

Opinion 04-2022 of the Scientific Committee established at the FASFC on the re-evaluation of the ratings attributed to the severity of the adverse effects of hazards within the framework of the FASFC analysis programme - residues of plant protection products, exogenous chemical contaminants and allergens

Background & Terms of reference

The Scientific Committee has been requested to assess, within the framework of the analysis programme of the FASFC, the rating attributed to the severity of the adverse effects of various hazards (parameters) which the FASFC monitors within the food chain. The present opinion concerns the parameters and parameter profiles (i.e. set of parameters) related to pesticide residues, exogenous contaminants and allergens included in the analysis programme.

Method

The opinion is based on expert opinion taking into account the information available in scientific literature, and opinions and reports of international bodies. The proposed modifications to the rating of the severity of the adverse effects are based on a pragmatic approach, analogous to the approach already applied for the rating of the severity of adverse effects of pesticide residues and proposed in SciCom opinion 18-2016.

Conclusions & Recommendations

In this opinion, the 'adverse effect' reflects the intrinsic adverse effect of the hazard or parameter on public health. The severity rating of the adverse effects refers only to dose-response information and does not take into account the frequency of occurrence or incidence, nor (the route of) the exposure to the hazard or parameter. The severity rating of the adverse effects is graded on a scale from "1" (low severity) to "4" (high severity).

The rating of the severity of adverse effects of **pesticide residues** is based on the approach proposed and described in the SciCom opinion 18-2016. This pragmatic approach links the rating scale from 1 to 4 to available health-based guidance values, in particular the acceptable daily intake or ADI.

The Scientific Committee has no remarks on the current attribution of ratings to the severity of the adverse effects of pesticide residues or of a profile of these residues.

For the severity rating of the adverse effects of **exogenous contaminants**, it is recommended to follow a semi-quantitative approach similar to the approach applied for pesticide residues. The severity rating scale for adverse effects under the proposed approach is first linked to the available health-based guidance value, such as the ADI. In the absence of such a guidance value, the rating is based on available toxicological dose-response reference points in combination with the 'Margin of Exposure' (MOE) approach. If the toxicological information is insufficient, the rating is linked to the threshold values obtained by applying the 'Threshold of Toxicological Concern' (TTC) concept or determined by expert opinion (i.e. a grading of 4 if there are indications of very serious adverse health effects or a default value of 2 if there are no such indications).

The section 'exogenous contaminants' of the analysis programme covers a large group of parameters including (heavy) metals and metalloids, persistent organic pollutants, components that may migrate from materials and objects in contact with food, as well as radiation and radioactivity. The annex to the opinion presents the proposed ratings based on the semi-quantitative approach together with the reasoning behind the attributed rating.

Analogously, it is proposed to link the rating scale of the severity of the adverse effects of **allergens** to the allergic potential of a protein, expressed by the eliciting dose ED_p. This is the amount of a protein that causes a reaction in a sensitive population or in a certain percentage 'p' of this population, and is translated into a reference dose for risk management purposes. In the absence of data, the default value of 2 can be used as a rating.

As such, it is proposed to reduce the severity rating of the allergenic effect of peanuts, eggs and milk to 2 and of crustaceans to 1, and to increase the severity rating of the allergenic effect of celery, sesame seed and molluscs to 2 and of mustard to 3.

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