SciCom

Opinion 08-2022 of the Scientific Committee established at the FASFC on reference doses for allergens (update SciCom opinion 24-2017)

Background & Terms of reference

In the absence of legal notification thresholds or reference doses for food allergens, the Scientific Committee has been asked in 2017 to give an opinion on the reference doses to be used in the context of the surveillance of allergen labelling. Since then, additional clinical data and new information have become available. As a result, the Scientific Committee decided, on its own initiative, to update the reference doses for allergens it proposed in 2017. It concerns the reference doses for the allergens of crustaceans, eggs, fish, groundnuts, soy, milk, celery, mustard, sesame seed, lupine, molluscs and certain nuts, listed in Regulation (EU) n° 1169/2011.

Method

The opinion is based on information from the scientific literature in combination with the opinion of experts.

Conclusions & Recommendations

The Scientific Committee recommends to apply the reference doses (RDs) recommended by the FAO/WHO. The RDs were determined by an FAO/WHO consultation group of experts for eight allergens considered to be priorities from a global perspective. These are grains containing gluten (e.g. wheat, rye, barley and related species), crustaceans, eggs, fish, milk, peanuts, sesame and specific nuts (almond, cashew, hazelnut, pecan, pistachio and walnut). For the other allergens required to be labelled under Regulation (EU) No 1169/2011, the Committee follows the same approach as the FAO/WHO consultation group for the derivation of a RD, namely:

(1) selection of the lowest mean eliciting dose that theoretically causes a reaction in 5% of the allergic population or the ED05 value,
(2) rounding of the ED05 value to one significant figure, and
(3) grouping of ED05 values into a single RD for foods with close ED05 values, with further rounding down if necessary.

Following reference doses are proposed by the Scientific Committee for risk assessment:

Allergenic commodity	Proposed reference dose (mg protein of the allergenic commodity)
Egg	**2**
Milk	**2**
Celery	**1**
musterd	**1**
peanut	**2**
hazelnut	**3**
almond, cashew, pecan, pistachio, walnut, brazil nut and macadamia nuts	**1**

Allergenic commodity	Proposed reference dose (mg protein of the allergenic commodity)
lupine	**5**
sesame	**2**
crustaceans	**200**
molluscs	**200**
fish	**5**
soybean	**5**
wheat (and all other cereals containing gluten)	**5**

In practice, the value obtained by multiplying the detected allergen concentration by the portion size is usually compared to the reference dose in order to assess the risk of the presence of an allergen in a food product for a sensitive person.

With regard to gluten-containing cereals, it is noted that a distinction must be made between grain allergy and gluten intolerance. According to Commission Implementing Regulation (EU) n° 828/2014, the statements “gluten-free” and “very low gluten” are allowed on products that contain no more than 20 mg/kg and 100 mg/kg of gluten respectively. Nevertheless, Regulation (EU) n° 1169/2011 always requires labeling of cereals containing gluten when they are used as an ingredient. In view of protecting consumers with an allergy to these cereals, the Committee proposes to apply for risk assessment the RD derived for wheat.

The information presented in this scientific opinion fits in the context of managing the risk that may arise from the presence of allergens in foods. Regardless of the surveillance of the possible presence of undeclared allergens, the proposed RDs do not, in principle, concern allergens which have been added as an ingredient to food products, as they are part of the product recipe and should always be labeled according to legislation. The proposed RDs must not be used as a basis for claiming a product to be "free" of a specific allergen. Furthermore, the use of precautionary allergen labeling (PAL) for the potential, sporadic presence of an allergen through cross contamination should be minimized by a proactive allergen management system. Application of such labeling should always be linked to a real risk based on the applied manufacturing process as described in the context of the HACCP – ‘Hazard Analysis and Critical Control Points’ system.

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