



**Food and Agriculture
Organization of the
United Nations**



**World Health
Organization**

**Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens –
guidance for risk assessment**

FAO HQ, Rome, Italy: 16 – 20 June 2025

SUMMARY AND CONCLUSIONS

Issued in July 2025

At the request of Codex, FAO and WHO held a series of expert meetings, beginning in 2020, on the risk assessment of food allergens and published the meeting reports, including Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment; Part 2: Review and establish threshold levels in foods for the priority allergens; Part 3: Review and establish precautionary labelling in foods of the priority allergens; Part 4: Establishing exemptions from mandatory declaration for priority food allergens; Part 5: Review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats.

In response to the recent request from Codex for scientific advice on guidance for food allergen risk assessment, FAO and WHO convened an expert consultation to provide recommendations on food allergen risk assessment.

This document summarizes the conclusions of this meeting and is made available to facilitate the deliberations of the Codex Committee on Food Labelling (CCFL) and Codex Committee on Food Hygiene (CCFH). The full report of the meeting will be published as part of the Food Safety and Quality Series.

The meeting participants are listed in Annex 1 of this summary report. Benjamin Remington served as Chairperson and Melanie Downs as Rapporteur.

More information on this work is available at:

<http://www.fao.org/food-safety/en/>

and

<https://www.who.int/foodsafety/en/>

The issuance of this document does not constitute formal publication. The document may, however, be freely reviewed, abstracted, reproduced or translated, in whole or in part, but not for sale or use in conjunction with commercial purposes.

Conclusions and Recommendations

- Food allergens are a distinct category of food safety hazards, with unique characteristics different from those of chemical, microbiological, and physical hazards. Differentiating food allergens from other hazards in risk assessment and risk management will improve food safety.
 - The panel recommends that relevant documents be updated accordingly.
- Food allergens should be controlled through appropriate food safety management systems.
 - This includes compliance with existing Codex documents (e.g., codes of practice), good allergen management, and other quality systems.
 - By adhering to existing food allergen labelling and information requirements, food business operators (FBOs) already hold much of the information needed to conduct food allergen risk assessment.
 - Unintended allergen presence (UAP) of priority allergenic foods¹ (including ingredients, food additives and processing aids) due to cross-contact should be eliminated or mitigated/controlled to a level as low as reasonably possible through good hygiene practices (GHPs), good agricultural practices (GAP), good manufacturing practices (GMP), and procedures based on HACCP principles (e.g., General Principles of Food Hygiene CXC 1-1969; Code of Practice on Food Allergen Management CXC 80-2020).
- The goal of food allergen risk assessment is to support informed decisions, e.g., on labelling or process control, and communication through the supply chain.
- The risk assessment process for food allergens is applicable and achievable for all FBOs, including primary producers.
 - Therefore, it is recommended that the definition of small and/or less developed businesses (SLDBs) and documents providing guidance to them (e.g., "FAO/WHO guidance to governments on the application of HACCP in small and/or less-developed food businesses²") should be reviewed and updated.
- Risk assessment of food allergens is interconnected with risk communication and risk management within the overall risk analysis framework.
- Food allergen risk assessment is part of a stepwise and iterative process with information requirements that may differ depending on the application.
- This iterative process allows for improvement of the supply of safe food through the investigation and potential implementation of risk mitigation practices.
 - Improvements in food allergen management may also have an overall positive impact on other food safety and quality aspects.

¹ Priority allergenic foods refer to the global priority allergenic foods and those relevant to the applicable national or regional jurisdictions

² FAO and WHO. 2006. FAO/WHO guidance to governments on the application of HACCP in small and less-developed food businesses. <https://www.fao.org/4/a0799e/a0799e00.htm> and <https://iris.who.int/handle/10665/43598>

