Food and Agriculture Organization of the United Nations

World Health Organization

FAO/WHO workshop on risk assessment of food allergens

Workshop report

Nanning, China 19–20 September 2025

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Acknowledgements

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@ FAO/Hao Ding

Abbreviations

AL	action level
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CFSA	China National Center for Food Safety Risk Assessment
CIP	clean-in-place
CXC	Codex Alimentarius Commission Code of Practice
CXS	Codex Alimentarius Commission Standard
ELISA	enzyme-linked immunosorbent assay
EWG	electronic working group
FAO	Food and Agriculture Organization of the United Nations
FBO	food business operator
GAP	good agricultural practices
GHP	good hygiene practices
GMP	good manufacturing practices
GSLPF	General Standard for the Labelling of Packaged Foods
HACCP	hazard analysis and critical control points
HBGV	health-based guidance value
MoE	margin of exposure
N/RBD	neutralized/refined bleached and deodorized
PAL	precautionary allergen labelling
RfA	reference amounts of food intake, food consumed per eating occasion
RfD	reference dose
UAP	unintended allergen presence
UHT	ultra-high-temperature
WHO	World Health Organization

Abstract

This FAO/WHO workshop in China (September 2025) brought together over 60 experts from 11 countries across Asia, Africa and Latin America to address and learn more about the growing challenge of food allergens. The primary goals were to enhance the capacity of Members in conducting food allergen risk assessments, reinforce the importance of moving from hazard to risk for food allergen assessment and management, and ensure alignment with the latest international standards.

The workshop provided participants with the latest science and methodologies developed by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to help them assess and manage food allergen risks. Participants appreciated the opportunity to attend the workshop. The participants also noted challenges such as diverse regulatory or risk assessment frameworks and standards, and resource limitations. Through expert-led sessions and interactive discussions, participants considered real-world scenarios and conducted practical exercises to gain the necessary knowledge and tools to identify, evaluate and manage food allergen-related risks. A field visit to a food business operator (FBO) producing dairy products provided an opportunity for real-world insights into food allergen management and allowed participants to evaluate the case-by-case approach to food allergen risk assessment applied in the industry.

Key recommendations included convening similar events in different regions to strengthen the capacity of managing food allergens' risk; developing supplementary guidance for the implementation of harmonized food allergen risk assessments (case studies, end-user guidance); and continuing collaboration between Codex members, relevant Codex Committees (e.g. the Codex Committee on Food Labelling [CCFL], the Codex Committee on Food Hygiene [CCFH], the Codex Committee on Methods of Analysis and Sampling [CCMAS]) and national authorities to refine tools and promote consistent, harmonized food allergen risk assessment and risk management through the whole food supply chain (from production to consumption), facilitating fair trade practices, transparent labelling and protection of consumers with food allergies.

Executive summary

Background and objective

The FAO/WHO Workshop on risk assessment of food allergens was held in Nanning, China, from 19–20 September 2025. Hosted by the China National Center for Food Safety Risk Assessment (CFSA), the workshop convened 60 participants from 11 countries, including CCFL delegates who work on the guidelines for the use of precautionary labelling (PAL), national authorities, food business operators (FBOs) and additional stakeholders, academia, and international organizations. The workshop aimed to:

- enhance the capacity of Members in conducting food allergen risk assessments through expert-led discussions, desktop exercises, group discussions, and a field visit;
- reinforce the importance of shifting from a hazard-based to a risk-based approach for assessment and management of food allergens;
- ensure alignment of practices with the latest international standards and the *Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)*; and
- support consistent, harmonized food allergen risk assessment and risk management through the whole food supply chain (from production to consumption).

Key messages and outcomes

Food allergens are a distinct hazard: Food allergens have unique characteristics which distinguish them from classic food safety hazard categories (chemical, microbiological, and physical). Differentiating food allergens from other hazards in regulatory frameworks, standards and guidelines for risk assessment and risk management will improve food safety.

Moving from hazard to risk: It is important to shift from hazard to risk for assessment and management of food allergens in order to provide consistent protection for consumers with food allergies and ensure alignment with the latest international standards. When moving from a hazard-based system to a risk-based system to assess and manage food allergen cross contact, shifts in thinking and available frameworks are required.

Case-by-case approach: The principles for conducting food allergen risk assessment are broadly applicable, and assessments are done on a case-by-case basis. Guidance in this area must reflect the complex nature of the whole food supply chain (from production to consumption) and be adaptable and applicable to local conditions.

Country perspectives: The participants recommended that similar events should be convened in different regions and places to strengthen the capacity for managing food

allergen risk. Regarding challenges, commonly identified hurdles included inconsistent application of risk assessment, insufficient risk assessment capacity, resource limitations, and the need for harmonized standards and guidelines.

Field visit: A visit to an FBO producing dairy products provided real-world insights into food allergen management practices (sourcing, transport, storage, production, cleaning, distribution) and allowed participants to compare food allergen risk assessment applied in the industry to the principles learned during previous expert-led sessions and group discussions. This practical application proved beneficial for clarifying the detailed, case-by-case approach taken when determining food allergen management plans and conducting food allergen risk assessments. Participants also reflected on the field visit and situation in their countries, and they recognized similar FBOs. By following good hygiene practices (GHPs) and good manufacturing practices (GMPs), such as those observed during the field visit, participants understood that allergen risks are already being managed to a large extent by FBOs in those situations. Participants also commented on how similar practices could be implemented in facilities not yet up to these standards.

Agreed upon actions and recommendations

Encourage continued collaboration among Codex Alimentarius Commission members, food allergen experts, and national authorities to refine tools, enhance capacity and promote alignment of national regulations and consistent application of food allergen risk assessment. This would facilitate international trade and improve consumer confidence in food allergen labelling.

Develop supplementary guidance to support implementation of consistent food allergen risk assessment and risk management through the whole food supply chain (from production to consumption), including:

- case studies and examples from different production systems;
- end-user guidance for different aspects of food allergen risk assessment;
- translations of the risk assessment frameworks for small- and medium- scale producers and field inspectors in different regions with different languages; and
- integration with Codex Alimentarius' codes of practice into national regulations.

1. Background

1.1. Context

Risk assessment and management of food allergens from primary production through to processing and consumption plays a crucial role in protecting consumers with food allergies. Food allergens cannot simply be removed from the global diet or international trade as many of the staple foods in diets around the world are on the list of global priority food allergens (i.e. milk, eggs, peanut, tree nuts [hazelnut, cashew, walnut, pistachio, pecan, almond], sesame, fish, crustacea and cereals containing gluten [i.e. wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species, and their hybridized strains]). Transparent risk assessment and food labelling practices are critical for promoting trust and confidence in the food system and protecting consumers with food allergies.

When moving from a hazard-based system to a risk-based system to assess and manage food allergen cross contact, shifts in thinking and available frameworks are required. During the 50th session of the Codex Committee on Food Hygiene (CCFH) (FAO and WHO, 2018) and the 45th session of the Codex Committee on Food Labelling (CCFL) (FAO and WHO, 2019), both recognized the need for additional guidance around food allergen risk assessment while respectively drafting the *Code of Practice on Food Allergen Management for Food Business Operators – CXC 80-2020* (FAO and WHO, 2020) and Guidelines on the Use of Precautionary Allergen Labelling (PAL, for adoption at Step 7). The committees requested the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to provide scientific advice in this area. In response, a series of ad hoc Joint FAO/WHO Expert Consultations on Risk Assessment of Food Allergens were held with the following outputs:

- **Food Safety and Quality (FSQ) Series Report No. 14 (2022), Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment.** The recommendations in this report provided the basis for an updated list of foods and ingredients listed in the General Standard for the Labelling of Packaged Foods (GSLPF, CXS 1-1985) that are considered to be priority allergenic foods.
- **FSQ Report No. 15 (2022), Part 2: Review and establish threshold levels in foods for the priority allergens.** It provides reference doses (RfDs), based on health-based guidance values (HBGVs), that "reflect a range of exposure without appreciable health risk" (page 93–94) for priority allergenic foods in Section 4.2.1.4 of the GSLPF CXS-1985.
- **FSQ Report No. 16 (2023), Part 3: Review and establish precautionary labelling (PAL) in foods of the priority allergens.** It provides a risk-based framework that utilizes a foundation of good food allergen management practices and the

previously recommended RfDs as part of the assessment for the potential use of PAL on a product.

- **FSQ Report No. 17 (2024), Part 4: Establishing exemptions from mandatory declaration for priority food allergens.** It provides a risk-based framework which utilizes a weight of evidence approach in combination with an exposure criterion (i.e. the previously recommended RfD/30) to provide a margin of exposure (MoE) for derivative safety assessment and potential exemptions from mandatory declaration for priority food allergens.
- **FSQ Report No. 23 (2023), 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.** It provides RfDs and potential "values for risk management" (page 7) for foods in section 4.2.1.5 of the GSLPF CXS-1985.

Additional ad hoc joint FAO/WHO expert consultations were requested at the 48th session of the CCFL (FAO and WHO, 2024b) for guidance on risk assessment and scientific advice on reference doses for cereals containing gluten or gluten, and their summary and conclusions are available while developing this workshop report (FAO and WHO, 2025a, 2025b).

At its 48th session the CCFL also requested that the FAO and WHO conduct capacity-building activities where participants are trained in the latest science and methodologies to help participants assess and manage food allergen risks (FAO and WHO, 2024b). This workshop is part of those capacity-building activities.

1.2. Objectives

The primary objective of the FAO/WHO workshop on risk assessment of food allergens was to enhance the capacity of Members in conducting food allergen risk assessments. The workshop aimed to:

- **present and discuss key findings** from the five reports of the ad hoc Joint FAO/WHO Expert Consultations on Risk Assessment of Food Allergens;
- **facilitate knowledge exchange** among participants;
- **stimulate participants to shift from hazard-based to risk-based systems** for food allergen assessment and management;
- **effectively practice** the implementation of precautionary allergen labelling (PAL); and
- **ensure alignment** with the latest international standards.

1.3. Training programme

Workshop participants, which included CCFL delegates who work on the guidelines for the use of PAL, national authorities, food business operators (FBOs) and additional

stakeholders, were trained in the different food allergy and food allergen risk assessment frameworks developed by Joint FAO/WHO Risk Assessments on Food Allergens and the *Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)*. A list of participants is provided in Annex 1.

These objectives were achieved through a combination of expert presentations, expert led-group discussions, case study analyses, and on-site validation activities. The workshop agenda is presented in Annex 2.

2. Workshop proceedings

2.1. Day 1: Setting the scene and introduction to risk assessment

2.1.1. Opening remarks

The workshop commenced with welcoming remarks from Yongxiang Fan (CFSA) and Hao Ding (CFSA), who expressed appreciation to FAO, WHO and Codex Alimentarius partners for their support in organizing the event. They emphasized the importance of the workshop in strengthening national and international capacity to apply risk-based tools for food allergen risk assessment, as well as the relevance of the FAO/WHO-developed tools for local implementation.

Kang Zhou (FAO) followed with an overview of FAO/WHO's role in providing scientific advice to governments and FBOs. He outlined the evolution of FAO/WHO work on food allergens, the importance of moving from hazard identification to risk assessment in the field of food allergens, the available risk-based systems for food allergen risk assessments, and the importance of integrating and harmonizing these tools across borders and FBOs.

2.1.2. Session 1: An overview of food allergies in Asia

1) Session lead
Gyanendra Gongal

2) Learning objective
To introduce the food allergy and food allergen landscape in Asia.

3) Key points covered
Food allergies are a significant health issue, but an under-appreciated one in Asia. In line with this thought, there is a lack of epidemiologic studies on food allergies in Asia and often confusion between food allergies and food intolerance. Food allergens of concern may differ between countries, age groups, and communities, and about 15 percent of people with food allergies also have asthma. To better identify and subsequently provide increased protection for consumers with food allergies, the food allergy management infrastructure requires concerted efforts from policymakers, healthcare systems, and pharmaceutical companies.

From a food production standpoint, undeclared food allergen presence (culinary landmine) and unintended allergen presence (UAP) are major challenges. Priority allergenic foods may differ across countries, and challenges arise due to the informal food production and distribution system, which can rely on very small family farmers in rural areas. Additionally, food allergen issues can arise because of parallel exportation, a process in which products intended to be exclusively for the domestic market enter foreign markets (where priority food allergens may differ) through unofficial channels.

4) Discussion outcome
Participants recognized the challenges discussed in the session, especially in resource-limited settings and noted the need for practical tools and examples to support implementation of risk assessment in both clinical food allergy and for FBOs and food allergens.

2.1.3. Session 2: Introduction to food allergies and food allergens

1) Session lead
Ben Remington

2) Learning objective
To provide a foundational understanding of the disease of food allergy, risk assessment of foods as potential priority allergenic foods, and variations in severity and perceptions of severity of allergic reactions.

3) Key points covered

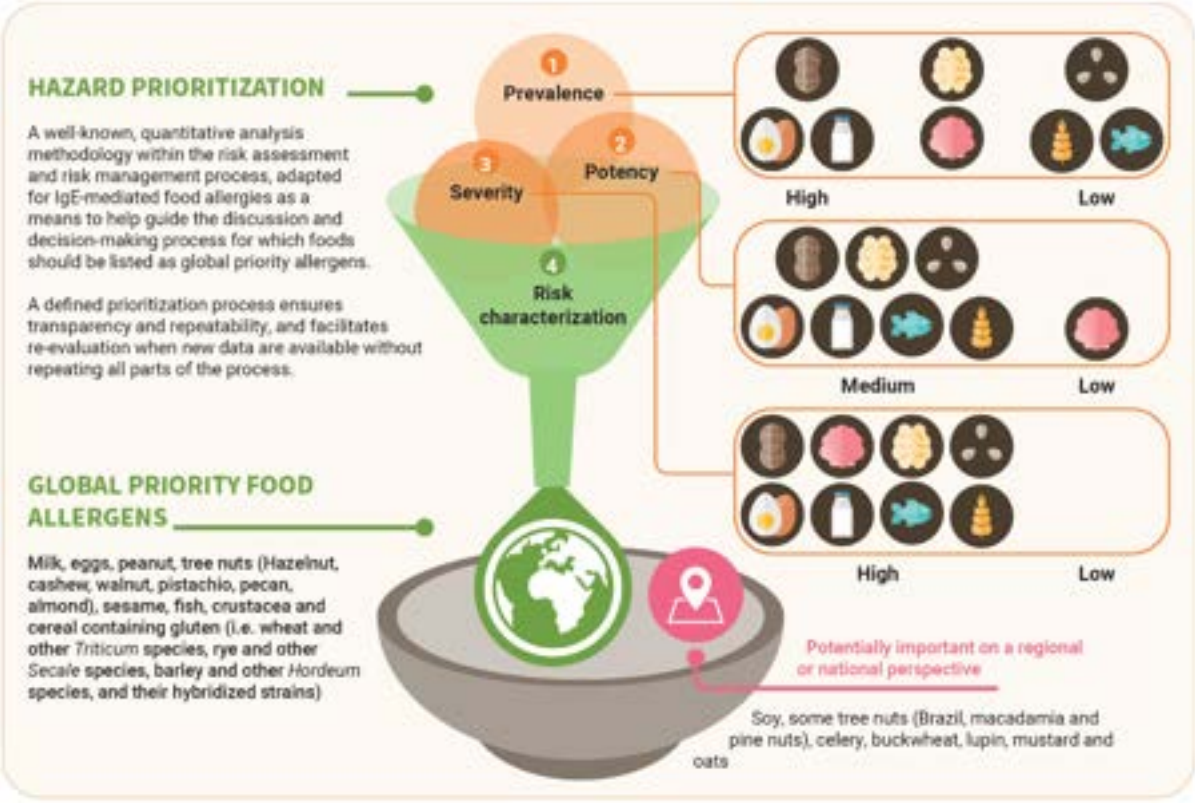
Burden of food allergy as a disease

- The clinical manifestations of food allergies were discussed, including adverse reactions to foods and their various pathways, as well as the signs and symptoms of an immunoglobulin E (IgE)-mediated food allergic reaction.
- Food allergies are a disease with high health, social, and economic impacts.
- No cure is available, and food allergic reactions can vary from mild (e.g. itchy mouth) to severe (e.g. life-threatening anaphylaxis). If not treated in a timely manner, severe reactions can be fatal.
- Lifelong avoidance of allergenic food is the main, and many times only, treatment that is available.
- There is a wide range of stakeholders active in food allergies, and communication among them is crucial to ensure the protection of consumers with food allergies.

Food allergens and priority allergenic foods

- Virtually all food allergens are proteins, although only a small percentage of the many proteins in foods are allergens (Hefle *et al.*, 1996).
- Any food that contains protein has the potential to cause allergic reactions in some individuals, and more than 160 foods identified as allergenic foods. However, a few foods or food groups are known to cause allergies more frequently than others (Hefle *et al.*, 1996).
- The original eight foods or food groups listed as priority food allergens were identified in a 1995 Technical Consultation organized by FAO (FAO, 1995).
- The original eight foods or food groups were reviewed and updated in Part 1 of the ad hoc Joint FAO/WHO Risk Assessments on Food Allergens (FAO and WHO, 2022a), with the updates now incorporated into the Codex Alimentarius General standard for the labelling of prepackaged foods CXS 1-1985 (FAO and WHO, 2024a).
    - The joint FAO/WHO expert consultation provided a systematic assessment, quantification and prioritization of risks from foods due to IgE-mediated food allergies through a science-based process comprised of three criteria (prevalence, potency, severity) (Figure 1).

