) and the allergic potential (i.e. based on the minimum amount of the allergen that causes an allergic reaction, or on the eliciting dose) in addition to the severity of the allergenic reaction when attributing a quotation to the 1st criterion of the statistical approach, the harmful effect (SciCom advice 18-2013). The Committee follows the argumentation for the scores attributed to the 2nd and 3rd criterion, i.e. the presence of allergens in the group of products to be controlled and the contribution of the group of products to be controlled to the total contamination in the food chain. However, these scores need to be adjusted if, for the application of the statistical approach, the allergens are no longer considered as one group but as separate parameters and the population of products to be sampled is divided into standard food products and products that are more specific for an allergic consumer (cf. "free of ..." labels or precautionary labelling).

The choice of matrix/allergen combinations to be sampled is complicated by the fact that allergens differ from "classic" contaminants. Allergens are for most consumers standard ingredients of a food and the possible health effect after ingestion of an allergen varies widely among food allergic consumers.
Given the relatively small number of programmed analyses versus the wide range of foods potentially to be sampled, the control efforts through analyses should be as effective as possible.
In addition to sampling products composed of many (compound) ingredients, it could be useful to program some of the samples for products susceptible to fraud (e.g. the use of peanuts instead of more expensive nuts) or for products that -according to the label- should be free of certain allergens and/or intolerance-causing ingredients.
With a view to a more targeted sampling or a further refinement of the analysis program, the Committee recommends a greater coordination between the analysis program and inspection activities. Based on the inspection program, possible gaps in the analysis program should be identified (i.e. better identification of products more at risk) so that the analysis program can be further adjusted with regard to allergen-matrix combinations to be considered. Based on the inspection program, possible gaps in the analysis program can be identified (i.e. better identification of products more at risk) so that the analysis program can be further adjusted with regard to allergen-matrix combinations to be considered.

Because the product matrix can strongly affect the analytical result of an allergen, it is recommended to consider only those allergen/matrix combinations for which a reliable (preferentially a validated) analytical method is available. It is therefore recommended to increase the number of validated analytical methods for relevant allergen / matrix combinations.

If a multi-annual vigilance program is considered for allergen control, this program should be aimed at allergen detection and not allergen prevalence estimation. In addition to a rather rigid multi-annual analysis program, there must however, remain sufficient room for flexibility. This not only to be able to adjust allergen-matrix combinations included in the analysis program (e.g. based on indications obtained during inspections), but also in view of developments in the field of allergen analysis.

Finally, the Committee notes that potential risks of the presence of traces of allergens have led to a certain amount of unnecessary "precautionary labeling", which greatly reduces the freedom of choice of the sensitive consumer. The use of such precautionary labeling should be minimized by a proactive allergen management of operators. In addition, the use of precautionary labeling must always be argued by the operator on the basis of a risk assessment.

The full text is available on this website in dutch and in french.