European Federation of Allergy and Airways Diseases Patients' Associations

To:

Klaus BEREND, Acting Director of Directorate E for Food and feed safety, innovation, DG SANTE

Sabine PELSSER, Head of Unit E1 for Food Information and Composition, DG SANTE

7 July 2022
Brussels

EFA calls for a harmonised allergen risk assessment in the EU: The case of the accidental contamination of soy lecithin with peanut protein

Dear Mr Berend, dear Ms Pelsser,

Representatives consumers living with food allergies, the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) we are writing to you to express our concern about the recent RASFF notifications on soy lecithin from India contaminated with peanut protein, and the impact that these may have on our patient community.

Beyond the immense health burden, the COVID-19 pandemic also caused the disruption of commodity supplies. Starting from 2021, Indian oil mills were seriously affected by supply problems, which, in the face of the lack of soybeans, have integrated in their processes other plant products, such as peanut seeds. However, the objective difficulties of sanitising the plants have caused the cross-contact (accidental and/or technically unavoidable contamination) of soybean-extracted lecithin with peanut protein residues.

Only in 2022, there are three notifications on the EU RASFF portal (with a follow-up in 24 EU and 39 non-EU countries) concerning the presence of peanut protein in soy lecithin from India. Specifically:

- Notification 2022.2286 from Germany, involving several Member States, including Italy. The European Commission is waiting for a follow-up from India. Peanut contamination levels in liquid soy lecithin were identified in three samples as 220 mg/kg, 110 mg/kg and 9.71 mg/kg (or ppm);
- Notification 2022.2788 from Spain on the same product of identical origin. The RASFF portal refers to 'serious risk', although no information is available on the levels of peanuts detected in the samples;
- Notification 2022.3272 from Italy. The portal identifies the risk as 'serious', and values are given for two samples, with contamination levels of 0.82 ± 0.35 and > 6 mg/kg (or ppm), respectively.

Despite the notifications, which involved in total 63 countries in five continents, it should be noted that **no allergic or otherwise adverse reaction was reported** among the population.

The EU General Food Law (Regulation (EC) 178/2002) introduced risk assessment as the cornerstone of the choices of the food business operators during risk management. Ensuring food safety and the health of vulnerable consumers is a prerequisite for producing, distributing and administering food products in the EU and every country in the world. This prerequisite must also be respected when managing the risk of unintended contamination by allergens, which must be harmonised and consistent with EU regulations (Art. 14 and 19 of the EU General Food Law).

Today, the test protocols and evaluation criteria applied by national food safety authorities are neither harmonised nor transparent. Therefore, the risk of cross-contact linked to the consumption of soy lecithin

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accidentally contaminated by peanut residues (or mustard, sesame etc), as in the present case, must be verified explicitly on individual foods.

In addition, the presence, in an ingredient and/or additive, of a minuscule quantity (or even a few tens of mg/kg) of peanuts is not sufficient for strong corrective measures. It appears not justifiable to take drastic actions such as withdrawal, recall etc or impose the re-labelling of food just because, due to cross-contact, it may contain a few hundred parts per million of allergens i.e. levels sometimes even lower than the LoDs (Level of Detection) of the analytical methods and, in any case, harmless.

The scientific community internationally, the food allergy patient associations and the more pragmatic authorities in risk analysis (e.g. BfR in Germany, FSA in the UK) have validated a quantitative approach in the analysis and management of allergen risk (inspired by VITAL 3.0).

Alarmist news of unfounded alerts based on false risk analyses, or abuses of 'may contain' labels, often result in lower precautions by the vulnerable population, who eventually tend to accept some risk. Counting more than 17 millions in the EU, consumers with food allergy are exposed to the redundancy of often unjustified alerts, which generate unnecessary stress and further reduce their food choices. The reckless use and lack of harmonised criteria for the so-called PAL (Precautionary Allergen Labelling) is a major aspect of the issue.

The food allergy patient community are calling for a decisive intervention from the European Commission to address a challenge which, in the case of soy lecithin, is also linked with risks other than food safety, such as unjustified food waste.

Given the uncertainties outlined above, and in light of rapidly increasing cases of soy lecithin contaminated with peanuts in various EU countries, EFA urges the Commission to take the following actions for the protection of food allergy consumers:

- **Review the inconsistent risk classifications** proposed in the three alerts in question, the impact of which on the internal market is potentially enormous;
- Adopt a **transparent position on allergen risk analysis and management**, in agreement with the national authorities including identical criteria in all of the 27 Member States;
- **Define detailed rules regarding the use of PAL**, exercising the delegation powers conferred by the legislator (EU regulation 1169/11, Art. 36.3.a). Type indications 'may contain… (allergen)' must always follow a risk analysis of cross-contact, in the self-control phase, inspired by the Vital 3.0 system of Allergens Bureau.

Our patient community is fully conscious that it is impossible to eliminate risk. But **since zero risk is impossible, we must do everything to ensure risk minimization, while safeguarding consumer choice**. For example, out-of-context PAL i.e. 'it may contain crustaceans' on the list of ingredients of ice cream, as well as widespread withdrawals of products with undetectable or anyhow harmless levels of allergens may result to a danger by lowering the average level of attention of sensitive consumers overwhelmed by unfounded alerts. In addition, we cannot forget the dramatic costs of unfounded recalls, also in terms of food waste.

Thanks in advance for considering the abovementioned asks, which reflect the perspective of the food allergy patient community in Europe. We remain fully at your disposal for a potential meeting or virtual call should you wish to elaborate on these aspects or need any further information.

Yours sincerely,

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