Figure 1. A structured, quantitative framework for prioritization of global priority food allergens



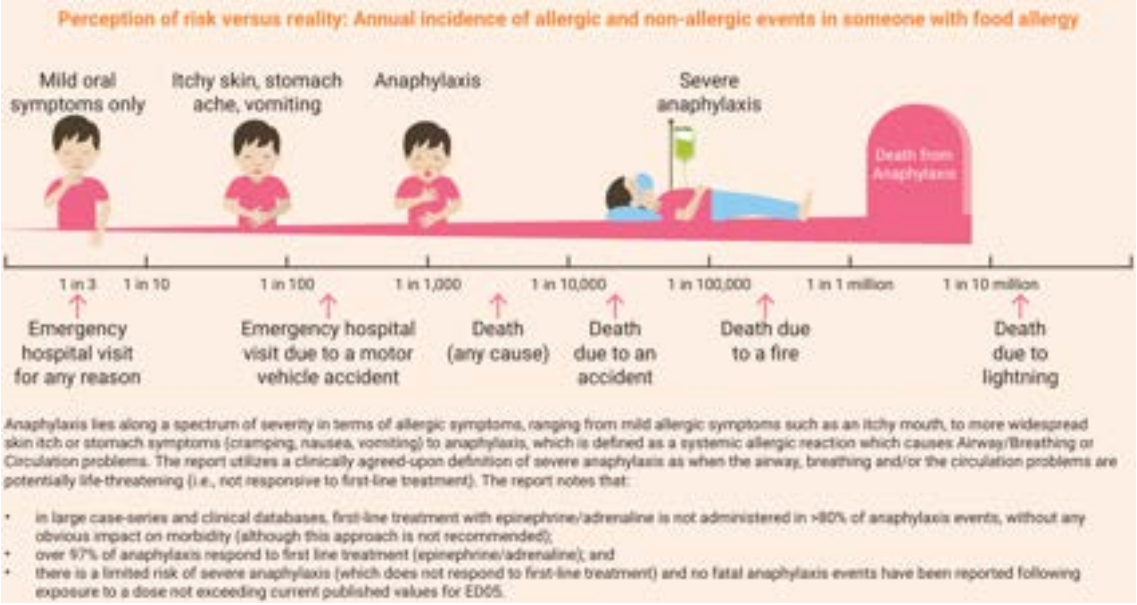
Source: FAO and WHO. 2024. In brief: Priority food allergens. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1091en

- This approach requires thorough understanding and careful consideration of the available data, and how to assess the quality of evidence and potential for biases within various studies that contain data for prevalence, potency, or severity of IgE-mediated food allergies. See Part 1 of the joint FAO/WHO expert consultation for more details (FAO and WHO, 2022a).
- The defined criteria, binning, and prioritization process in Part 1 of the joint FAO/WHO expert consultation provides transparency and repeatability of the assessment when re-evaluation of new foods or new data is deemed necessary (FAO and WHO, 2022a).

Severity of allergic reactions and perception of risk

- Severity is a highly subjective term which stakeholders use and interpret in different ways.
- Multiple factors impact the severity of a reaction.
- Fatal reactions are rare but also unpredictable.
- What if we limit exposure doses to below the ED05, the milligram protein amount or eliciting dose predicted to provoke reactions in 5 percent of the population with food allergies?
- Anaphylaxis lies along a spectrum of severity in terms of allergic symptoms, ranging from mild allergic symptoms such as an itchy mouth, to more widespread skin itch or stomach symptoms (cramping, nausea, vomiting) to anaphylaxis, which is defined as a systemic allergic reaction which causes airway/breathing or circulation problems. Part 2 of the joint FAO/WHO expert consultation utilizes a clinically agreed-upon definition of severe anaphylaxis as when the airway, breathing and/or the circulation problems are potentially life-threatening (i.e. not responsive to first-line treatment) (FAO and WHO, 2022b). The report notes that:
    - in large case-series and clinical databases, first-line treatment with epinephrine/adrenaline is not administered in > 80 percent of anaphylaxis events, without any obvious impact on morbidity (although this approach is not recommended);
    - over 97 percent of anaphylaxis respond to first line treatment (epinephrine/adrenaline);
    - there is a limited risk of severe anaphylaxis (which does not respond to first-line treatment); and
    - no fatal anaphylaxis events have been reported following exposure to a dose not exceeding current published values for ED05 (Figure 2).

Figure 2. Perception of risk versus reality: Annual incidence of allergic and non-allergic events in someone with food allergy



Source: FAO and WHO. 2024. In brief: Food allergen reference doses. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1093en

4) Discussion outcome

Participants gained a deeper understanding of food allergies and greater awareness of allergens as hazards that need to be controlled. The range of stakeholders active in food allergies was discussed, as were the severity of allergic reactions and perceptions of risk. Communication between stakeholders was discussed, and its importance was highlighted to ensure a clear understanding and consistent protection of consumers with food allergies.

2.1.4. Session 3: Overview of FAO/WHO work

1) Session lead
Kang Zhou

2) Learning objective
To understand the FAO/WHO role in providing scientific advice to governments and FBOs, as well as the evolution and rationale for their work on food allergens.

3) Key points covered
Requests for FAO/WHO scientific advice on food allergens have been made by CCFH and CCFL. Over the last six years, the joint FAO/WHO expert consultation on risk assessment of food allergens has been convened and has produced five reports:

- Part 1 (Figure 1), full report: https://doi.org/10.4060/cb9070en
- Part 2 (Figure 3), full report: https://doi.org/10.4060/cc2946en
- Part 3 (Figure 4), full report: https://doi.org/10.4060/cc6081en

- Part 4 (Figure 5), full report: https://doi.org/10.4060/cc9554en
- Part 5, full report: https://doi.org/10.4060/cc8387en

These publications provide scientific advice and risk-based frameworks for the assessment of food allergens.

Additionally, two-page brochures are available for each of the reports in English, Arabic, Chinese, French, Russian and Spanish. They can be found at: https://www.fao.org/food-safety/scientific-advice/food-allergens/en

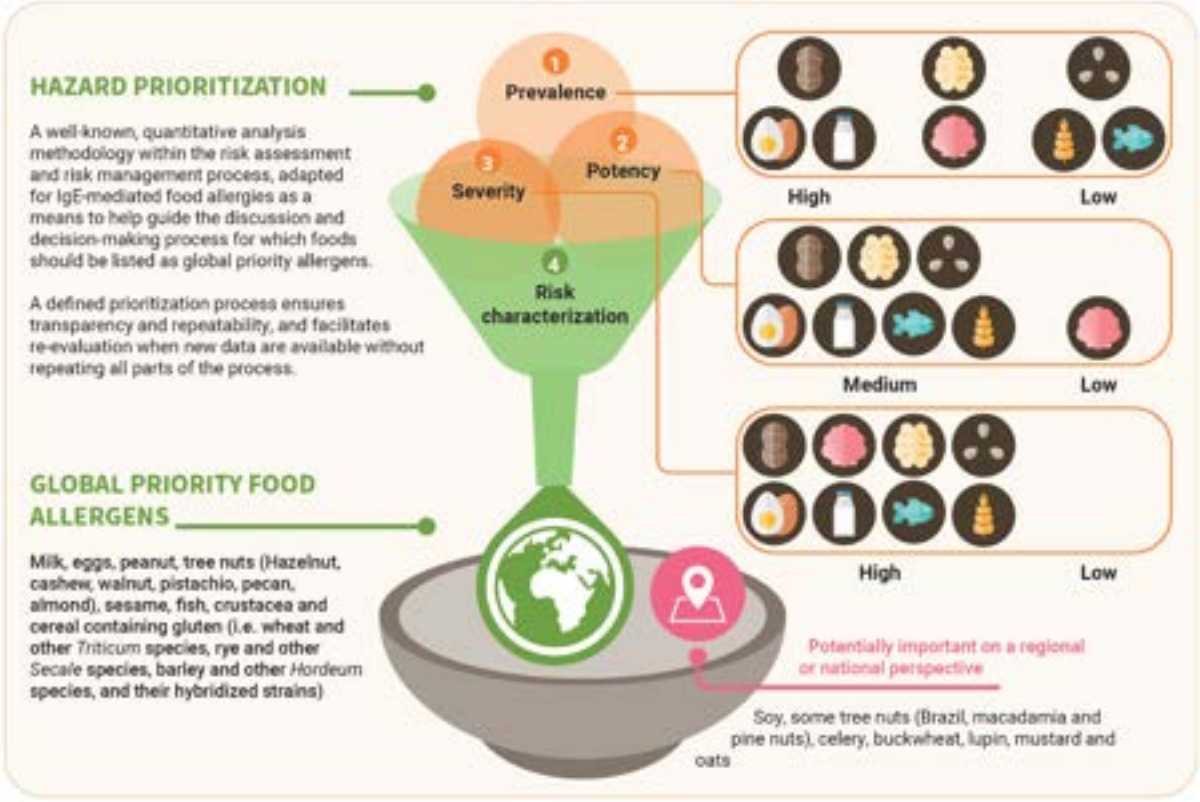
The reports of the Joint FAO/WHO Expert Consultations provide the scientific background for the development of risk assessments conducted for the purposes of food allergen labelling or to determine product safety. These reports were made available for CCFL, CCFH, CCMAS or other committees to inform them the risk assessment outcome for developing their standards, guidelines and codes of practice.

Kang Zhou also highlighted FAO/WHO's capacity-building activities in the area of food allergen risk assessment, videos produced to increase awareness, and discussed the recent joint FAO/WHO expert consultation on risk assessment (FAO and WHO, 2025a) and the future joint FAO/WHO expert consultation on an RfD for gluten (FAO and WHO, 2025b).

4) Discussion outcome

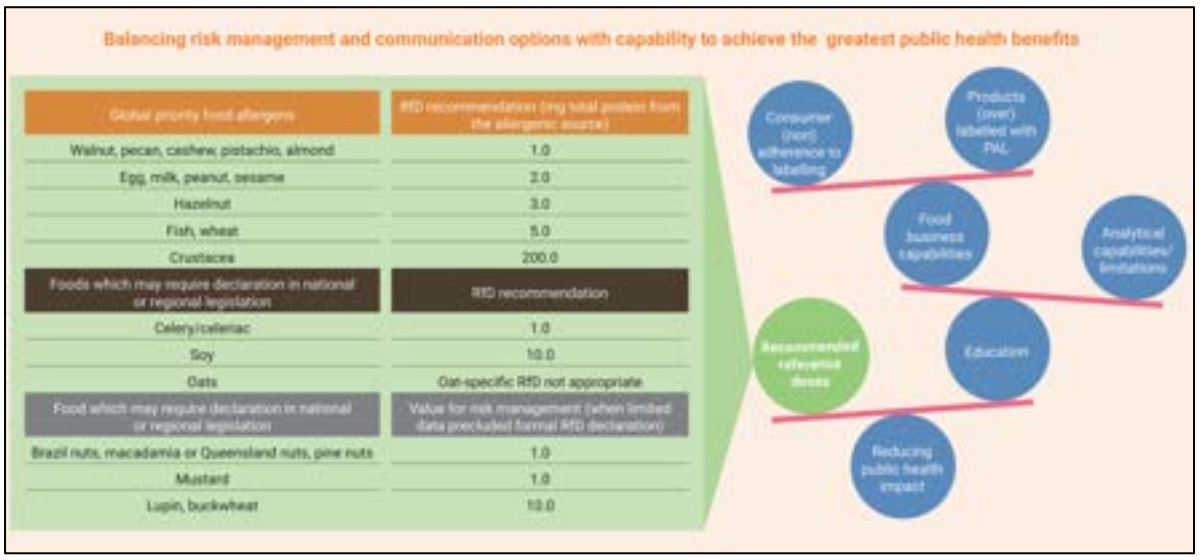
Participants acknowledged the value of the FAO/WHO reports and risk assessment frameworks developed and noted the need for practical tools and examples to support implementation of any changes to Codex Alimentarius guidelines, especially in resource-limited settings.

Part 1: validated and updated the list of foods and ingredients considered priority food allergens (Figure 1)



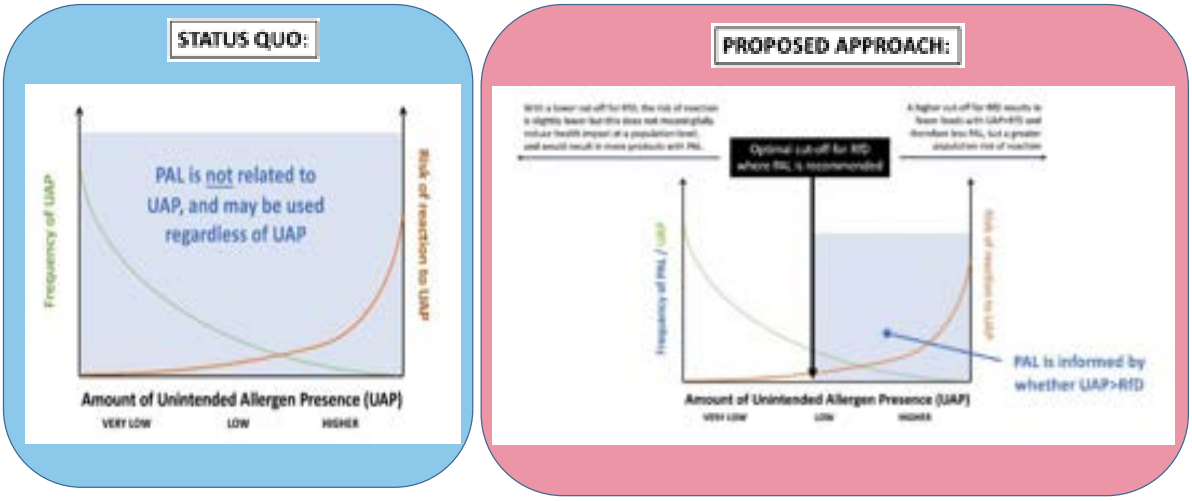
Source: FAO and WHO. 2024. In brief: Priority food allergens. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1091en

3. Part 2: recommended reference doses (RfDs), based on health-based guidance values (HBGVs) for each of the priority allergenic foods and with considerations for real-world capabilities to achieve the greatest public health benefit



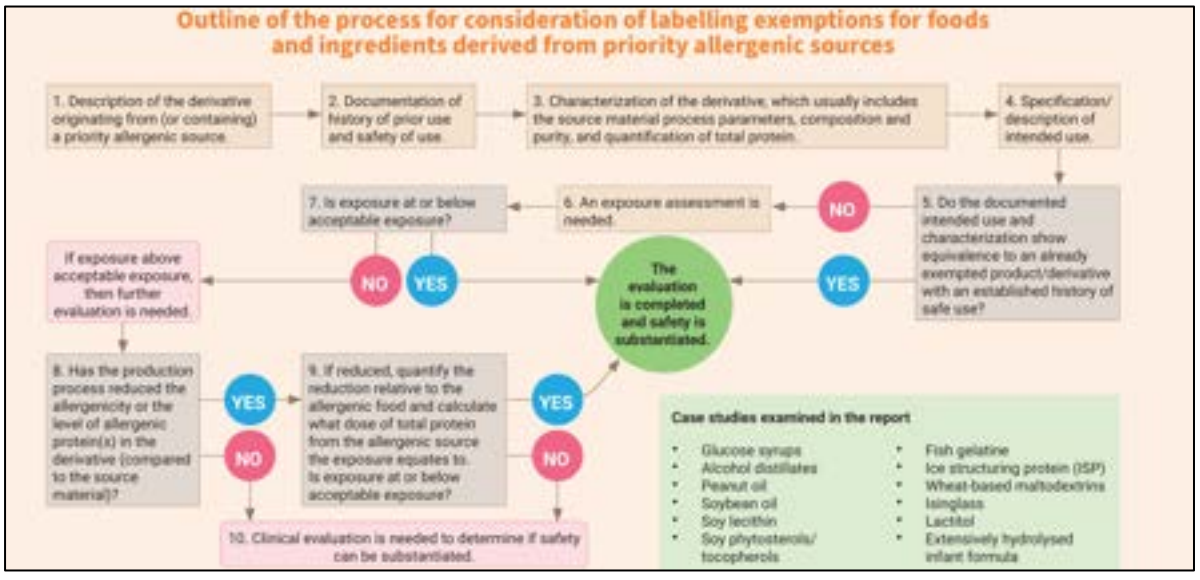
Source: FAO and WHO. 2024. In brief: Food allergen reference doses. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1093en

Figure 4. Part 3: recommended a risk-based framework for precautionary allergen labelling (PAL) utilizing a basis of good food allergen management practices, grounded in the *Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)*, and risk assessment utilizing the previously recommended RfDs



Source: FAO and WHO. 2023. *Risk assessment of Food Allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens*. Meeting report. Rome, FAO. https://doi.org/10.4060/cc6081en

Figure 5. Part 4: recommended a risk-based framework for assessing potential exemptions from mandatory food allergen declaration requirements, utilizing a weight of evidence approach in combination with an exposure criterion (RfD/30), and potentially clinical studies to establish safety



Source: FAO and WHO. 2024. In brief: Exemptions from mandatory food allergen declaration. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1096en

2.1.5. Session 4: Introduction to food allergen risk assessment

1) Session lead
Ben Remington

2) Learning objective
To provide the core concepts of food allergen risk assessment and effective food allergen management, and to detail how to estimate exposure in different risk assessment scenarios.

