

## EFA's response to the Food Safety, Allergies & Food Waste – New EU rules for Regulation (EC) No 852/2004 on food hygiene (Directorate General for Health and Food Safety)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 39 national associations from 24 countries and channel their knowledge and demands to the European institutions. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care and a safe environment.

EFA supports the revision of Regulation (EC) No 852/2004 on food hygiene, and its goal to reinforce the hygiene rules applicable to foodstuffs in the supply chain and production process. Overall, we are uplifted to see the European Commission taking seriously into consideration the food information and management needs of people living with food allergy, and thrilled that those needs are included in legislative revisions like the present one. Moreover, we are thankful that the concerns of the food allergy community in Europe that we represent are embedded into the much broader EU approaches devised through the Farm-to-Fork strategy, and the EU Green Deal.

We find very positive that the proposed new rules take into account the ongoing work of the Codex Alimentarius Commission (CAC) on allergen management. This is a sign that the recent activities of Codex in areas such as quantitative risk assessment and Precautionary Allergen Labelling (PAL) are hopefully gaining traction at EU level, responding to the expectation of consumers living with food allergies.

Today, about 17 million people in Europe are suffering from food allergies. For them, consuming food, prepacked or non-prepacked, privately or in a food establishment, might incur serious health risks. Their realities and recommendations have been collected in EFA's 2019 Report "[Quality of Life for People with Food Allergies in Europe: A Menu for Improvement](#)". Given the increasing prevalence of food allergy in Europe and globally, especially among children, patients and consumers with food allergies request more and more access to clear, accurate and timely food information to be protected.

In consultation with EFA Food Allergy Working Group, our federation has the following comments to the draft Regulation and Annex proposed by the European Commission:

1. The proposed Draft Regulation and Annex make several **references to Annex II of Regulation 1169/2011 on the provision of food information to consumers**, which includes the list of the 14 recognised foods and substances that need to be labelled separately as allergens. However, Regulation 852/2004 as it stands now does not offer acknowledgement of the risks posed by food allergies, in the sense that food allergies are not mentioned at all from a hygiene perspective. Given the importance and weight that Regulation 1169/2011 has for food information and safety, EFA recommends the European Commission to add a specific reference to the full piece of legislation in both documents. For example, we suggest that the amended Regulation 852/2004 puts avoidance/reduction of cross-contact of food allergens at the same level of other hygienic risks.
2. We are concerned that **Chapter Va on the Redistribution of Food for the purpose of food donation only refers to pre-packed food**. We call the European Commission to clarify if the proposed Chapter Va also applies to donated non-prepacked food, and if so, to specify the aspects to respect when managing that food. From EFA perspective, **every patient and consumer**

**with food allergy should be able to get the ingredients information independently on whether it is or not a donated food and whether it is packed or non-prepacked, and this according to Art. 8.6 of Regulation 1169/2011.**

3. With regards to the proposed amendment 5a in Annex I, Part A, Section II, we are wondering whether this provision applies only to plant products, or also to animal products as well (Annex I, Part A, Section II, par. 4). EFA believes that **hygiene provisions for plant products should also be applicable to products of animal origin**. Risks may arise also by cross-contact to other foods, when milk, egg, fish, molluscs and crustaceans are 'produced' and handled.
4. With regards to the proposed amendment 5a in Annex I, Part A, Section II, we know of several incidences where cross-contact occurred via transport containers. EFA proposes a **mandatory procedure for cleaning, if allergenic food has been transported and the containers are used for non-allergenic food**. Cleaning should not only be mandatory if allergenic food (see Regulation 1169/2011, Annex II) has been transported and should not just consist of '*checking at least for the absence of any visible debris of that substance*' – because visible checking might not be sufficient, when allergenic residues are hidden in tubes, hoses or under sieves or filters.
5. EFA welcomes the addition of the "**food safety culture**" concept in existing rules (Chapter XIa), and we hope that it becomes a fully integrated approach within the food hygiene systems of Food Business Operators (FBOs). From our patient perspective, **allergen management must be a cornerstone of such systems**, regardless of the size or the position of the operator in the supply chain. EFA considers the following elements are key in the roll-out of the "food safety culture" concept:
  - **Apply it to all people involved in food management**. Food is managed and served beyond business and employees with commercial interests and contractual relationships. However, the concept as it is presented in the current drafts excludes non-for-profit and volunteering schemes involved in food management (i.e. community-based groups redistributing food surplus or religious charities serving hot meals). Given these structures and people also provide food to consumers with food allergies, EFA recommends the Commission to propose terms to include all actors in this food safety culture.
  - **Require training on allergen management**: Food safety culture must aim at increasing awareness among FBO staff via **mandatory training on allergen management**. While in some EU Member States such as Austria, Denmark, Spain and the UK, there are extensive guidelines on the issue, most countries do not oblige FBO staff to be trained on allergen management. Naturally, training should increase knowledge on issues going from handling of equipment and transport/processing/storage of food, to dealing with a food allergy episode. In sum, allergen management needs to become an integral part of food hygiene training and practice.
  - **Systems that embrace ambition and change**: Food safety culture should become the driver for **allergen management systems that facilitate regular controls, set clear, verifiable outcomes, and enable reviews** when required.