- Irrespective of the size of business, risk assessment for food allergens should be evidence-based, and information should be collected and be able to support a decision.
 - The initial steps of any food allergen risk assessment are common for all FBOs and primary producers, types of products, and manufacturing processes.
 - Information required for such risk assessment is qualitative and, depending on the situation, may need to be supplemented with quantitative information.
 - Often, a completed risk assessment may solely rely on qualitative information obtained in the initial steps.
 - When needed, quantitative information mainly concerns estimation of the possible level or amount of UAP. Such estimation may be based on product formulation, volumes or sizes of observed allergenic material, volumes or sizes of production equipment, and/or appropriate analytical results.
 - Very often, risk assessment can be completed without analytical data.
 - When needed, analytical data can include, for example, results of total protein estimation (e.g., based on nitrogen determination), gravimetric analysis (e.g., weighing of particulates), and allergen-specific methodology (e.g., immunoassay results).
 - Analytical data in isolation is insufficient to complete a risk assessment.
- Conducting a food allergen risk assessment is required to justify precautionary allergen labelling (PAL) decisions³.
- A food allergen risk assessment framework was developed to enable risk communication and informed risk management decision-making. Figure 1 is a summary representation of this framework.
 - The detailed framework with explanatory notes will be included in the full report.
 - It is recommended that this detailed framework is used by FBOs, competent authorities, and other stakeholders to conduct food allergen risk assessment.
 - The proposed framework does not differentiate between exclusively qualitative and quantitative approaches, rather it utilizes qualitative information and, where required, the combination of qualitative and quantitative information.
 - The potential combination of qualitative and quantitative information within a risk assessment is not unique to food allergens and is common in other fields of risk assessment for food.
 - Most or all information needed to conduct a food allergen risk assessment is available within a producer's own facility, which includes supply chain-related information.

³ For more information, refer to FAO and WHO. 2023. Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens. <https://doi.org/10.4060/cc6081en>

- The risk assessment framework helps to identify relevant information already available.
- The risk assessment framework helps to identify gaps and points to where more information may be required.
- The framework will include visual representation of amounts of foods (e.g., as a photo) corresponding to the FAO/WHO reference doses (RfDs)⁴.
 - These visualizations will benefit all stakeholders conducting a risk assessment, including competent authorities, FBOs, and primary producers.
 - Additionally, consumers with food allergy and health care professionals can utilize these visualizations for food allergy management purposes.
- The outcome of a food allergen risk assessment is to be used for risk communication and/or risk management of UAP in foods, such as informing and facilitating transfer of information through the whole food supply chain (from production to consumption), food trade, decisions on the application of precautionary allergen labelling (PAL), recall decisions, risk mitigation measures, and opportunities for process improvement.
 - To enable these various applications, it is recommended that competent authorities and others developing guidance separate reference doses (RfDs) from PAL guidelines. For example, by establishing separate annexes for PAL and the FAO/WHO RfDs within the General Standard for the Labelling of Prepackaged Foods (GSFLPF).

⁴ For more information on the FAO/WHO reference doses (RfDs), refer to FAO and WHO. 2022. Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens, <https://doi.org/10.4060/cc2946en> and FAO and WHO. 2023. Risk Assessment of Food Allergens – Part 5: Review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats, <https://doi.org/10.4060/cc8387en>.

Annex 1. List of participants

EXPERTS

Helen Arrowsmith, Food Standards Agency (UK FSA), the United Kingdom of Great Britain and Northern Ireland

Elena Cubero-Leon, European Commission, Joint Research Centre, Belgium

Melanie Downs, University of Nebraska-Lincoln, the United States of America

Alessandro Fiocchi, Pediatric Hospital Bambino Gesù, Italy

Tatsuki Fukuie, National Center for Child Health and Development, Japan

Geert Houben, Netherlands Organisation for Applied Scientific Research TNO, the Kingdom of the Netherlands

Sébastien La Vieille, Health Canada, Canada

Benjamin Remington, Remington Consulting Group B.V., the Kingdom of the Netherlands

Gustavo Polenta, Instituto Nacional de Tecnología Agropecuaria, Argentina

Paul Turner, Imperial College London, the United Kingdom of Great Britain and Northern Ireland

Sirinrat Srikulnath, Kasetsart University, Thailand

RESOURCE PERSONS

Jasmine Lacis-Lee, Merieux NutriSciences AQ, Australia

Clare Mills, University of Surrey, the United Kingdom of Great Britain and Northern Ireland

Susanne Siebeneicher, R-Biopharm AG, Germany

Douglas Balentine, U.S. Food and Drug Administration, the United States of America

Patrick Sekitoleko, Joint FAO/WHO Food Standards Programme, Italy

Esther Garrido Gamarro, Fisheries and Aquaculture Division, FAO, Italy

SECRETARIAT

Akio Hasegawa, Department of Nutrition and Food Safety, WHO, Switzerland

Jeffrey LeJeune, Agrifood System and Food Safety Division, FAO, Italy

Kang Zhou, Agrifood System and Food Safety Division, FAO, Italy

Figure 1. Summary representation of the food allergen risk assessment framework developed to enable risk communication and informed risk management decision-making.