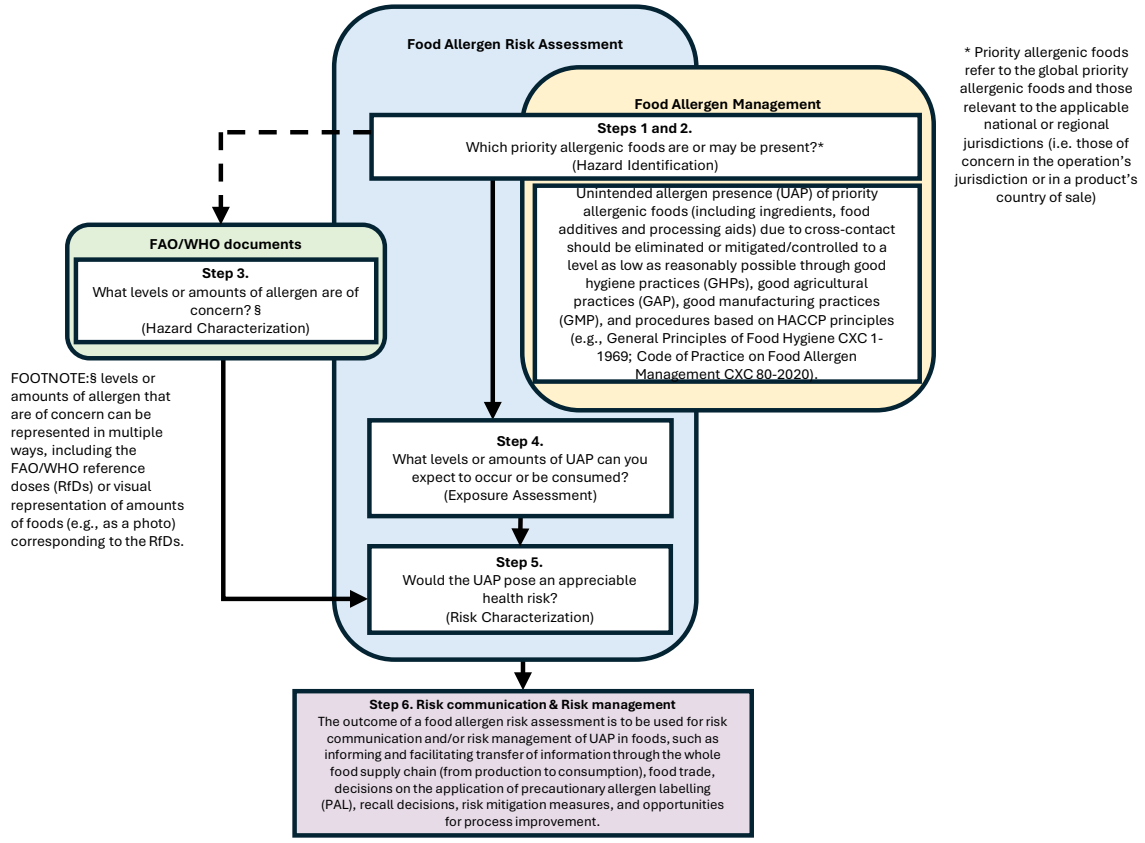
3) Key points covered
Food allergens are a distinct type of hazard

- Food allergen hazards present unique considerations compared to traditional chemical, biological/microbial, or physical hazards in a food facility.
- Differentiating food allergens from other hazards in risk assessment and risk management will improve food safety.
- Treatments lethal for pathogenic microorganisms, such as heating, high pressure processing and so forth generally do not destroy allergenic proteins.
- Processes that degrade proteins, such as enzymatic or acid hydrolysis, should not be relied upon to eliminate or completely destroy allergenic proteins.
- Food allergens do not "grow".
- Heat does not "kill" allergens/proteins.
- Physical removal of allergen residue is critical to minimize food allergen cross contact.

General principles for food allergen risk assessment (Figure 6)

- Which priority allergenic foods are or may be present? (Hazard identification)
    - What levels or amounts of food allergens are of concern? (Hazard characterization)
- What levels or amounts of UAP can you expect to occur or be consumed? (Exposure assessment)
- Would the UAP pose an unacceptable level of risk? (Risk characterization)

Figure 6. Summary representation of a food allergen risk assessment framework which enables risk communication and informed risk management decision-making



Source: Adapted from FAO and WHO. 2024. Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens – guidance for risk assessment. Summary and Conclusions. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd6046en

Food allergens should be controlled through appropriate food safety management systems.

- This includes compliance with existing Codex documents (e.g. codes of practice), good food 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.
- Food allergens need to be managed throughout the supply chain and production process.
- Unintended allergen presence (UAP) of priority allergenic foods (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 hazard analysis and

critical control points (HACCP) principles (e.g. *General Principles of Food Hygiene CXC 1-1969*; *Code of Practice on Food Allergen Management CXC 80-2020*).

- Food allergen risk assessments support informed decisions and communication through the supply chain.
- Consistent food allergen risk assessment and risk management will improve food safety and public health.
- It is important that FBOs are able to identify the allergenic nature of the foods, including ingredients and processing aids they handle and take steps to manage any potential presence of undeclared food allergens.
- The Codex Alimentarius *Code of Practice on Food Allergen Management (CXC 80-2020)* (FAO and WHO, 2020) provides guidance to FBOs, including primary producers, for a proactive approach to:
    - ensure the correct food allergen label is applied to prepackaged foods;
    - prevent or minimize the potential for food allergen cross contact that is of risk to the consumer with a food allergy;
    - prevent or minimize the potential for undeclared food allergens being present in a food due to errors arising in the supply chain; and
    - ensure that accurate information can be provided to consumers at point of sale when the food is not prepackaged.
- Food business operators are encouraged to have documented (i.e. written), detailed food allergen management policies and procedures specific to the food business (CXC 80-2020). Implementing food allergen management policies and procedures, and compliance with these:
    - allows a business to demonstrate it is taking all necessary steps to eliminate or reduce the likelihood of a food allergen being unintentionally present in a food;
    - increases accuracy of allergenic ingredient declarations;
    - provides an opportunity for businesses to demonstrate adequate skills and knowledge in food allergen management; and
    - reduces the risk to the consumer with a food allergy from the presence of an unintended food allergen.

Box 1. Highlights and excerpts from the Codex Alimentarius *Code of Practice on Food Allergen Management CXC 80-2020*

- Personnel engaged in food operations should have sufficient training in food allergen management to implement measures to prevent or minimize food allergen cross contact and ensure the correct label with appropriate allergen information is applied to food.
- Consumers should have access to adequate and accurate information on the allergenic nature of the food. This should ensure that those with allergies can avoid allergenic foods and ingredients.
- The Code of Practice raises awareness regarding potential factors contributing to potential unintended or undeclared food allergen exposures during harvesting, handling, storage and transportation, as well as during the manufacturing process.
- The Code of Practice includes sections and practices to prevent or minimize the potential food allergen cross contact during:
    - primary production;
    - design and facilities;
    - control of operation;
    - maintenance and sanitation;
    - personal hygiene;
    - transportation;
    - product information and consumer awareness; and
    - training.
- For example:
    - Where the introduction of a food allergen may adversely affect the allergen profile of food at later stages of the food chain, primary production should be managed in a way that reduces the likelihood of introducing such food allergens. This includes assessing segregation and cleaning practices for previous crops in the growing area and close proximity, shared equipment, storage facilities, and transport vehicles.
    - Manufacturers should identify steps in the operation that are critical to ensuring food allergens are properly declared, including reviewing recipes and labels on compound ingredients, ensuring that the correct ingredients are used, and ensuring that the correct product is packed in the correct package (i.e. with the correct label). When reviewing recipes, product enhancement processes, such as egg washes on baked products for glossy finish, should also be included.

- Establishment design should prevent or minimize the potential for food allergen cross contact with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.
    - Food manufacturing facilities commonly handle multiple food allergens, frequently on the same equipment. Where feasible, manufacturers should consider the use of dedicated lines, containers, utensils and tools.
- The unintentional presence of food allergens in food is prevented or minimized by taking preventive measures through good hygiene practices (GHPs) and hazard analysis critical control points (HACCP)-based controls at appropriate stages in the operation.
- If the same production area is used for foods with different food allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles (e.g. process foods that do not contain allergens before foods with allergens).
- Where possible, allergenic ingredients should be added as late in the production process as possible, or as far downstream as possible in the processing line (e.g. closest to the filling and packaging equipment), to minimize the amount of equipment in the production area that comes in contact with the food allergen.
- "Allergen mapping" (a diagram that identifies where food allergens are stored, handled and prepared on site, overlaid with the processes involved) can be useful in identifying areas where controls should be applied to prevent or minimize food allergen cross contact.
- Effective cleaning procedures should be in place to clean shared equipment, shared containers, shared utensils, and shared tools before using them for food with a different food allergen profile.
- Cleaning procedures to remove food allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools, and materials used for cleaning.
- Equipment may need to be disassembled, where feasible, to adequately remove food allergen residues. However, if some equipment cannot be disassembled, the food allergen management programme should take this into account.
- Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible and appropriate, through an analytical testing programme.

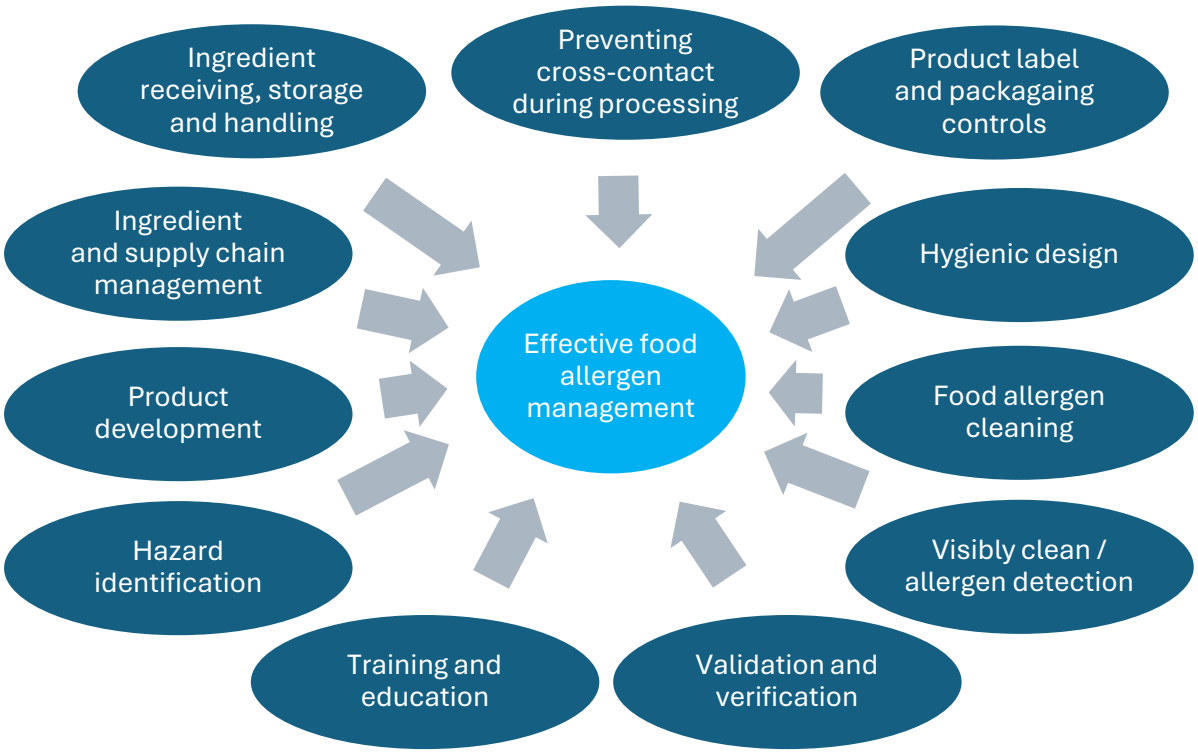
- Minimizing food allergen cross contact also includes assessment of and periodic review of:
  - rework and work-in-process;
  - application of product labels;
  - monitoring and verification; and
  - product development and change.
- Information that may be helpful in assessing food allergen cross-contact risk includes:
  - food allergens present in the facility;
  - food allergens that share the same processing line;
  - the nature of the food allergen (i.e. whether the food itself is an allergenic food, derived from an allergenic food, or the allergenic food is a component in an ingredient);
  - whether food allergens are, or may be, present, as notified by the supplier;
  - whether the food allergen is a particle, powder, liquid or paste;
  - the processing steps where the food allergen is used;
  - ease of preventing food allergen cross contact between processing lines;
  - ease of cleaning the equipment used to process foods with different food allergen profiles; and
  - the maximum amount of a food allergen due to allergen cross contact (if the information is available).
- Incoming material requirements to ensure appropriate labelling and minimize food allergen cross-contact risks are as follows:
  - Retail and food service operators should purchase ingredients for which the food allergen profile is known (e.g. packaged foods that list all ingredients).
  - Manufacturers should ensure that their suppliers have good food allergen management practices to prevent or minimize the likelihood of food allergen cross contact between foods with different allergen profiles.
  - Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information or on the label of the finished product (e.g. milk in a spice blend ingredient used in a food).
  - Suppliers should have processes in place to manage food allergen labelling.

- Manufacturers should have programmes in place to assess the food allergen control programmes of suppliers when necessary (e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's food allergen management plan, including food allergen cross-contact controls and cleaning programmes).

- Food business operators should:
  - identify any steps in their operations that pose the likelihood of food allergen cross contact, assess the level of risk to the consumer with a food allergy at those steps and ascertain the ones that are critical;
  - implement effective food allergen management procedures to prevent or minimize food allergen cross contact at those steps;
  - monitor, and when appropriate document, food allergen management procedures to ensure their continuing effectiveness;
  - review food allergen management procedures periodically, particularly when the operations change;
  - ensure suppliers are familiar and comply with food allergen specifications;
  - notify customers in a timely manner of any changes to the food allergen profile of the product; and
  - ensure personnel are aware of and follow food allergen management procedures.

Source: FAO and WHO. 2020. *Codex Alimentarius, Code of Practice on Food Allergen Management For Food Business Operators - CXC 80-2020*. Rome, FAO. https://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

Figure 7. Effective food allergen management is a multifaceted process



Source: Authors' own elaboration.

What levels or amounts of food allergen are of concern? (Hazard characterization)

The joint FAO/WHO expert consultation recommended RfDs for utilization within food allergen risk assessments (Figure 3, Table 1). These RfDs are small, milligram amounts of total protein from the allergenic food which meet the criteria for health-based guidance values (HBGV) and "reflect a range of exposure without appreciable health risk" (FAO and WHO, 2022b [page 93-94], 2023b [page 7]).

Table 1. Joint FAO/WHO expert consultation recommended reference doses (RfDs)

Global priority allergenic foods	RfD Recommendation (mg total protein from the allergenic food)
Walnut, pecan, cashew, pistachio, almond	1.0
Egg, milk, peanut, sesame	2.0
Hazelnut	3.0
Fish, wheat *	5.0 *
Crustacea	200
Foods which may require declaration in national or regional legislation	**RfD Recommendation (mg total protein from the allergenic food)**
Celery/celeriac	1.0
Soy	10.0
Oats	Oat-specific RfD not appropriate
Foods which may require declaration in national or regional legislation	**Value of risk management (when limited data precluded formal RfD declaration) (mg total protein from the allergenic food)**
Brazil nuts, macadamia or Queensland nuts, pine nuts	1.0
Mustard	1.0
Lupin, buckwheat	10.0

Notes: * During preparation of this workshop report, an RfD of 4 mg gluten was recommended by the joint FAO/WHO expert consultation (FAO and WHO, 2025b) for risk assessment of unintended presence of gluten and cereals containing gluten. The RfD of 4 mg gluten also aligns with the previously recommended 5.0 mg total protein from wheat, after conversion from mg total protein from wheat to mg gluten.

Source: Table adapted from FAO and WHO. 2024. In brief: Food allergen reference doses. In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1093en

- In order to conclude that the recommended RfDs met the criterion of "exposure without appreciable health risk" (FAO and WHO, 2022b, page 43–60) the report took a number of factors into consideration, including:
    - the nature of symptoms which might be experienced at potential reference doses, and by what proportion of the food-allergic population;
    - the proportion of reactions occurring at potential RfDs which would be defined as anaphylaxis;
    - the reproducibility of these data and their applicability to "real world" food allergen exposure; and
    - the impact of co-factors such as exercise, stress, concomitant medication, and so forth on reaction severity.
- It is recommended that the RfD values should be expressed as milligrams of total protein from the allergenic food, since the (allergenic) protein constitutes the hazard to individuals with food allergies.
- The RfDs are envisioned to be used for risk assessment management of UAP in foods, such as application in the management of risk-based precautionary allergen labelling (PAL), decisions on product safety in recall situations, trade rejection, as well as in advice to people with food allergies for managing their individual food allergies.

- If another type of risk assessment was needed, such as for assessment of potential exemptions from mandatory food allergen declaration, an additional safety factor or margin of exposure (MoE) should be applied to the RfDs (i.e. RfD/30) for use within these frameworks. See Section 2.2 of this report and Part 4 of the joint FAO/WHO expert consultation for more information (FAO and WHO, 2024c).
- The RfDs are not appropriate, nor intended to be used to define "allergen-free" labelling. Additional guidance may be warranted in this area.

What levels or amounts of unintended allergen presence (UAP) can you expect to occur or be consumed? (Exposure assessment)

- Selection of an approach to evaluate how much UAP may occur depends on the nature of the food allergen source (e.g. particulate vs. dispersed, allergenic food vs. compound ingredient, and so forth), the type of evidence available about the potential cross contact (e.g. visual observations, product composition and production data, food allergen-specific analysis, and so forth), and the specifics of the UAP being assessed (e.g. UAP in an ingredient, UAP in final product to be consumed, carryover estimates for UAP due to shared equipment, and so forth).
- Often, a combination of types of evidence will be available and utilized together to achieve the most informative risk assessment.
- Exposure estimates are comprised of two major inputs:
  - the amount of food consumed; and
  - the concentration of allergenic protein in the food being consumed (from composition data, product formulation, and concentration estimated or analysed during cross-contact assessment).
- The FBO already has evidence that can be used to estimate the amount of UAP expected to occur, including product formulations and ingredient specifications.
  - If additional analytical data needs to be collected, it may take different forms, depending on the details of the product and process being evaluated. 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 food allergen-specific methodology (e.g. immunoassay results).