EFA general comments:

1. At EFA we advocate for the harmonisation of Precautionary Allergen Labelling (PAL) in the European Union. Considered as voluntary information under article 36 of the Regulation 1169/2011 today PAL is used in various ways in Member States, triggering preventable health risks and confusion. As patients and consumers with food allergies, we need a **harmonised PAL system, based on an appropriate quantitative risk assessment derived from reference doses for**

**allergenic food.** A system to be used by food operators based on science and measurable levels, therefore a trusted system allowing accurate food choices for food allergy patients. Such a harmonised PAL would also partially solve the food recalls at national and EU levels, many due to unintended allergen presence that has not been declared. Therefore, beyond health benefits, a harmonised PAL system can lead to food waste reduction, contributing further to the objectives of the Farm-to-Fork Strategy.

2. Upgrading requirements on good hygiene practices in line with the upcoming **Codex Code of Practice (COP) on Food Allergen Management for FBOs** is a positive step to address the risks posed by unintended allergen presence, and enable stronger oversight. However, the aspect that would significantly improve the way allergens can be managed is **quantitative risk assessment on the basis of reference doses for food allergens**, that are relevant to health for patients and therefore protect the majority of consumers with food allergies from allergic reactions, while giving food manufacturers a tool to apply and authorities a framework for enforcement. Regretfully, CCFH has currently opted to delete all aspects referring to PAL and quantitative risk assessment from the draft COP As CAC Observers, and active contributors in various procedures undertaken by the two mentioned committees, EFA has opposed this decision, arguing that the two terms should be included in the text not only to enhance awareness, but also to facilitate future reviews once the WHO/FAO consultation is concluded. We therefore call on the Commission to embrace our perspective and to consider when assessing the new rules for Regulation (EC) No 852/2004 and work towards implementing allergen management guidance that includes quantitative risk assessment and reference doses for allergens.
3. As for the primary sector, substances used in vegetable farming, such as **Plant Protection Products (PPPs) and fertilizers including biocides, can remain on the edible parts of the plants.** These residues may include the 14 substances listed as allergens in Annex II of Regulation 1169/2011 and therefore may pose a serious risk to the health of food allergy patients. However, PPPs are authorised through Regulation 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, which classifies them as residues and not as ingredients. Their presence falls out of the scope of food information provided to consumers and is therefore not labelled. At EFA we call on the Commission to **pay special attention to the PPPs containing any of the 14 recognised allergens so that the risk they might pose to consumers is evaluated by EFSA through rigorous scientific risk assessment - and if necessary followed by appropriate labelling requirements in Regulation 1169/2011.** We also recommend including allergenicity considerations within Regulation 396/2005.

Please find below a table summarizing EFA's suggested changes:

Reg. 852/2004	Recommended addition	Reasoning
Annex I, Part A, Section II, par. 4	Equipment, conveyances and/or containers used for the harvesting, transport or storage of one of the substances or products causing allergies or intolerances, referred to in Annex II to Regulation (EU) No 1169/2011, shall not be used for the harvesting, transport or storage of any food not containing that substance or product, unless the equipment, conveyances and/or containers have been cleaned and checked	Hygiene provisions for plant products should also be applicable to products of animal origin. Risks may arise also by cross-contact to other food, when milk, egg, fish, molluscs and crustaceans are 'produced' and handled.

	at least for the absence of any visible debris of that substance or product.'	
Annex I, Part A, Section II, par. 5	A mandatory procedure for cleaning conveyances and/or containers is required, in case allergenic food has been transported and the containers are used for non-allergenic food.	Visible checking might not be sufficient, when allergenic residues are hidden in tubes, hoses or under sieves, or filters.
Annex I, Part B, par. 2	Addition of another point: (f) The management of food allergens listed in Annex II, Regulation 1169/2011 and avoidance or where not completely possible reduction of cross-contact with food allergens.	Including allergens in the list of aspects that need to be examined under good hygiene practices is key and should be the conclusion from the Code of Practice of the Codex Alimentarius Committee on Food Hygiene, as also mentioned in the Commission reasoning for the amendment of Regulation 852/2004.
Annex II, Chapter Va,	The Commission to clarify if the proposed Chapter Va also applies to donated non-prepacked food, and if so, to specify the aspects to respect when managing that food.	Every patient and consumer with food allergy should be able to get the ingredients information independently on whether it is or not a donated food and whether it is packed or non-prepacked
Both the proposed Regulation and Annex	The proposed amendments should highlight the links between food hygiene and allergen management. In this regard, the links with Reg. 1169/2011 should become much more visible through a specific reference to it in both documents.	Regulation 852/2004 as it stands now does not offer acknowledgement of the risks posed by food allergies, in the sense that food allergies are not mentioned at all from a hygiene perspective