EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director (acting)

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

Dear Ms Podestà,

I would like to thank you for your letter, dated 7 July 2022, related to the case of the accidental contamination of soy lecithin with peanut protein. We take note of the concerns raised in your letter.

According to Article 14(1) of Regulation (EC) 178/2002[1] only safe products may be placed on the EU market. Food business operators at all stages of production, processing and distribution within the businesses under their control have to verify that the relevant requirements of food law are met. Member States are responsible for enforcing food law, monitoring and verifying that the relevant requirements of food law are fulfilled by food business operators.

If allergens are present in foods, in this case as a result of incidental contamination, Member States have to carry out a risk assessment in accordance with Regulation (EC) No 178/2002 prior to deciding what action is necessary[2]. Based on the outcome of this

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1

[2] Remedial and enforcement action along the agri-food chain is also governed by the provisions of Regulation (EU) No 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives

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risk assessment, Member States are competent to decide on the implementation of appropriate risk management measures, which may include recalls, withdrawals or placing on the market with appropriate labelling.

As regards the three cases at stake, the respective national competent authority have made their assessment and informed, as this is their duty as competent authorities, the other Member States via the RASFF so as to allow them to take appropriate risk management measures. Let me underline that the Commission is a facilitator of the exchange of information between Member States but in no way the "owner" of -or responsible for- the notifications circulated within the RASFF. Those stay under the full responsibility of the notifying Member State.

In relation to the possible and unintentional presence of allergens, a requirement to provide information regarding these unintended substances is not regulated in Regulation (EU) No 1169/2011. The Regulation, however, foresees to empower the Commission to adopt an implementing act harmonising this area (Article 36(3)(a)). The Commission's empowerment to adopt an implementing act on the voluntary information related to information on the possible and unintentional presence of allergens is not subject to a deadline. On previous occasion, the Commission had informed EFA that work on the so-called Precautionary Allergens Labelling (PAL) awaits for the progress of this work at CODEX level, which is still ongoing. It is very important to distinguish cases where there is a "possible and unintentional" presence of an allergen from cases such as this one which involves a verified presence of peanut in soy lecithin.

Finally, let me emphasise that, although we agree with your call that everything must be done to ensure risk minimisation while safeguarding consumer choice, it is essential that our actions take into account first and foremost the interest of consumers with food allergies and in particular of the almost 10 % of food allergic people who may have acute anaphylactic reactions that could be fatal to their lives.

Yours sincerely,

[e-signed]
Klaus Berend

89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1