- A number of considerations can influence the UAP assessment and subsequent concentration estimate, including but not limited to:
    - the form of allergenic food or ingredient and subsequent UAP (e.g. powder, liquid, paste, lump or particulate); and
    - the distribution of allergenic food or ingredient and subsequent UAP:
        - readily dispersible, uniform, homogeneous
        - clumped, nonuniform, isolated, heterogeneous
            - Consideration: Will the cross contact remain intact (lump or particulate exposure) or will it be redispersed throughout a larger batch of the product due to specific processes such as mixing or grinding?
    - composition of allergenic food or ingredient and subsequent UAP:
        - Composition is 100 percent from the allergenic food.
        - Recipe composition is < 100 percent from the allergenic food.
        - What is the inclusion rate for the ingredient in question? Is it a sub-ingredient (i.e. the ingredient in question is part of a formulation included as part of another final formulation)?
            - For example, the ingredient in question is part of a seasoning mixture, where the seasoning mixture is further used in a ready-to-eat meal.
        - What is the approximate protein content (%) for the ingredient in question? What is the usage rate / usage r?
- It should be noted that analytical data in isolation is insufficient to complete an assessment.
    - If food allergen-specific analysis is conducted, the analytical test methods must have a demonstrable fitness-for-purpose and should be validated to demonstrate that they are suitable for their end use (i.e. that they have the intended specificity, accuracy and precision).
    - The test methods should provide a quantitative result for use in risk assessment, ideally reporting in “mg of protein from the allergenic food kg of food analysed” (FAO and WHO, 2022b [page 95]; FAO and WHO, 2023a [Pages, 44–46]) or providing conversion factors to reach such a unit.
    - Analytical testing (e.g. food allergen-specific ELISA testing) is not recommended for evaluation of particulates, given the sporadic nature in which UAP may occur.
- If particulate cross contact is being assessed, gravimetric analysis (e.g. weighing of particulates) can be utilized, in combination with:
    - the composition of the particle(s) (e.g. peanut piece, dough containing peanut butter); and
    - the number of particulates in a single eating occasion or package to conservatively estimate exposure.

- Food consumption estimates utilized for food allergen risk assessments and food allergen risk management programmes should:
    - be conservative in nature;
    - be based on consumption at a single eating occasion;
    - not be solely based on the serving size;
    - consider how the food is packaged for sale;
    - consider the traditional use of the food; and
    - consider what is reasonably consumed by one person at a single eating occasion.

Exposure estimate utilizing visualizations and/or calculations

- Examples and case studies were presented to the group with an emphasis on the decision-making process for selecting a consumption amount with an exposure assessment and how to perform exposure calculations. Exposure assessment was discussed for particulate forms of food allergens, readily dispersible forms of food allergens, and how the composition of the food being consumed (e.g. milk, or a dough containing milk) will impact an exposure assessment.
- To enable estimating exposure or other calculations, conversions from total food or allergenic material to total protein from the allergenic food are likely to be needed.

    - These conversions can be done with the following calculation:

Concentration of the allergenic material in the food (in mg/kg or %)	X	**Protein fraction in that ingredient** (%)	=	**Concentration of protein of the allergenic food in the food being consumed** (in mg total protein from the allergenic food per kg food)
Examples…				
100% roasted peanuts	X	**25% protein** (roasted peanuts contains 25% protein on supplied ingredient information)	=	**25% peanut protein**
100% roasted peanuts	X	**250 000 mg/kg peanut protein** (roasted peanuts contain 25% protein on supplied ingredient information, 25% equates to 250 000 mg/kg)	=	**250 000 mg/kg peanut protein** (in mg total protein from the allergenic food per kg food)
50 mg sesame flour/kg food	X	**20% protein** (sesame flour contains 20% protein on supplied ingredient information)	=	**10 mg sesame protein/kg food** (in mg total protein from the allergenic food per kg food)

- Particulate forms of food allergens
    - Visual representation of amounts of foods and particulates (e.g. such as a photo) corresponding to the FAO/WHO RfDs is a valuable tool for use in risk assessment.
        - Visual observation of the material can be made by comparing the particulate to the visualizations corresponding to the FAO/WHO RfDs.
        - It is indicated in the summary and conclusions from the recent Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens – guidance for risk assessment, that the full report will include visual representation of amounts of foods (e.g. such as a photo) corresponding to the FAO/WHO RfDs.
        - If the largest particulate collected is smaller than the visualization corresponding to the FAO/WHO RfDs, the estimated exposure from that particulate would not necessarily pose an appreciable health risk. Considerations must still be given regarding any evidence for multiple particulates to be present or not present in a consumption amount before determining if multiple particulates are likely to be consumed and if they would exceed the RfD, thus posing an appreciable health risk.
        - If the largest particulate exceeds the visualization corresponding to the FAO/WHO RfDs, the estimated exposure from that would pose an appreciable health risk.
    - Alternatively, exposure estimates for particulate forms of allergenic foods and ingredients can also be calculated using the following equation:

Size or mass of particulate (in mg)	X	**Composition of the particulate(s)** (% ingredient in food, % protein in ingredient)	X	**Number of particulates in a single eating occasion**	=	**Particulate estimated exposure** (mg total protein from the allergenic food)
Examples…						
100 mg peanut particulate	X	**25% protein**	X	**1 particulate in a single eating occasion**	=	**25 mg peanut protein**
100 mg dough particulate	X	**0.75% peanut protein in dough** (3% peanut butter, peanut butter is 25% peanut protein)	X	**1 particulate in a single eating occasion**	=	**0.75 mg peanut protein**

- Readily dispersible, uniform, homogeneous forms of food allergens
    - Estimated exposures for readily dispersible, uniform forms of allergenic foods and ingredients can be calculated using the following equation:

Amount of food consumed (in kg)	X	**Concentration of allergenic protein in the food being consumed** (in mg total protein from the allergenic food per kg food)	=	**Estimated exposure** (mg total protein from the allergenic food)
Examples…				
0.050 kg (50 g)	X	**29 mg milk protein per kg food**	=	**1.45 mg milk protein** (mg total protein from the allergenic food)
0.150 kg (150 g)	X	**50 mg peanut protein per kg food** (in mg total protein from the allergenic food per kg food)	=	**7.5 mg peanut protein** (mg total protein from the allergenic food)

- If a concentration of allergenic foods or ingredients is known, it may be of interest to consider the amount of food required to be consumed to reach an exposure equal to the RfD. A follow-up question is, is it feasible to consume this amount of product?
    - The amount of food, with a specified concentration of food allergen, required to be consumed to reach an exposure equal to the RfD may be calculated using the following equations.
    - These may also be referred to as reverse or backward calculations by some.

Reference Dose (RfD) (mg total protein from the allergenic food)	÷	**Concentration of allergenic protein in the food being consumed** (in mg total protein from the allergenic food per kg food)	=	**Amount of food required to be consumed to reach an exposure equal to the RfD** (in kg)
Example…				
2 mg milk protein (mg total protein from the allergenic food)	÷	**3 mg milk protein per kg food** (in mg total protein from the allergenic food per kg food)	=	**0.667 kg** (667 g)

- The amount of food, with a specified composition or product formulation (%) of total protein from an allergenic food, required to be consumed to reach an exposure equal to the RfD may be calculated using the following equations.

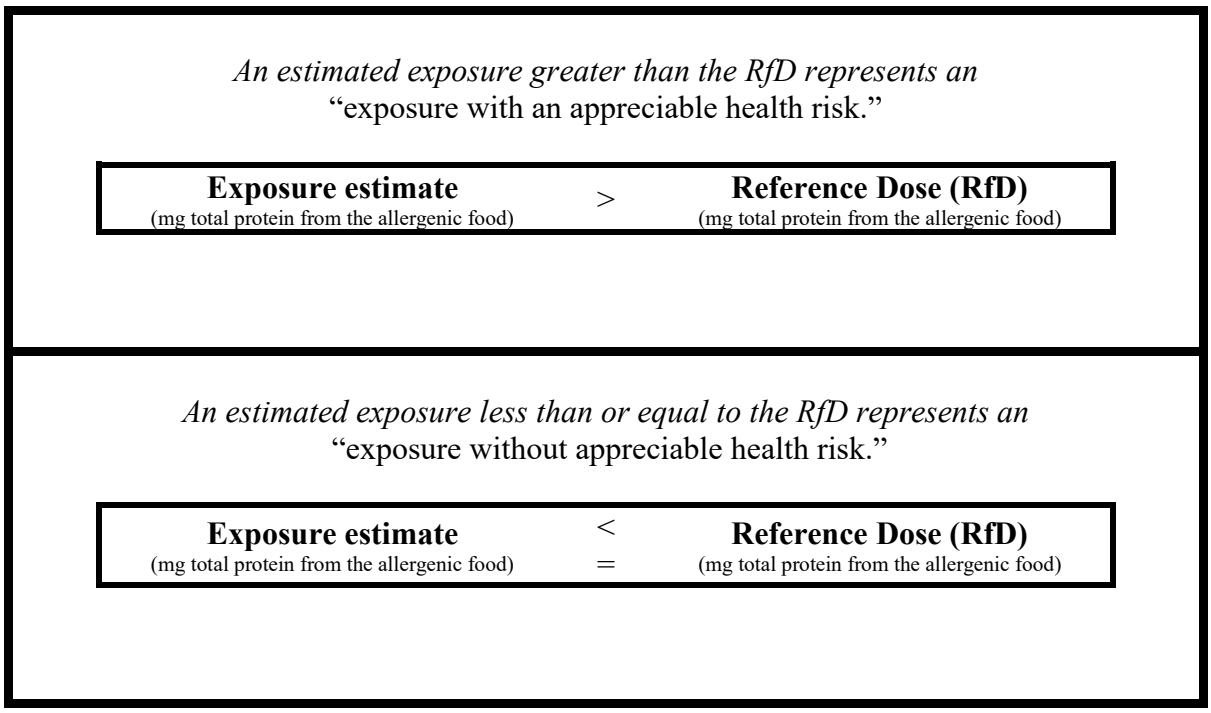
Reference Dose (RfD) (mg total protein from the allergenic food)	÷	**Composition of the food being consumed with respect to the allergenic protein of interest** (% ingredient in food, % protein in ingredient)	=	**Amount of food required to be consumed to reach an exposure equal to the RfD** (in kg)
Examples…				
2 mg sesame protein (mg total protein from the allergenic food)	÷	**0.00008% sesame protein in ready to eat meal** (0.2% seasoning in dish, 2% sub ingredient in seasoning, 2% sesame protein in sub ingredient,) (0.00008% equates to 0.8 mg/kg)	=	**2.5 kg** (2 500 g) (2 500 000 mg)
2 mg peanut protein (mg total protein from the allergenic food)	÷	**0.75% peanut protein in dough** (3% peanut butter, peanut butter is 25% peanut protein) (0.75% equates to 7 500 mg/kg)	=	**0.000267 kg** (0.267 g) (267 mg)

- It may also be of interest to consider the amount of carryover of prior recipe (kg) required in a specified equipment size to reach an exposure estimate equivalent to the RfD in an estimated consumption amount. A follow-up question is: Is it feasible to have that much carryover when GHPs/GMPs are in place? This may be calculated using the following equations.
- These equations may also be referred to as reverse or backward calculations by some.

$\frac{\left(\frac{RfD\ (mg\ protein)}{Consumption\ amount\ (kg)} \times Next\ batch\ (kg)\right)}{\substack{Percentage\ (\%)\ total\ protein \\ from\ the\ assessed\ priority \\ allergen\ in\ prior\ recipe}} \times \frac{1\ kg}{1\ 000\ 000\ mg} =$	**Amount of carryover of prior recipe (kg) due to shared equipment required to remain in the next batch to reach an exposure estimate equivalent to the RfD in an estimated consumption amount**
Example	
$\frac{\left(\frac{2\ mg\ protein\ RfD}{0.030\ kg} \times 1000\ kg\right)}{\substack{0.05\%\ total\ protein \\ from\ the\ assessed\ priority \\ allergen\ in\ prior\ recipe}} \times \frac{1\ kg}{1\ 000\ 000\ mg} =$	133 kg carryover of prior recipe required to remain in the next batch of 1 000 kg to reach an exposure estimate equivalent to RfD of 2 mg protein in an estimated consumption of 30 g. 133 kg is a visible amount of food! Is it feasible to have that much carryover when GHPs/GMPs are in place?

Would the UAP pose an unacceptable level of risk? (Risk characterization)

- In this step, context is placed around the information gathered throughout the prior parts of the assessment to produce an overview of the assessed risk.
- Depending on the situation, questions may arise during the risk characterization step of a risk assessment which could provide further context for the overall assessment. These questions could include, but are not limited to the following:
    - Is the estimated exposure greater than the RfD?
    - Is the expected level of UAP above, at, or below the RfD?
    - How does visual observation of the particulate material compare to the visualizations corresponding to the RfD?



Source: Author own elaboration

- If working from a backward or reverse calculation to determine the amount of food required to be consumed to reach an exposure equal to the RfD or the amount of carryover of prior recipe (kg) required in specified equipment size to reach an exposure estimate equivalent to the RfD in an estimated consumption amount, questions could include but are not limited to:
    - Is it feasible to consume this amount of product?
    - Is it feasible to have that much carryover when GHPs/GMPs are in place?
- If conducting a risk assessment for potential application of PAL, PAL should only be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level for a food allergen based on the RfDs (FAO and WHO, 2023a). This framework utilizes an iterative process to highlight the need to investigate all reasonable risk mitigation options if a risk is identified at the first review.

- For ingredient suppliers, it is necessary to ensure that the captured information is able to be summarized and communicated clearly for use by a following party for their risk assessments and/or in dialogues regarding product specification requirements.

4) Discussion outcome

- All participants were quite interested in knowing how to assess "How clean is clean enough?" This topic was raised by all stakeholders and was asked in different ways across multiple questions. It was acknowledged that these assessments are done on a case-by-case basis, and multiple concepts were discussed, including the importance of visibly clean equipment within a food allergen risk assessment. Participants were directed to the *Code of Practice on Food Allergen Management for Food Business Operators (CXC 80-2020)*, which states:

> Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate food allergens and thereby prevent or minimise food allergen cross-contact. The validation process should be specific to the food allergen, process, and product matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible and appropriate, through an analytical testing program (FAO and WHO, 2020, pg. 16).

- It was noted that the use of any testing done to verify the efficacy of cleaning (e.g. surface swabs and rinse waters) will not lead to quantitative data for use as an input in your exposure assessment. The results from testing rinse samples or surface swabs will only verify that the cleaning processes are effectively removing food allergens.
- The questions regarding cleaning verification and testing of surface swab prompted additional conversations regarding the importance of moving from hazard to risk. It was understandable that some who have worked predominantly in hazard-based systems for food allergen management were initially hesitant to move to a risk-based system for food allergen assessments and management, even though participants agreed that risk-based assessments were the future.
- Participants acknowledged it can be difficult to determine when analytical testing is appropriate and if it is appropriate, which analytical test to use. It was also highlighted that potential specific needs for analytical testing and understanding of the product being tested differed per stakeholder (e.g. FBOs or national authorities), which can influence the ability to select a fit-for-purpose test and the eventual analytical test results.

- All participants were interested in how to estimate the amount of food consumed per eating occasion. There is a need for practical guidance and harmonization of these estimates in a number of food allergen risk assessment settings, but especially for foods produced in or exported to countries with potentially different eating habits.
- The importance of training and capacity building was highlighted, particularly for small-scale producers and inspectors.
- Participants acknowledged the value of the Codex Alimentarius guidelines but noted the need for practical tools and examples to support implementation, especially in resource-limited settings.

2.1.6. Session 5: Case studies

1) Session lead
Ben Remington

2) Learning objective
To conduct real-world exposure estimates for both readily dispersible (e.g. powder, liquid, paste) and particulate forms of allergenic foods, and apply the results within a risk assessment.

3) Session structure and key points covered
The case studies were selected for participants to conduct exposure assessments requiring considerations for the concentration of protein from the allergen in the food being eaten, the amount of food consumed, the form of food, the size / mass of a particulate, and the composition of the food being consumed (e.g. hazelnut piece, dough containing whole egg powder).

Participants worked in groups to stimulate discussion.

The first round of exposure assessments focused on the calculations to estimate exposure. Participants were introduced to a quick reference table, or a multiplication table with pre-set values for easy estimation of exposure or a range of potential exposure (example in **Box 2**), and the equations from Session 4 (2.1.5) were available for guiding further calculations.

The first example aligned with the present values in the quick reference table, and participants could complete the exposure estimate without the use of a calculator, if they so choose (example in **Box 2**).

The second example did not quite align with the pre-set values in the quick reference table, and participants could use the table to first estimate the range of potential exposure before determining if an exact calculation of the estimated exposure was needed. For example, if all estimates were above or below the RfD of interest, then an exact calculation might not be necessary to complete the risk assessment. If estimates

span the RfD of interest, as in this example, further calculations will be necessary to estimate the exposure and compare it with the relevant RfD (example in **Box 2**).

The third and fourth examples focused on particulates and estimated exposure based on the size or mass of the particulate and the composition of the particulate being consumed, either a piece of hazelnut or a dough containing whole egg powder.

