

3.7 Allergens

Allergens must be considered as part of the food safety management system, as the possible and unintentional presence in food of substances or products causing allergies or intolerances poses a hazard to food allergic consumers. Regulation (EU) No 1169/2011¹ on food information to consumers requires that the information is always provided to the consumers on the presence of any ingredient or processing aid or derived from a substance or product causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. The list of regulated substances or products causing allergies or intolerances can be found in Annex II of Regulation (EU) No 1169/2011 and includes the following: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seed, sulphur dioxide and sulphites, lupin and molluscs. Guidance on the allergen labelling requirements can be found in Commission Notice 2017/C 428/01².

Regulation (EC) 178/02 makes certain information mandatory for the consumer's benefit (Article 14). According to the General Food Law, food must be safe to eat; however, food is considered unsafe if it is harmful to health. It defines food safety conditions that consider the health needs (particular sensitivity) of vulnerable categories of consumers.

The label that does not report, or does so incorrectly or incompletely, information on allergens represents a severe risk to the health of allergic consumers, as an anaphylactic reaction that can lead to death.

Regulation (EC) No 852/2004 lays down provisions on allergen management both in primary production and stages thereafter, underlining the need for a comprehensive preventive approach along the whole food chain. Good hygiene practices are required to prevent or limit the presence of substances causing allergies or intolerance due to contamination of foodstuffs (cross-contamination). The production process and working methods might have to be reviewed to comply with this requirement. At primary production, allergen management should consider the following in order to prevent or minimize the risk for allergen contamination:

- Awareness by the primary producers on the use of products (e.g. crops unintentionally contaminated with cress of celery or mustard), substrates (e.g. straw of cereals used for growing mushrooms) and plant protection products, including basic substances (e.g. sulphites)), that are recognized as allergens;
- Consideration of crop rotation, in particular if products (allergens) grown from previous crops may contaminate new crops;
- Avoidance and checking of cross-contamination during harvesting, slaughter (e.g. egg yolk in slaughtered laying hens, cereals in crop of poultry), handling, storage and transport.

¹ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18)

² COMMISSION NOTICE of 13 July 2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (2017/C 428/01)

At the next stages of food production, the following should be considered to prevent or minimize the risk for allergen contamination:

- Attention being paid to incoming raw materials, including requests for specifications of the ingredients of these raw materials if not obvious;
- If allergens or products containing allergens are used as raw materials or ingredients, awareness of staff on allergen management should be ensured and specific attention should be paid to the correct storage (minimum risk of contamination of other products), allergen labelling and recipe application of these products;
- Procedures should be in place to prevent the exchange of products (raw materials, intermediated products and finished end products) and labels;
- Strict measures to minimize cross-contamination should be applied with products potentially containing regulated allergen(s) to other products without allergens or containing different allergens. Segregation should be applied by the use of segregated production lines, receptacles and storage facilities (e.g. closed packages where appropriate) when possible, or by a specific work methodology/production order e.g. **scheduling** end of the day production of products with (the highest amount of) allergens, awareness of workers and compliance with hygiene rules before returning to work from breaks for eating or drinking;
- Attention of cross-contamination should also be paid at preparatory stages (debugging, preliminary handling and weighting of ingredients, etc.) and post-production stages e.g. bulk transport.

At all stages where routine checking on the absence of visible debris is not possible, increased attention should be paid to the frequency and the robustness of cleaning of the equipment. Also validation/verification of the cleaning method by sampling and analysis, might be relevant. Example: chocolate production is “closed” and it is not possible to look into pipes to see if something is left. It is also difficult to clean easily with water. In this example validation/verification of the cleaning method by sampling and analysis is therefore relevant. **In other cases, when wet cleaning is used the cleaning water can be analysed for allergen residues.**

The extent of control measures for the prevention of cross-contamination of allergens needs to be elaborated depending on the number and amount of allergens used, the complexity of the handling (e.g. processing with mixing compared to pure handling of prepacked food), the number of change-overs of products (risk of cross-contamination) and the frequency and robustness (easy to apply or not) of cleaning procedures.

According to Regulation (EU) No 1169/2011 compulsory labelling only applies where **allergenic** products or substances have been intentionally added as ingredients **or processing aids**. Information on the possible and unintentional presence in food of substances or products causing allergies or intolerances may be provided on a voluntary basis³ (Article 36 of Regulation (EU) No 1169/2011, paragraph 3, point a)). Voluntary information provided to the consumers has to comply with the provisions of Article 36 of the Regulation. In particular, such voluntary information must not mislead the consumer, must not be ambiguous or

³ Regulation (EC) No 178/2002 lays down the general principals and requirements of food law. It states in Article 14(3) that "*In determining whether any food is unsafe, regard should be had to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods*".

confusing for the consumer; and must, as appropriate, be based on the relevant scientific data. Pending the adoption of such harmonised provisions, food business operators are responsible to ensure that such information when provided is not misleading, ambiguous or confusing for consumers.

Such voluntary information, precautionary allergen labelling (PAL), should only be used where a preventive strategy cannot be efficiently implemented and the product may present a risk to allergic consumers. Precautionary allergen labelling is a separate statement **that, from consumers perspective, should be mandatory and its use and absence should be clearly defined. Aspects that should be regulated are the wording used, that it should be placed next to the list of ingredients should be based on the findings of a quantitative risk assessment, conducted by the food manufacturer** to evaluate the possible and unintended presence of allergens. Cross-contact of allergenic ingredients should not be included in the list of ingredients as they are not intentionally added and no part of the formula of the product. Such labelling should never be used as an alternative to preventive measures, **such as quantitative risk assessment.**

In summary, allergens are a food safety issue in food production. Therefore, allergen management must be included in the entire process of the Hazard Analysis and Critical Control Point (HACCP) system. In addition to this framework of allergen management that comprises at all steps from farm to fork, harmonized reference doses / action levels for unintended allergen presence need to be established to enable food manufacturers as well as food inspection authorities to validate food production and food products.

More detailed guidance can be found in:

- Codex Alimentarius Code of Practice on Food Allergen Management for Food Business Operators⁴
- Codex Alimentarius Guidance on [precautionary allergen or advisory labelling] ⁵.
- **3rd report of the ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Review and establish precautionary labelling in foods of the priority allergens**
- The Guidance on Food Allergen Management for Food Manufacturers, developed by FoodDrink Europe⁶
- Precautionary Allergen Labelling (PAL): a science-based approach based on Quantitative Risk Assessment⁷



⁴ CXC 80-2020; http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B80-2020%252FCXC_080e.pdf

⁵ Being drafted at the moment of this publication

⁶ https://www.fooddrinkeurope.eu/uploads/press-releases_documents/temp_file_FINAL_Allergen_A4_web1.pdf

⁷ <https://www.fooddrinkeurope.eu/wp-content/uploads/2021/05/Precautionary-Allergen-Labeling.pdf>