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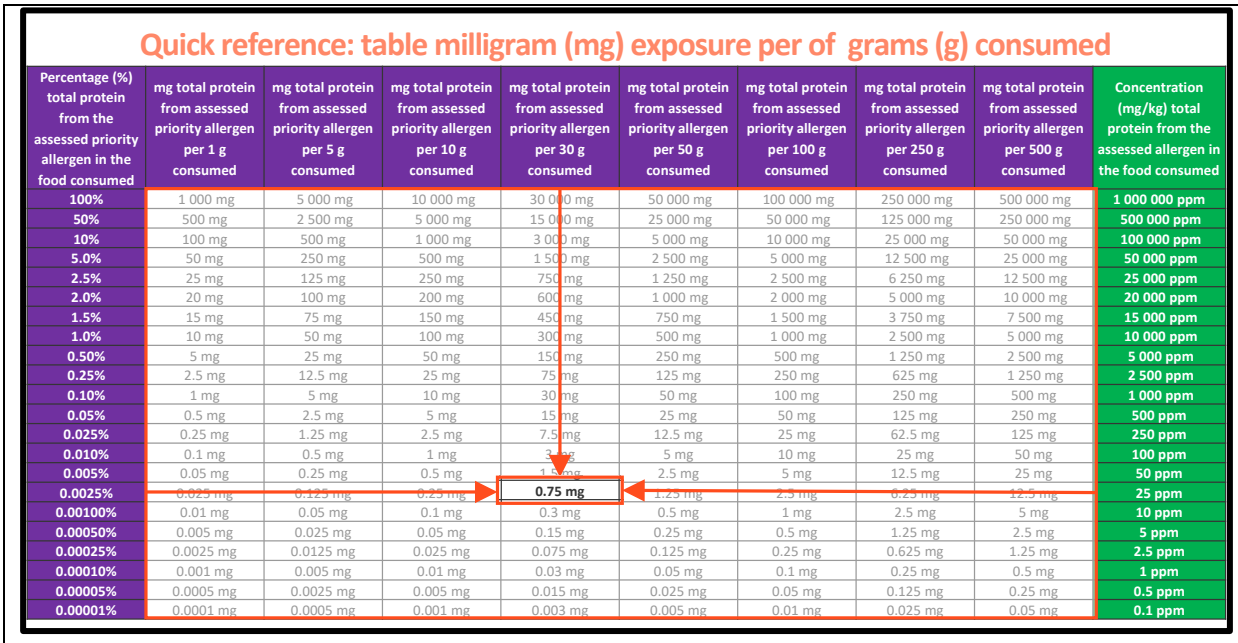
Box 2. Quick reference table with pre-set values for estimation of exposure or range of potential exposure. A similar table has been proposed for inclusion in the full report of the ad hoc joint FAO/WHO expert consultation for guidance on risk assessment

Two options are presented for quick reference, as some stakeholders will communicate and conduct exposure assessments utilizing compositional data conveyed as a percentage of the product formulation (i.e. the percentage [%] total protein from the assessed priority food allergen in food being consumed) (column 1, purple), and others will communicate and utilize information conveyed as a concentration (i.e. mg/kg or ppm total protein from the assessed food allergen in food being consumed) (column 10, green).

Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	1.25 mg	2.5 mg	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

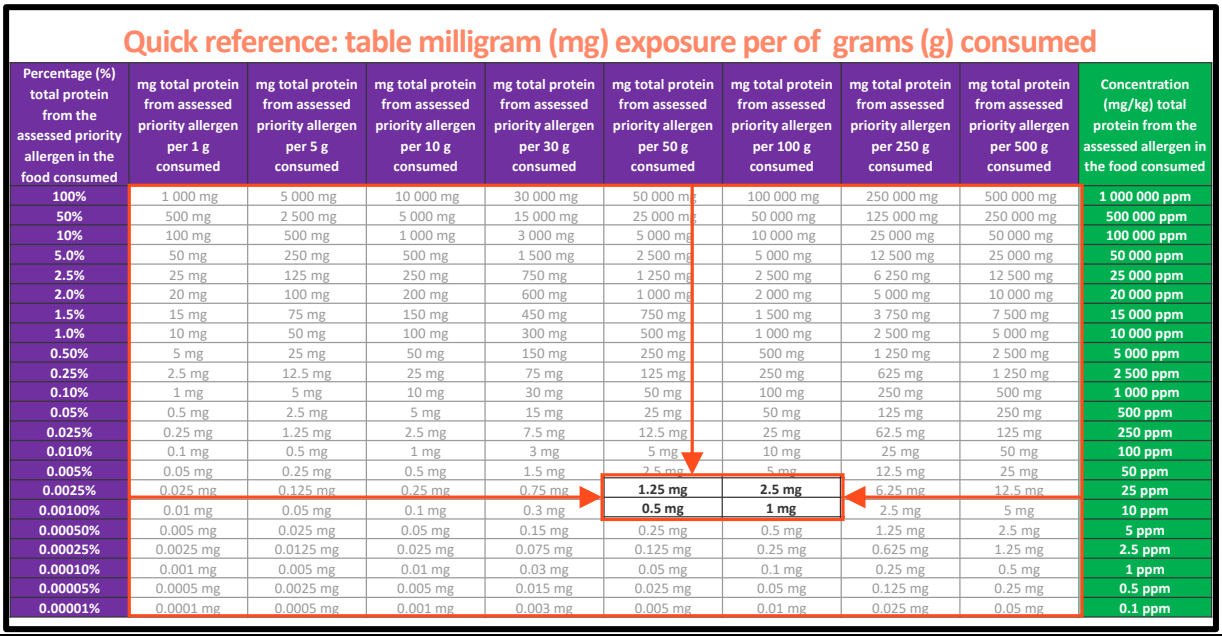
In this first example, 30 g or 0.030 kg of a product with a concentration of 25 mg milk protein per kg of food is consumed. The estimated exposure is 0.75 mg milk protein.



Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	1.25 mg	2.5 mg	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

In this second example, 65 g or 0.065 kg of a product with a concentration of 15 mg egg protein per kg of food is consumed. The potential exposure range from the quick reference table is 0.5 to 2.5 mg egg protein. The RfD for egg is 2 mg total egg protein and estimated exposures from the quick reference table span above and below the RfD for egg. Still, while we can roughly guess that the exposure is likely to be in the range of 0.5 to 1.25 mg egg protein (as a consumption of 65 g is closer to 50 g than 100 g, and a concentration of 15 ppm is closer to 10 ppm than 25 ppm), a detailed calculation is needed to estimate exposure for completion of the risk assessment. Further calculation (0.065 kg × 15 mg egg protein per kg) estimates an exposure of 0.975 mg egg protein.



Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	1.25 mg	2.5 mg	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

Note: A similar table has been proposed for inclusion in the full report of ad hoc joint FAO/WHO expert consultation for guidance on risk assessment (FAO and WHO, 2025a).
Source: Authors own elaboration

After conducting exposure assessments, the results were discussed in the context of a risk assessment for potential application PAL, where all reasonable risk mitigation practices have been explored and implemented, and there is still UAP due to cross contact. Exposure estimates and PAL recommendations are in Table 2.

Table 2. Exposure estimates are listed for four case studies and PAL recommendations after all reasonable risk mitigation practices have been explored and implemented, and there is still residual unintended allergen presence (UAP) due to cross contact

Concentration (mg/kg)	**× Consumption (kg)**	**= Exposure**	**Above RfD? PAL Recommended?**
25 mg milk protein per kg	× 0.03 kg (30 g)	= 0.75 mg milk protein exposure	Below RfD - PAL not recommended
15 mg egg protein per kg	× 65 g	= 0.975 mg egg protein exposure	Below RfD - PAL not recommended
Size / Mass (mg)	**× Composition**	**= Exposure**	**Above RfD? PAL Recommended?**
70 mg hazelnut particle	× 15% protein	= 10.5 mg hazelnut protein exposure	Above RfD - PAL recommended
110 mg dough particle	× 3% whole egg powder × 47% protein in whole egg powder	= 1.55 mg egg protein exposure	Below RfD - PAL not recommended

Source: Author own elaboration

Further case studies were assigned as homework at the end of Day 1 and can be found in Annex 3. In addition to calculating exposure, the homework required participants to take decisions within the exposure assessments regarding the amount of food consumed and the composition (e.g. protein content) of different foods. Participants documented their assumptions and resources used to support their decisions. The homework was discussed on Day 2 of the workshop (Section 2.2).

4) Discussion outcome

Each group discussed their feedback in a plenary session. Participants engaged in a lively discussion, sharing their experiences not only from the case study exercise but how it might be viewed in their own countries. Nuances of the calculations were discussed and participants offered suggestions for improving the presentation to enable understanding by the wider community.

Participants had not previously used a tool such as the quick reference table and recognized its usefulness for estimating exposure.

The session reinforced the importance of introducing and tailoring risk assessment tools to diverse production contexts and ensuring they are accessible to all stakeholders.

2.1.7. Session 6: Risk assessment/analysis as an iterative process

1) Session leads
Ben Remington and Kang Zhou

2) Learning objective
To reinforce the core concepts for risk assessment of food allergens and discuss risk assessment in context as an iterative process.

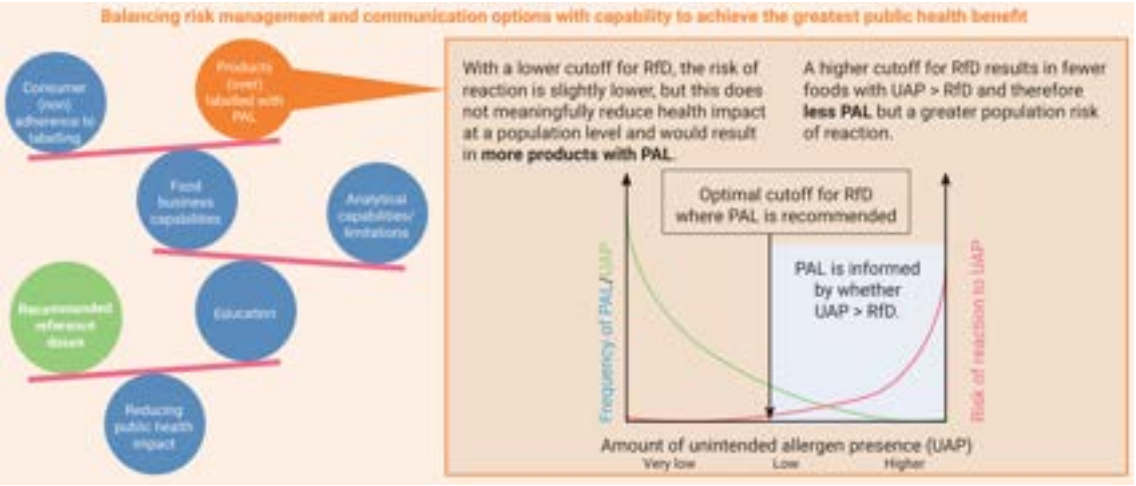
3) Key points covered
Risk assessment was discussed within the context of the broader situation and how risk assessment is an iterative process. It might be necessary to revisit the assumptions within a risk assessment and refine your estimates when additional risk mitigation options are possible or more information becomes available.

The importance of moving from hazard to risk, or from hazard-based systems focused on hazard identification to risk-based systems focused on comprehensive risk assessment were discussed. It was again acknowledged that shifts in thinking and use of data within an assessment are required when moving from a hazard-based system to a risk-based system to assess and manage food allergen cross contact.

The session reinforced the need to balance risk management and communication options with the capability to achieve the greatest public health benefit. Examples of these concepts are in Figure 3 (e.g. RfDs in balance safety and capabilities) and Figure 8 (e.g. balance of safety and capabilities to reduce over labelling of PAL, and increase in consumer trust of food allergen labelling), and advances by all stakeholders (e.g. consumers, healthcare professionals, regulators, and industry) are necessary as the safety of consumers with food allergies is a shared responsibility.

It was acknowledged that continued work will be needed to address current gaps and deficiencies in risk assessment, risk management and risk communication options.

Figure 8. Recommended reference doses (RfDs), based on health-based guidance values (HBGVs), for each of the priority food allergens and with considerations for real-world capabilities to achieve the greatest public health benefit



Source: FAO and WHO. 2024. In brief: Precautionary allergens labelling (PAL). In: *Open Knowledge FAO*. Rome, FAO. https://openknowledge.fao.org/handle/20.500.14283/cd1097en

4) Discussion outcome

Participants finished Day 1 with a clearer understanding of food allergies and food allergen risk assessment options and expressed strong interest in refining and applying these risk assessment frameworks in their own countries and operations.

2.2. Day 2: Field visit and group reflections

1) Session leads:
Ben Remington and Kang Zhou, site leaders

2) Learning objective
To conduct real-world food allergen risk assessment through a field visit and apply learnings in further discussions on risk assessment, food allergen management and case studies.

3) Morning session: field visit to a factory to observe practical risk assessment implementation
After technical training, the participants assessed real-world food allergen management and food allergen risk at an FBO producing dairy products.

Activities and discussions

During the factory visit, the site leaders detailed products made at their facility and their food allergen management programme.

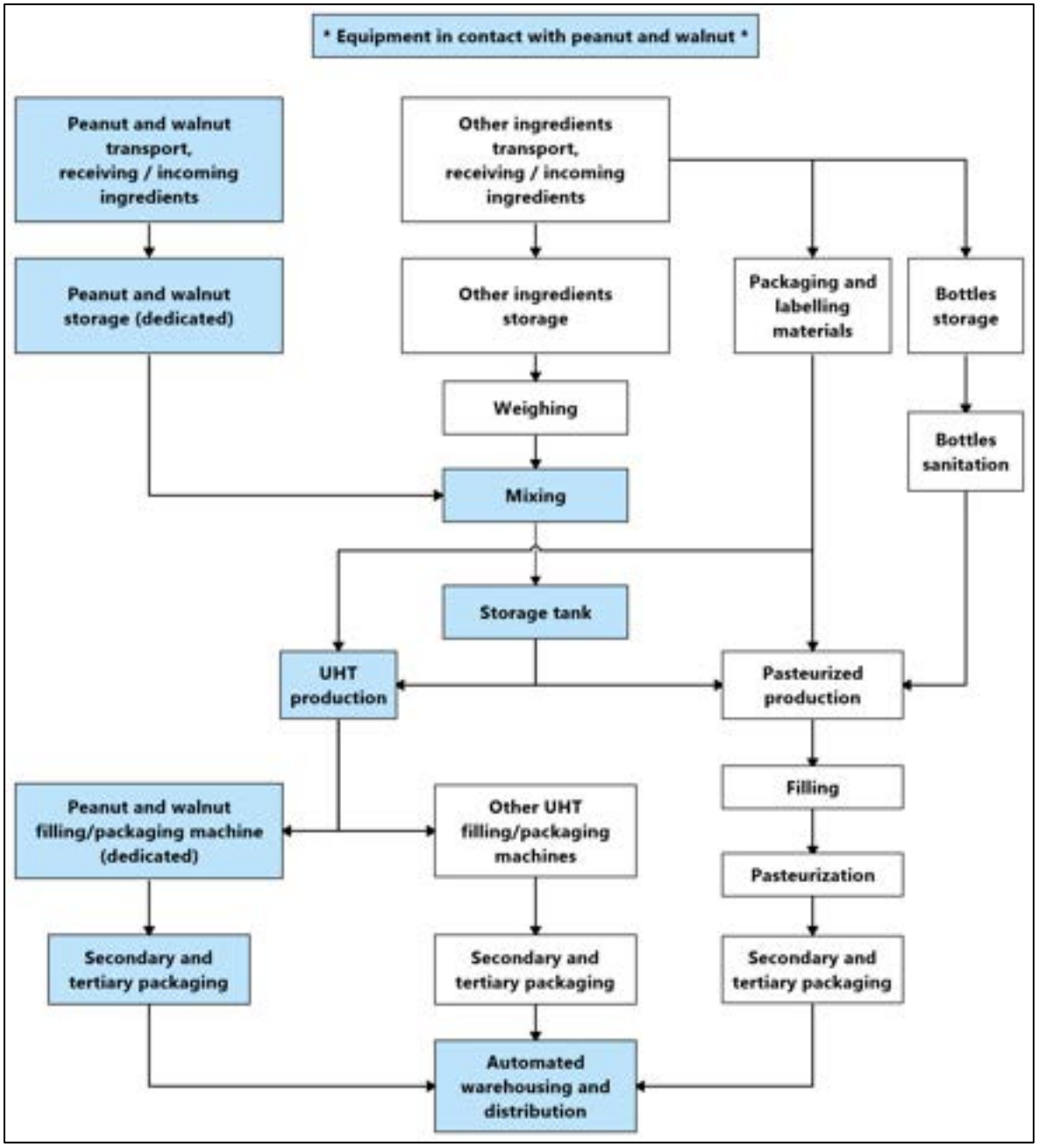
- Allergenic foods present in the facility:
    - All products made at the facility contain buffalo milk. One child-focused product contained a combination of walnut flour and peanut butter/paste. There were no other food allergens present in the facility.
    - Walnuts and peanuts were the focus of food allergen management programmes and food allergen risk assessment, as they were only present in one product, and potential cross contact from these food allergens could affect the safety of other products being produced.
    - For the rest of the factory visit, peanut and walnut were collectively referred to as the “allergenic food ingredients” or “allergen-containing products.”

Figure 9. Example of child-focused product contained a combination of walnut flour and peanut butter/paste, and other products without these allergenic food ingredients

Source: Royal Group (皇氏集团).

- General production flow / food allergen map
    - A food allergen map of the factory can be useful in identifying areas where controls should be applied to prevent or minimize food allergen cross contact, and a high-level version can be seen in Figure 11.
    - A high-level version of the food allergen map was chosen for this activity to easily convey the principles being discussed.
    - Allergenic food ingredients were transported in dedicated transport and stored in separate, dedicated areas apart from other ingredients used at the facility.
    - It should be noted that the mixing area in the facility has multiple mixers, each with multiple closed transport pipes leaving it. The mixing area is also shared for products containing peanuts and walnuts, as well as products that do not contain peanuts or walnuts. The high-level food allergen map presented here could benefit from additional detail in situations with multiple pieces of equipment and multiple closed transport pipes to identify the exact flow or possible flows of allergenic foods through the facility.

Figure 10. Food allergen map of the factory



Source: Authors' own elaboration

After the factory walkthrough, a plenary session was held, and the site leaders/workers again detailed the comprehensive food allergen management plan implemented at the facility, accompanied by a presentation to facilitate further understanding and discussion.

Ben Remington facilitated a highly interactive discussion between the participants and the site leaders, with questions raised and discussed at every step of the food allergen management programme (i.e. from transport-shipping/receiving, to packaging and distribution). Particular interest was given to the flow of allergenic materials and how cleaning was used to mitigate potential cross contact in shared systems, such as the mixers and transfer of material through closed pipe systems to the dedicated ultra-high-temperature (UHT) treatment and aseptic packaging machine.

Figure 11. Closed transportation by special vehicle, isolated storage in a warehouse

Source: Royal Group (皇氏集团).

Figure 12. Top view of mixing tank and dosing area for powders and pastes containing food allergens

Source: Royal Group (皇氏集团).

- As the point of entry for powders and pastes containing food allergens, participants were interested in understanding the shared mixer design and dosing procedures, as well as the cleanliness of the workspace to ensure control of food allergens during production was maintained, and that food allergens were not spilled outside of the mixer during dosing and unintentionally spread through the facility. Photos of the mixer were reviewed, and the participants agreed that a clean workspace was maintained, and that appropriate food allergen controls were used at the mixer.
- Participants asked questions about the mixing process to understand the homogenization process and any potential residual risks for clumping of allergenic ingredients and potential particulate cross contact within the closed system. Mixing procedures and product quality standards ensured no clumps formed, and participants agreed the risk of particulate cross contact was mitigated.

Figure 13. Examples of potential actions taken during cleaning verification

Source: Royal Group (皇氏集团).

- The facility utilized verified clean-in-place (CIP) systems to clean mixing equipment, pipe work, and machinery where food allergen-containing products were made. The CIP systems were effective in removing food allergens.
- As expected, after completion of the CIP systems, the shared mixer was visibly clean, and the risk of cross contact in the mixer was seemingly mitigated. Potential carryover of peanut or walnut from the prior product (e.g. material remaining in a mixer) into the following products was discussed by participants and comments were made regarding the visible amount of material that would need to remain in the mixer before a food allergen risk would arise in the following product. The combination of CIP systems, visibly clean equipment and the amount of visible material required for a food allergen risk in the following product led the participants to conclude the shared mixer was not a risk for food allergen cross contact under normal operating procedures.

- Multiple closed transport pipes left the mixer and led to semifinished product storage tanks. Participants discussed the CIP systems in place, as well as the procedures to ensure the food allergen containing material did not exit the mixer into the wrong pipe. Participants agreed the closed transport pipes and storage tanks were not a risk for food allergen cross contact under normal operating procedures.

Figure 14. Materials pipelines (with arrows), pumps and semifinished storage tank

Source: Royal Group (皇氏集团).

Figure 15. Ultra-high-temperature sterilizer, homogenizer, and aseptic tank

Source: Royal Group (皇氏集团).

- Checks were in place to ensure the appropriate label and package were applied to the appropriate product. Additionally, the product containing peanuts and walnuts utilizes a distinct package to easily identify it as a unique product. All expected food allergen information was communicated on the product label. No participants raised concerns regarding the package or product label.

Figure 16. Example of a product leaving the aseptic filling and packaging machine

Source: Royal Group (皇氏集团).

Figure 17. Aseptic filling and packaging machine

Source: Royal Group (皇氏集团).

- Additional discussions were had regarding maintenance plans and contingencies in place in the situation that the dedicated UHT treatment and aseptic packaging machine had an unscheduled outage and was not able to be used during production of the product containing peanut and walnut. It was indicated that the combination of production needs for that product and the CIP systems in place would allow for production of the food allergen-containing product to wait or stop and wait until repairs had been completed on the dedicated filling/packaging machine. Participants agreed that the dedicated filling/packaging machine was not a risk for food allergen cross contact under normal operating procedures.

Figure 18. Warehousing palletizer and automated storage and retrieval system

Source: Royal Group (皇氏集团).

- Sealed products were clearly labelled in warehousing and distribution systems. The only risk of food allergen cross contact at this stage would come from improper clean up of an opened/spilled product, which would still need to enter another closed product to cause a food allergen risk. This was considered an extremely unlikely event and not part of the normal cross-contact assessment for food allergens. If an incident such as this were to occur, however unlikely, it would trigger other risk mitigation protocols due to the error in or deviation from appropriate quality control, GHPs and GMPs. Participants agreed that warehousing and distribution systems were not a risk for food allergen cross contact.

Discussion outcome

All participants agreed that the FBO had implemented a comprehensive food allergen management plan and were following the policies and procedures laid out in the Codex Alimentarius *Code of Practice on Food Allergen Management (CXC 80-2020)*. All participants agreed that the risk of food allergen cross contact to peanuts or walnuts was mitigated under normal operating procedures.

Participants reflected on the field visit and situation in their countries, and they recognized similar FBOs in their countries. By following GHPs and GMPs, such as those observed during the field visit, participants understood that allergen risks are already being managed to a large extent by FBOs in those situations. Participants also commented how similar practices could be implemented in facilities not yet up to these standards.

Key observations

- Food allergen risk assessment and food allergen management programmes are evidence-based and detail-oriented but still practically achievable.
- The comprehensive food allergen management programme already in place enabled a focused food allergen risk assessment.
- All information needed to conduct a food allergen risk assessment was available within the FBO's own facility, including supply chain-related information.
- Similar facilities following GHPs and GMPs, such as those observed during the field visit, are already managing and mitigating food allergen risks to a large extent.
- Similar GHPs and GMPs practices could be implemented in similar facilities not yet up to these standards.

Challenges identified

- As previously mentioned, the FBO detailed their comprehensive food allergen management programme and participants agreed that the risk of food allergen cross contact was mitigated under normal operating procedures. As such, the challenges discussed here are not particular to this facility but apply to all facilities already following good food allergen management plans.
- Production scheduling: Multiple closed transport pipes left the mixers and monitoring of the production scheduling for the use of these pipes (e.g. processing foods that do not contain peanut and walnut before foods with peanut and walnut, and always performing a CIP directly after production of the product containing peanut and walnut). This will continue to ensure that food allergen-containing products do not enter or remain in transport pipes for non-allergen-containing products.
- Valve integrity: Multiple closed transport pipes left the mixers, and the structure of seals and valves should continue to be monitored to ensure that peanut- and walnut-containing product does not leak into transport pipes designated for other products.
- Continued supply chain verification: Continue regular reviews of supply chains, incoming ingredients and processes for changes to food allergen identification. For example, a new PAL or "may contain"-type statement may appear on an incoming ingredient, and follow-up with the supplier would be required to evaluate its relevance within the overall risk assessment process.
- Loss of dedicated equipment: If it is not possible in the future to continue to have dedicated transport, dedicated storage, and/or a dedicated UHT treatment and aseptic packaging machine for products containing peanut and walnut, then the risk assessment for these food allergens would need to be redone.
- Introduction of other food allergens into the facility: If additional priority allergenic foods are introduced to some, but not all products in the facility, then a comprehensive risk assessment would need to be done for the new allergenic foods.

4) Afternoon session: factory visit debrief, continuation of case studies and discussion on the different applications of risk assessment for food allergens

Following the factory visit, participants reconvened to further discuss their observations and apply their learnings in discussions on risk assessment, food allergen management and case studies.

Key points covered

- Debrief factory visit
    - Reinforced the importance of food allergen management plans and a farm-to-table approach within the overall risk assessment.
    - Discussed again the general principles of food allergen management for FBOs, including control of source materials, considerations for use of shared equipment and utensils, proper preparation (sequence and schedule), management of cleaning, employee buy-in to food safety systems, and training.
- Homework review / Case study review
    - Further case studies were assigned as homework at the end of Day 1 and are available in Annex 3. In addition to calculating exposure, the homework required participants to make decisions within the exposure assessments regarding the amount of food consumed and the composition (e.g. protein content) of different foods. Participants documented their assumptions and resources used to support their decisions.
    - Participants discussed the homework in groups and compared their assumptions made within the exposure assessments.
    - Participants' assumptions varied for all factors considered. Consumption estimates varied for the form of noodle, either wet or dry, as well as the exact consumption amount estimated for either form. Compositional estimates or the amount of protein present in an ingredient varied depending on the data source or database utilized.
        - Participants recognized the need for guidance in these areas.
- Action Levels (ALs) within food allergen risk assessment
    - Briefly, action levels are the transition point where action is required (e.g. the use of PAL, decisions on product safety in recall situations, trade rejection) when concentrations of UAP above the action level are indicated in the risk assessment.

- Action Levels are determined by dividing the RfD by an appropriate value for the amount of food consumed (reference amount [RfA]), using the formula:
- $$Action\ Level\ (AL)^1 = \frac{Reference\ Dose\ (in\ mg\ total\ protein\ from\ the\ allergenic\ food)}{Appropriate\ amount\ of\ food\ consumed\ (in\ kg)}$$

  Note: [1] AL: in mg total protein from the allergenic food/kg food.
- The amount of food should be established based on the quantity that can reasonably be expected to be consumed on a single eating occasion, preferably using the 50th percentile (FAO and WHO, 2023a).
- If food allergen-specific analysis is conducted, the analytical test methods must have a demonstrable fitness-for-purpose and should be validated to demonstrate that they are suitable for their end use (i.e. that they have the intended specificity, accuracy and precision).
- The test methods should provide a quantitative result for use in risk assessment, ideally reporting in "mg of protein from the allergenic food kg of food analysed" (FAO and WHO, 2022b [page 95]; FAO and WHO, 2023a [pages, 44–46]) or providing conversion factors to reach such a unit.
- Actions Levels are often used in assessments for PAL. If conducting a risk assessment for potential application of PAL, PAL should only be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level for a food allergen based on the RfDs (FAO and WHO, 2023a).

- Assessment of carryover or material potentially remaining in equipment after cleaning
  - A case study and quick reference table to enable exposure assessments for carryover from the prior product (e.g. powder remaining in a mixer) were discussed.
  - It is possible to estimate the amount of carryover of prior recipe (kg) required in specified equipment size to reach an exposure estimate equivalent to the RfD in an estimated consumption amount per eating occasion (g). In many cases, cross-contact levels necessary to cause a risk to consumers with food allergies would also be very visible with the equipment and constitute an error in or deviation from appropriate quality control, GHPs and GMP. In cases where it is identified that a large amount of visible food is required before a food allergen issue would arise, FBOs could be assured that their quality control systems, GHPs and GMPs in place and working to a visibly clean standard will also protect consumers with food allergies. FBOs can then focus their resources on other, potentially more impactful areas of food allergen management in these situations (e.g. label verification, control of source material) (Figure 12).

Figure 19. Quick reference table to exposure assessment for carryover from the prior product (e.g. powder remaining in a mixer)

Two options are presented for quick reference, as some stakeholders will communicate and conduct exposure assessments utilizing compositional data conveyed as a percentage of the product formulation (i.e. the percentage [%] total protein from the assessed priority food allergen in the prior recipe) (column 1, blue), and others will communicate and utilize information conveyed as a concentration (i.e. mg/kg or ppm total protein from the allergenic food in the food being consumed) (column 10, green).

Quick reference: kilograms (kg) of carry-over from prior recipe in a mixer into the following product required to reach an RfD exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in prior recipe	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 1 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 10 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 30 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 50 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 75 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 100 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 250 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 500 g	kg carry-over of prior recipe to reach RfD of 2mg protein, in a 1 000 kg mixer with a consumption of 1 000 g	Concentration (mg/kg) total protein from the assessed allergen in prior recipe
10.0%	20.41 kg	2 kg	0.67 kg	0.4 kg	0.27 kg	0.2 kg	0.08 kg	0.04 kg	0.02 kg	100 000 ppm
5.0%	41.67 kg	4.02 kg	1.34 kg	0.8 kg	0.53 kg	0.4 kg	0.16 kg	0.08 kg	0.04 kg	50 000 ppm
2.5%	86.96 kg	8.06 kg	2.67 kg	1.6 kg	1.07 kg	0.8 kg	0.32 kg	0.16 kg	0.08 kg	25 000 ppm
1.0%	Greater than 10% of mixer capacity	20.41 kg	6.71 kg	4.02 kg	2.67 kg	2 kg	0.8 kg	0.4 kg	0.2 kg	10 000 ppm
0.50%	Greater than 25% of mixer capacity	41.67 kg	13.51 kg	8.06 kg	5.36 kg	4.02 kg	1.6 kg	0.8 kg	0.4 kg	5 000 ppm
0.25%	Greater than 50% of mixer capacity	86.96 kg	27.4 kg	16.26 kg	10.78 kg	8.06 kg	3.21 kg	1.6 kg	0.8 kg	2 500 ppm
0.10%	Greater than 50% of mixer capacity	Greater than 10% of mixer capacity	71.43 kg	41.67 kg	27.4 kg	20.41 kg	8.06 kg	4.02 kg	2 kg	1 000 ppm
0.05%	Greater than 50% of mixer capacity	Greater than 25% of mixer capacity	Greater than 10% of mixer capacity	86.96 kg	56.34 kg	41.67 kg	16.26 kg	8.06 kg	4.02 kg	500 ppm
0.025%	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 25% of mixer capacity	Greater than 10% of mixer capacity	Greater than 10% of mixer capacity	86.96 kg	33.06 kg	16.26 kg	8.06 kg	250 ppm
0.010%	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 25% of mixer capacity	Greater than 25% of mixer capacity	Greater than 10% of mixer capacity	86.96 kg	41.67 kg	20.41 kg	100 ppm
0.001%	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 50% of mixer capacity	Greater than 25% of mixer capacity	Greater than 10% of mixer capacity	10 ppm

Note: A similar table has been proposed for inclusion in the full report of ad hoc joint FAO/WHO expert consultation for guidance on risk assessment (FAO and WHO, 2025a).
Source: Author own elaboration

- Additional case studies were assessed from different points of view and with varying levels of information that may be available to different stakeholders (e.g. governmental agency or import/border control in comparison to an FBO).

- Exemptions from mandatory food allergen declaration requirements
    - The FAO/WHO recommended risk-based framework for assessing potential exemptions from mandatory food allergen declaration requirements was discussed. This framework utilizes a weight of evidence approach in combination with an exposure criterion (RfD/30) and potentially, clinical studies to establish safety (FAO and WHO, 2024c).
    - Considerations for analytical methods were discussed, specifically how fit-for-purpose methods in normal production scenarios may no longer be fit-for-purpose for highly processed derivatives in an exemption application (FAO and WHO, 2024c).
    - Quantification of total protein in neutralized/refined bleached deodorized (N/RBD) soybean oil, also referred to as highly refined, and exposure assessments for residual protein in N/RBD soybean oil were discussed as a model case study for characterizing a derivative applying for an exemption from mandatory food allergen declaration requirements (EFSA, 2007; FAO and WHO, 2024c; Rigby *et al.*, 2011).

Discussion outcome

- Participants noted the need for practical tools and examples to support implementation, especially in resource-limited settings.
- The session reinforced the importance of introducing and tailoring risk assessment tools to diverse production contexts and ensuring they are accessible to all stakeholders.
- Participants appreciated the opportunity to work through case studies, apply the tools in realistic scenarios, and provide constructive feedback to inform future revisions.
- There is a need for practical guidance and harmonization for estimating the amount of food consumed in a number of food allergen risk assessment settings, but especially for foods produced in or exported to several countries with potentially different eating habits.
- It was noted that harmonizing the food composition database(s) could be of benefit.
- The session reinforced that risk assessments can often be completed without analytical data.
- When food allergen specific analytical test methods and data are needed, the session reinforced the importance of ensuring food allergen-specific analytical test methods provide a quantitative result for use in risk assessment. Ideally, results would be reported in “mg of protein from the allergenic food kg of food analysed” (FAO and WHO, 2022b [page 95]; FAO and WHO, 2023a [pages, 44–46])

or provide conversion factors to convert to a unit and enable more consistent risk assessments.

- Participants appreciated the nuances involved in assessing potential exemptions from mandatory food allergen declaration requirements. Particular interest was indicated regarding how many standardized, commercially available analytical methods are likely no longer fit-for-purpose in an exemption application due to the highly processed nature of derivatives undergoing assessment.
- Participants expressed a deeper understanding of the quick reference table and recognized its usefulness for estimating exposure due to consumption of a food or due to carryover of a prior recipe remaining in production equipment.
- Participants acknowledged the importance of viewing a situation and risk assessment from different stakeholder viewpoints to facilitate communications and expectations.
- Participants agreed there is a need for continued promotion of collaboration among Codex Alimentarius members, national authorities, FBOs, and food allergen experts to support implementation of food allergen risk assessment frameworks.

3. Conclusions and recommendations

3.1. Overall reflections

The FAO/WHO Workshop on risk assessment of food allergens successfully brought together a diverse group of stakeholders, including CCFL delegates who work on the guidelines for the use of PAL, national authorities, FBOs and additional stakeholders, academia, international organizations, from over 11 countries to explore the application of risk-based approaches to food allergen management, risk assessment and labelling.

Over the course of two days, participants engaged in technical presentations, hands-on validation exercises, and a field visit that reviewed the updated international regulations and policies on food allergens, as well as the practical nuances of food allergen risk assessment and exposure assessments. The workshop provided a valuable platform for knowledge exchange, practical learning, and collaborative problem-solving.

Participants reflected on the field visit and situation in their countries, and they recognized similar FBOs in their countries. By following GHPs and GMPs, such as those observed during the field visit, participants observed that allergen risks are already being managed to a large extent by FBOs in those situations. Participants also commented how similar practices could be implemented in facilities not yet up to these standards.

Participants affirmed the importance of the frameworks and tools being developed by FAO/WHO. They recommended several areas where further activities, materials and tools could be provided to better reflect and understand the complexity and diversity of real-world production systems and ensure that the FAO/WHO recommendations and tools can be adopted effectively.

Participants finished the workshop with a clearer understanding of food allergies and food allergen risk assessment options and expressed strong interest in refining and applying these risk assessment frameworks in their own countries and operations.

3.2. Key conclusions

Terminology needs clarification

- 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 regulatory frameworks, standards and guidelines for risk assessment and risk management will improve food safety.

Contextual adaptation is essential

- Food business operators (FBOs) are highly variable, and guidance in this area must reflect the complex nature of the whole food supply chain (from production to consumption).
- Guidance must be adaptable and applicable to local conditions.

Training and support materials are needed

- Training for FBOs, inspectors and regulators is essential to build capacity and promote consistent application across food allergen risk assessments.
- African and Latin American participants discussed and requested a similar workshop in their regions, as it would be helpful for stakeholders in their regions to attend such a workshop.
- Participants from Asian countries, including regulators, industry and academia, highlighted the need and benefit to have such a workshop offered again in different locations within Asia.
- To ensure effective implementation, risk assessment guidance should be accompanied by user-friendly case studies and visual aids.

3.3. Recommendations and next steps

Promote harmonization and knowledge sharing

- Encourage alignment of national regulations with Codex Alimentarius principles and FAO/WHO recommendations while allowing for local adaptation.
- Stimulate shift from a hazard-based to a risk-based approach for assessment and management of food allergens.
- Facilitate regional workshops and technical exchanges to share best practices and lessons learned.
- Explore opportunities to differentiate food allergens from other categories of food safety hazards in risk assessment and risk management to improve food safety.
- Participants are encouraged to pilot the risk assessment frameworks in their national contexts and share further insights with relevant Codex committees working on food allergens (e.g. CCFL, CCFH, CCMAS).
- Continued collaboration among Codex Alimentarius members, food allergen experts and national authorities will be essential to ensure the tools are practical, science based and widely applicable.

Support capacity building

- African and Latin American participants discussed and requested a similar workshop in their regions, as it would be helpful for stakeholders in their regions to attend such a workshop.
- Participants from Asian countries, including regulators, industry and academia, highlighted the need and benefit to have such a workshop offered again in different locations within Asia.
- Design and deliver training modules tailored to different user groups (e.g. regulators, FBOs, auditors, analytical laboratories).
- Promote the integration of risk-based food allergen management and risk assessment into existing food safety management systems (e.g. HACCP, GHPs).

Develop supplementary guidance

- Provide annotated examples and case studies from different production systems.
- Create end-user guidance for how to estimate the appropriate amount of food consumed per eating occasion.

- Create end-user guidance for cleaning validation, verification and the appropriate use of analytical testing or lack thereof, with annotated examples and case studies.
- Translate the risk assessment frameworks/guidance for small-scale producers and field inspectors in different regions with different languages.

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Annexes

Annex 1. List of participants

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Annex 2. Workshop agenda

Source: FAO and WHO. 2025 FAO/WHO workshop on risk assessment of food allergens. In: *FAO.* Rome. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-727-23%252FLinks%252FCCASIA23_Timetable_templateSE.pdf

Annex 3. Case study "homework" used and reviewed in the workshop

A3.1 Homework

A3.1.1 Homework 1, muesli bar / granola bar

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Concentration	× **Consumption**	= **Exposure**
50 mg milk protein per kg muesli bar	× 0.05 kg (50 g)	= _____ mg milk protein exposure

- **Use the provided calculation table to estimate milk protein exposure due this muesli bar.**
  - What is the estimated exposure? _____

- **Personal notes:**

A3.1.2 Homework 2, noodle

© FAO/Alessia Pierdomenico.

- **Concentration** × **Consumption** = **Exposure**
- 25 mg egg protein per kg noodle × _____ g noodle = _____ mg egg protein exposure

- **Where did your consumption estimate for noodles come from?**

  _____

- **Use the provided calculation table to estimate egg protein exposure due this noodle.**
  - What is the estimated exposure (range)? _____
  - Was your consumption estimate in the table? It does not need to be. If not, what did you do to adjust your estimate? e.g. Did you estimate a range of exposure?

- **Personal notes:**

A3.1.3 Homework 3, cashew particle

© Robin Hammond/NOOR for FAO

- **Size / Mass** × **Composition** = **Exposure**
- 70 mg cashew particle × _____% protein = _____ mg cashew protein

- **Where did your protein estimate for cashew come from?**

  _____

- **Personal notes:**

A3.1.4 Homework 4, dough particle

© FAO / Thomas Nicolon.

- **Size / Mass** × **Composition** = **Exposure**
- 150 mg dough particle × 2% peanut butter/paste in recipe × ____ % protein in peanut butter/paste = _____ mg peanut protein

- **Where did your protein estimate for peanut butter/paste come from?**

  _____

- **Personal notes:**

A3.1.5 Table for quick reference

Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	1.25 mg	2.5 mg	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

A3.2 Homework answers

A3.2.1 Homework 1, muesli bar / granola bar

- **Concentration** × **Consumption** = **Exposure**
- 50 mg milk protein per kg muesli bar × 0.05 kg (50 g) = _2.5__ mg milk protein exposure

- **Use the provided calculation table to estimate milk protein exposure due this muesli bar.**
  - What is the estimated exposure? ___2.5_mg milk protein_____

Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	1.25 mg	2.5 mg	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

- **Personal notes:**

Exposure of 2.5 is greater than the FAO/WHO RfD of 2.0 mg milk protein. If the context of this exposure assessment was part of a larger risk assessment to apply PAL or not apply PAL, and all reasonable risk mitigation practices have been explored/implemented and there is still residual UAP due to cross contact, my recommendation would be to apply PAL for milk to this product.

A3.2.2 Homework 2, noodle

- **Concentration** × **Consumption** = **Exposure**
- 25 mg egg protein per kg noodle × __55__ g noodle = __1.4__ mg egg protein exposure
- **Where did your consumption estimate for noodles come from?**
  - It was not specified if these noodles were dry or prepared/wet. This was left vague to emphasize the teaching point that it is important to clarify all information included in an exposure and risk assessment. For the sake of this exercise, I am assuming they are dry noodles as based on the picture, and this is information that would be readily available to a company doing the risk assessment, or an item for clarification before any exposure calculations were completed if it is not clear which type of noodles were being assessed.
  - United States reference amounts customarily consumed per eating occasion, pastas, plain,140 g prepared; 55 g dry. Double checked with Meima *et al.*, 2021 for consistency with other per eating occasion estimates done with USA data.

Source: Meima, M. Y., Blom, W. M., Westerhout, J., Kruizinga, A. G., Remington, B. C. & Houben, G. F. 2021. A systematic comparison of food intake data of the United States and the Netherlands for food allergen risk assessment. *Food and Chemical Toxicology*, 150: 112006–112006. https://doi.org/10.1016/j.fct.2021.112006

- **Use the provided calculation table to estimate egg protein exposure due this noodle.**
  - What is the estimated exposure (range)? 1.25 (50 g) – 2.5 (100 g), 55 g is just above 50 g, so very close to 1.25 and will not be much higher than that.
  - Was your consumption estimate in the table? It does not need to be. If not, what did you do to adjust your estimate? e.g. Did you estimate a range of exposure?

I estimated the range of exposure and indicated it is very close to the 50 g consumption amount. After checking the table for quick reference, I would do the actual calculation to reach 1.4 mg egg protein.

Quick reference: table milligram (mg) exposure per of grams (g) consumed

Percentage (%) total protein from the assessed priority allergen in the food consumed	mg total protein from assessed priority allergen per 1 g consumed	mg total protein from assessed priority allergen per 5 g consumed	mg total protein from assessed priority allergen per 10 g consumed	mg total protein from assessed priority allergen per 30 g consumed	mg total protein from assessed priority allergen per 50 g consumed	mg total protein from assessed priority allergen per 100 g consumed	mg total protein from assessed priority allergen per 250 g consumed	mg total protein from assessed priority allergen per 500 g consumed	Concentration (mg/kg) total protein from the assessed allergen in the food consumed
100%	1 000 mg	5 000 mg	10 000 mg	30 000 mg	50 000 mg	100 000 mg	250 000 mg	500 000 mg	1 000 000 ppm
50%	500 mg	2 500 mg	5 000 mg	15 000 mg	25 000 mg	50 000 mg	125 000 mg	250 000 mg	500 000 ppm
10%	100 mg	500 mg	1 000 mg	3 000 mg	5 000 mg	10 000 mg	25 000 mg	50 000 mg	100 000 ppm
5.0%	50 mg	250 mg	500 mg	1 500 mg	2 500 mg	5 000 mg	12 500 mg	25 000 mg	50 000 ppm
2.5%	25 mg	125 mg	250 mg	750 mg	1 250 mg	2 500 mg	6 250 mg	12 500 mg	25 000 ppm
2.0%	20 mg	100 mg	200 mg	600 mg	1 000 mg	2 000 mg	5 000 mg	10 000 mg	20 000 ppm
1.5%	15 mg	75 mg	150 mg	450 mg	750 mg	1 500 mg	3 750 mg	7 500 mg	15 000 ppm
1.0%	10 mg	50 mg	100 mg	300 mg	500 mg	1 000 mg	2 500 mg	5 000 mg	10 000 ppm
0.50%	5 mg	25 mg	50 mg	150 mg	250 mg	500 mg	1 250 mg	2 500 mg	5 000 ppm
0.25%	2.5 mg	12.5 mg	25 mg	75 mg	125 mg	250 mg	625 mg	1 250 mg	2 500 ppm
0.10%	1 mg	5 mg	10 mg	30 mg	50 mg	100 mg	250 mg	500 mg	1 000 ppm
0.05%	0.5 mg	2.5 mg	5 mg	15 mg	25 mg	50 mg	125 mg	250 mg	500 ppm
0.025%	0.25 mg	1.25 mg	2.5 mg	7.5 mg	12.5 mg	25 mg	62.5 mg	125 mg	250 ppm
0.010%	0.1 mg	0.5 mg	1 mg	3 mg	5 mg	10 mg	25 mg	50 mg	100 ppm
0.005%	0.05 mg	0.25 mg	0.5 mg	1.5 mg	2.5 mg	5 mg	12.5 mg	25 mg	50 ppm
0.0025%	0.025 mg	0.125 mg	0.25 mg	0.75 mg	**1.25 mg**	**2.5 mg**	6.25 mg	12.5 mg	25 ppm
0.00100%	0.01 mg	0.05 mg	0.1 mg	0.3 mg	0.5 mg	1 mg	2.5 mg	5 mg	10 ppm
0.00050%	0.005 mg	0.025 mg	0.05 mg	0.15 mg	0.25 mg	0.5 mg	1.25 mg	2.5 mg	5 ppm
0.00025%	0.0025 mg	0.0125 mg	0.025 mg	0.075 mg	0.125 mg	0.25 mg	0.625 mg	1.25 mg	2.5 ppm
0.00010%	0.001 mg	0.005 mg	0.01 mg	0.03 mg	0.05 mg	0.1 mg	0.25 mg	0.5 mg	1 ppm
0.00005%	0.0005 mg	0.0025 mg	0.005 mg	0.015 mg	0.025 mg	0.05 mg	0.125 mg	0.25 mg	0.5 ppm
0.00001%	0.0001 mg	0.0005 mg	0.001 mg	0.003 mg	0.005 mg	0.01 mg	0.025 mg	0.05 mg	0.1 ppm

- **Personal notes:**

Exposure of 1.4 mg is less than the FAO/WHO RfD of 2.0 mg egg protein. If the context of this exposure assessment was part of a larger risk assessment to apply PAL or not apply PAL, and all reasonable risk mitigation practices have been explored/implemented and there is still residual UAP due to cross contact, my recommendation would be to NOT apply PAL for egg to this product.

- **Did anyone use prepared noodle weights?**

25 mg egg protein per kg noodle × _140_ g noodle = _3.5_ mg egg protein exposure

If this assessment was being completed in cooked/prepared/wet noodles, then the exposure estimated of 3.5 mg egg protein would be greater than the FAO/WHO RfD of 2.0 mg egg protein and would change the recommendation compared to the dry noodle assessment.

It is important to clarify the appropriate form of the food to be used within exposure assessments and risk assessments.

A3.2.3 Homework 3, cashew particle

- **Size / Mass** × **Composition** = **Exposure**
- 70 mg cashew particle × 17.4 % protein = 12.2 mg cashew protein

- **Where did your protein estimate for cashew come from?**

The United States Department of Agriculture (USDA) FoodData Central nutritional information database, which compared protein estimates for raw cashew (17.4 percent), dry roasted cashew (15.3 percent), and oil roasted cashew (16.8 percent), and we used the most conservative value as we were not given more specific information about cashew on the form.

(Other protein databases are available, and if a company is performing this exposure assessment then they should have the food composition data [nutrient compositional data] from their ingredient specification information).

- **Personal notes:**

Exposure of 12.2 is greater than the FAO/WHO RfD of 1.0 mg cashew protein. If the context of this exposure assessment was part of a larger risk assessment to apply PAL or not apply PAL, and all reasonable risk mitigation practices have been explored/implemented and there is still residual UAP due to cross contact, my recommendation would be to apply PAL for cashew to this product.

A3.2.4 Homework 4, dough particle

- **Size / Mass** × **Composition** = **Exposure**
- 150 mg dough particle × 2% peanut butter/paste in recipe × _25_ % protein in peanut butter/paste = _0.75__ mg peanut protein

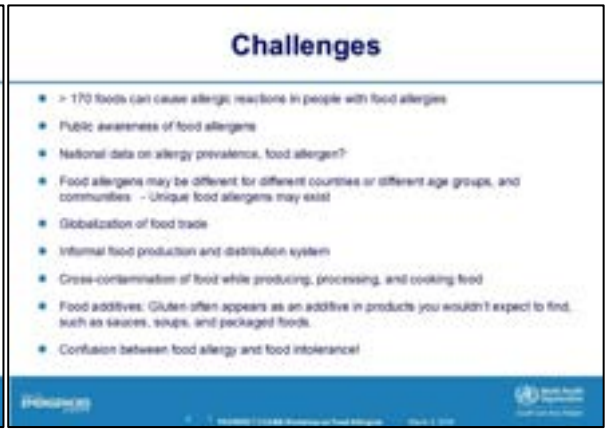
Where did your protein estimate for peanut butter/paste come from?
The USFDA FoodData Central nutritional information database, in combination with prior experience in this area. Previously, grocery store searches led to the result that peanut butters can contain anywhere from 55 percent to 100 percent peanuts in the product formulation due to addition of other ingredients. That equates to 14 percent to 25 percent protein in peanut butter from peanuts. I used 25 percent peanut protein assuming a single ingredient peanut butter with only ground peanuts.
(Other protein databases are available, and if a company is performing this exposure assessment then they should have the food composition data [nutrient compositional data] from their ingredient specification information).

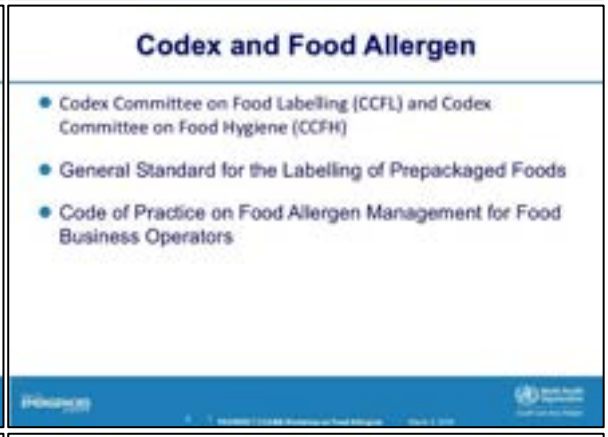
- **Personal notes:**

Exposure of 0.75 mg is less than the FAO/WHO RfD of 2.0 mg peanut protein. If the context of this exposure assessment was part of a larger risk assessment to apply PAL or not apply PAL, and all reasonable risk mitigation practices have been explored/implemented and there is still residual UAP due to cross-contact, my recommendation would be to NOT apply PAL for peanut to this product.

Annex 4. Presentations

A4.1 An overview of food allergies in Asia (Gyanendra Gongal)





The reality check

- **Allergen labelling regulations differ** between Indonesia and Australia, especially regarding how allergen information is presented to consumers on product labels.
- The instant noodle products that did not comply with Australian labelling standards were **originally produced for the Indonesian domestic market** and **not intended for export.**
- This issue arose because of **parallel exportation**, where products meant exclusively for the domestic market entered foreign markets through unofficial channels.

Regulation of food allergens

- **EU**: Mandatory Labelling of 14 Allergens: The regulation requires the mandatory labelling of 14 allergens when used as ingredients in **pre-packaged foods**
- **Canada**: Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Following the death of 13-year-old Sabrina Shannon from an anaphylactic reaction in school, Ontario passed **"Sabrina's Law"** in 2006. **Food Allergy Canada** is the leading national advocacy and education organization for **over 2.6 million** Canadians with food allergies.
- **India**: The Food Safety Standards Authority of India (FSSAI) lists eight major food allergens that must be declared on **food products.**

Food allergies continue to rise and are a matter of consumer health concern.

A4.2 Introduction to food allergies and food allergens (Ben Remington)

Signs or symptoms of an IgE-mediated food allergic reaction

- Organ systems
  - Skin
  - Eyes/Upper respiratory
  - Respiratory
  - Oropharyngeal
  - Gastrointestinal
  - Cardiovascular
  - Neurological
- Severity of reaction?
- Anaphylaxis?
  - Varying definitions
- Mild/moderate/severe?
- Potentially fatal?

Signs or symptoms of an IgE-mediated food allergic reaction

Example of signs or symptoms of an IgE-mediated food allergic reaction

1996: Allergenic Foods

- Virtually all food allergens are proteins, although only a small percentage of the many proteins in foods are allergens.
- Any food that contains protein has the potential to cause allergic reactions in some individuals.

1996: Allergenic Foods

- More than 160 foods identified as allergenic foods
- However, a few foods or food groups are known to cause allergies on a more frequent basis than other foods.

Global priority food allergens

- In 1995, eight allergenic foods and groups prioritized on a global level

Global priority food allergens

- In 2022, eight allergenic foods and groups prioritized on a global level
- Potentially important allergenic foods on a regional or national perspective have also been identified
  - Soy, some tree nuts (Brazil, macadamia and pine nuts), celery, buckwheat, lupin, mustard, and oats

Relevant definitions

- "Allergenic food" means a food (including ingredients, food additives and processing aids) that can elicit immunoglobulin class E (IgE)-mediated or other specific immune-mediated reactions in susceptible individuals.
- "Food allergen" means the substance in an allergenic food, usually a protein or protein derivative that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.
- "Food allergy" means a reproducible adverse health effect arising from an IgE antibody or non-IgE antibody immune-mediated response following oral exposure to a food.
- "Coeliac disease" means a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

Immune-mediated adverse reactions to food

- Prevalence
- Potency
- Severity
- How many?
- How much?
- How bad?

How many?

Prevalence of Immune-mediated adverse reactions to food

GROUP	GEOGRAPHIC CLASSIFICATION	DEFINITION AS % PREVALENCE
0	Insufficient data	Not applicable
1	Very low	< 0.5% in one region only OR < 0.1% in all regions
2	Low	< 0.5% in all regions
3	Mixed	> 1% in one region AND 0.5–1.0% in at least one other region
4	High	> 1.0% in more than one region

Prevalence of IgE-mediated food allergy?

- Reporting / Survey / Study methods
  - Self-reported
  - Blood test
  - Skin prick test (SPT)
  - Food Challenge (Open, DBPCFC)

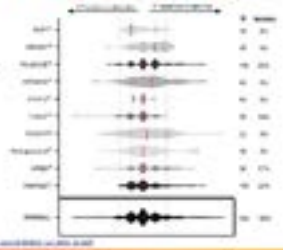
Prevalence of Immune-mediated adverse reactions to food

How much?

Framework to help guide the determination of individual allergic thresholds for risk assessment and risk management

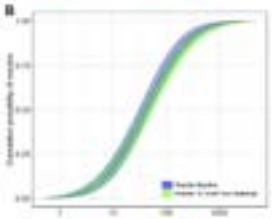
Change in reaction thresholds during repeat challenges

- Repeat challenges:
  - Individual level: Some go up, some go down, some stay the same
  - Population level: Similar dose distribution for the two challenges (when analysis was possible)*



Change in reaction thresholds during repeat challenges

- Repeat challenges:
  - Individual level: Some go up, some go down, some stay the same
  - Population level: Similar dose distribution for the two challenges (when analysis was possible)*



How bad?

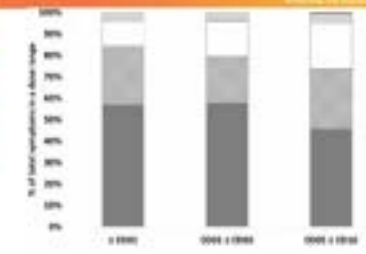
Perception of severity

- Severity is a highly subjective term which stakeholders use and interpret in different ways.
- Multiple factors impact the severity of a reaction.
- Fatal reactions are rare but also unpredictable.
- Historically...

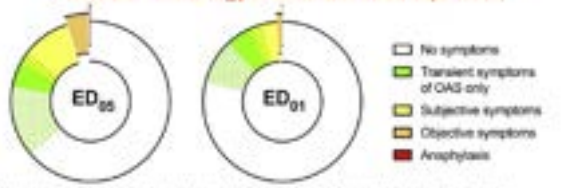
Factors that can modulate severity of allergic reactions

What if we limit the dose below the ED05?

Nature of all symptoms distributed in the different EDp ranges

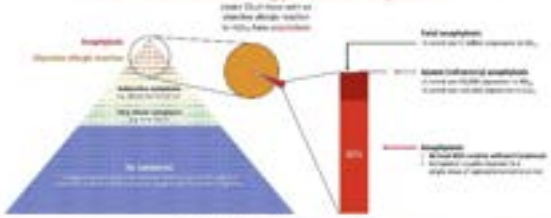


Hierarchy of risks faced by people susceptible to IgE-mediated food allergy at ED05 and ED01 exposures.



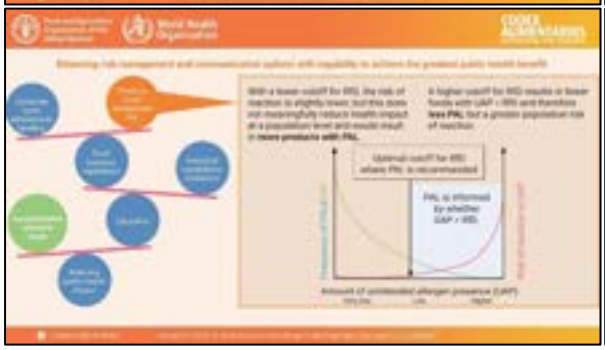
- Frequency of allergic symptoms/signs following an ED05 and ED01 level of exposure in peanut allergic individuals.
- While five times more people would have objective reaction to ED05 (compared to ED01), the rate of subjective symptoms is only increased by ~50%.

Hierarchy of risks faced by people susceptible to IgE-mediated food allergy at ED05 exposure.



When we put all available information together…

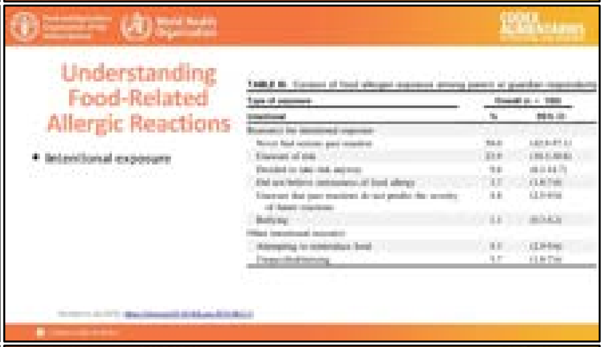
Priority food allergens / allergenic foods




Understanding Food-Related Allergic Reactions
/
Where can risk assessment make an impact (or not)?


Understanding Food-Related Allergic Reactions
Most have multiple food allergies
Roughly half report a reaction per year, average number of reactions vary
TABLE I. Characteristics of FARE Registry respondents

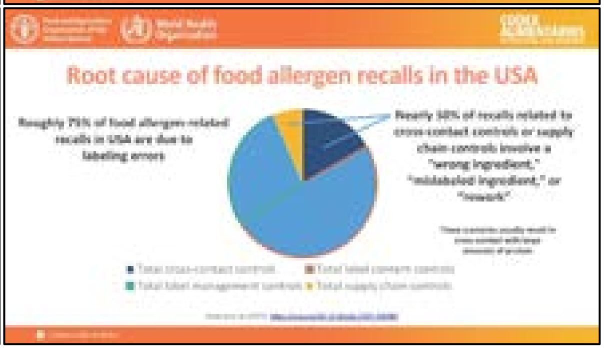

Understanding Food-Related Allergic Reactions
Not all reactions are due to accidental consumptions
10% of reactions are due to intentional consumption of an allergen


Understanding Food-Related Allergic Reactions
Intentional exposure

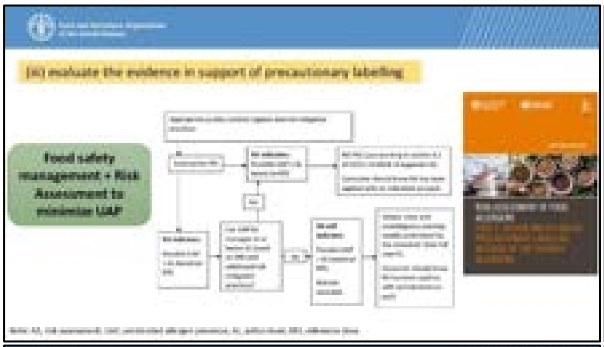

Understanding Food-Related Allergic Reactions
Some accidental consumptions contain the allergen as an ingredient in the food
**Cross-contamination could still include misreading and/or misinterpretation of food ingredients, food labels, and/or packaging

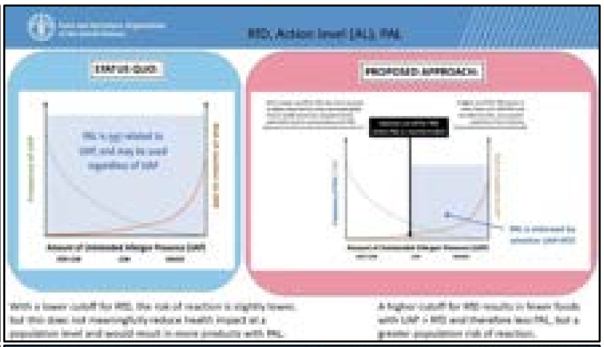

Opportunities for Improvement
Example: US FDA Warning Letters
You did not identify and evaluate allergens as a hazard requiring a preventive control.
You did not identify and evaluate undeclared allergens as a known or reasonably foreseeable hazard to determine whether they are a hazard requiring a preventive control.
A knowledgeable person manufacturing/processing food in your circumstances would identify [allergens/undeclared allergens] as a hazard requiring a preventive control.

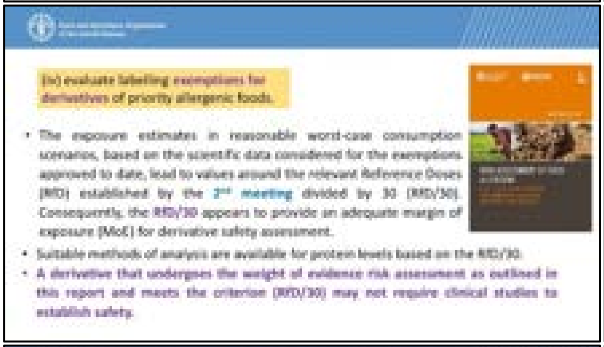

Opportunities for improvement
Roughly 75% of food allergen-related recalls in USA are due to labeling errors
Australian companies surveyed:
Roughly 75% of precautionary allergen labelling (PAL) are due to particulates
Cross-contact in ingredients is a main driver for PAL

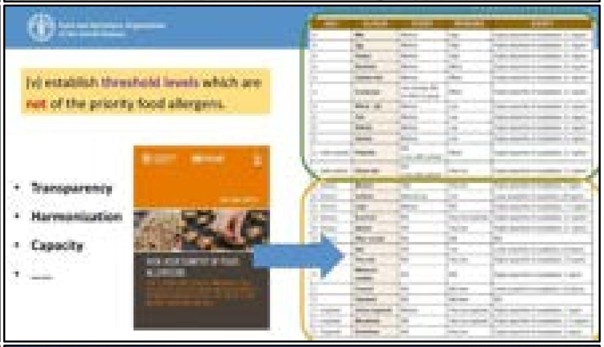

Root cause of food allergen recalls in the USA
Roughly 75% of food allergen-related recalls in USA are due to labeling errors
Nearly 50% of recalls related to cross-contact controls or supply chain controls involve a "wrong ingredient," "mislabeled ingredient," or "rework"

A4.3 Overview of FAO/WHO work (Kang Zhou)


(iii) evaluate the evidence in support of precautionary labelling
Food safety management + Risk Assessment to minimize UAP


RfD, Action level (AL), PAL
STATUS QUO
PROPOSED APPROACH
With a lower cutoff for RfD, the risk of reaction is slightly lower, but this does not meaningfully reduce health impact at a population level and would result in more products with PAL.
A higher cutoff for RfD results in fewer foods with UAP > RfD and therefore less PAL, but a greater population risk of reaction.

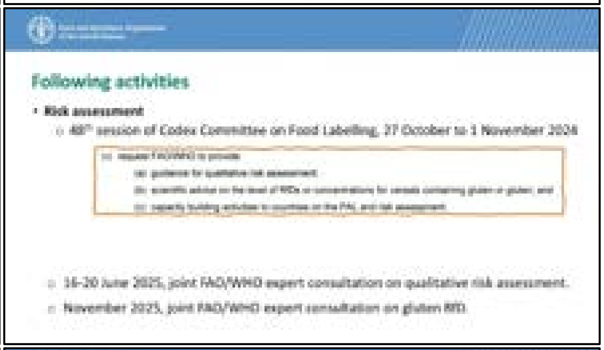

(iv) evaluate labelling exemptions for derivatives of priority allergenic foods.
The exposure estimates in reasonable worst-case consumption scenarios, based on the scientific data considered for the exemptions approved to date, lead to values around the relevant Reference Doses (RfD) established by the 2nd meeting divided by 30 (RfD/30). Consequently, the RfD/30 appears to provide an adequate margin of exposure (MoE) for derivative safety assessment.
Suitable methods of analysis are available for protein levels based on the RfD/30.
A derivative that undergoes the weight of evidence risk assessment as outlined in this report and meets the criterion (RfD/30) may not require clinical studies to establish safety.

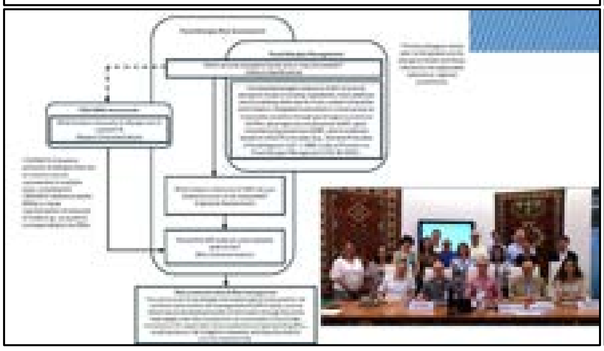

(v) establish threshold levels which are not of the priority food allergens.
Transparency
Harmonization
Capacity

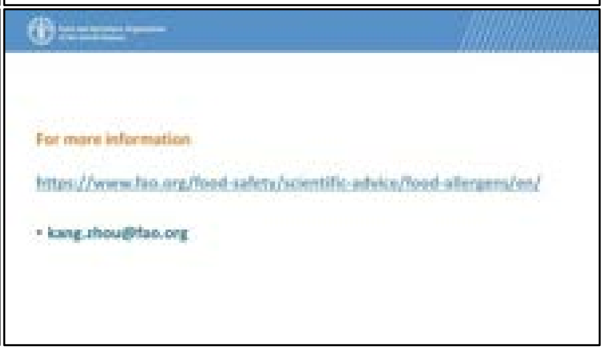

Brochures
Arabic
Chinese
French
Russian
Spanish
A4 version


3-fold version
1. Priority food allergens
2. Food allergen reference dose
3. Precautionary labelling
4. Exemption


Other activities
Promotion
Videos
Capacity building
Workshop during the FAO/WHO Coordinating Committee for Asia (CCASIA), September 2025
Workshop in other regions in 2026
220 000 000


Following activities
Risk assessment
48th session of Codex Committee on Food Labelling, 27 October to 1 November 2024
16-20 June 2025, joint FAO/WHO expert consultation on qualitative risk assessment.
November 2025, joint FAO/WHO expert consultation on gluten RfD.




For more information
https://www.fao.org/food-safety/scientific-advice/food-allergens/en/
kang.zhou@fao.org

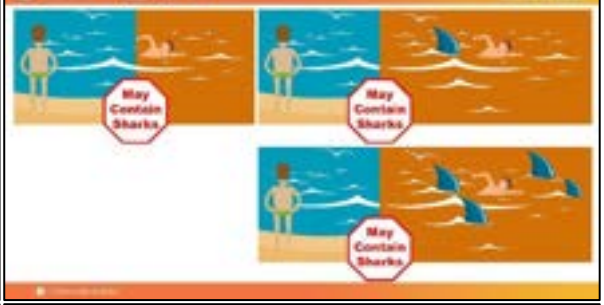
A4.4 Introduction to food allergen risk assessment (Ben Remington)

Was the sign placed after a risk assessment?

How thorough was the assessment?

- Sharks live in the ocean, this is ocean water

- How often do sharks swim in the shallow water near the beach?
  - Seasonal changes in frequency?
- How long do they stay after appearing in the area?
- How many sharks appear at the same time?
- What's the probability of a shark in the water while the beach is open?
  - Night vs day
- How often does a shark bite a nearby swimmer?
- How many people are at risk.
  - Today, this week, month, year?



Different types of hazards in a food facility

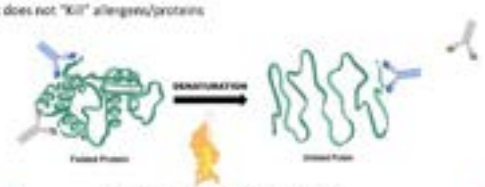
- Biological / microbial
- Chemical
  - Allergens
- Physical

Microbes ≠ Allergens

- Allergens do not "Grow"

Allergens ≠ Microbes

- Heat does not "Kill" allergens/proteins



Physical removal of allergen residue is critical to minimize allergen cross-contact

Allergens ≠ Chemicals

- Cannot analytically test for allergens in the normal way we test for chemical hazards

Other considerations needed if testing for allergens is deemed necessary

Hazard Analysis and Risk-Based Preventive Controls (HARPC)

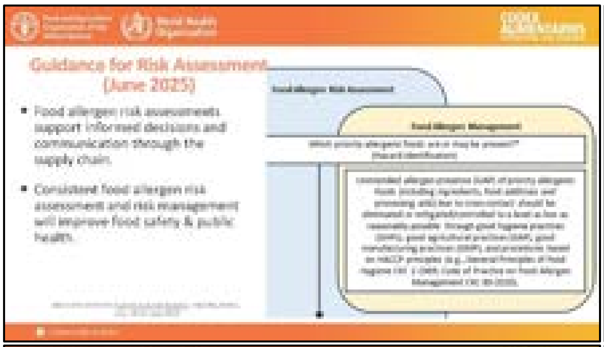
- Food allergens are classified as chemical hazards
- If a facility handles any food allergens:
  - Food allergens are almost certainly a hazard requiring control
  - Food allergen controls are applicable
  - A food safety plan is required
- Food allergens can be managed with a combination of good manufacturing practices (GMPs) and preventive controls

General Principles for Food Allergen Risk Assessment

- Which priority allergenic foods are or may be present? (Hazard Identification)
- What levels or amounts of allergen are of concern? (Hazard Characterization)
- What levels or amounts of UAP can you expect to occur or be consumed? (Exposure Assessment)
- Would the UAP pose an unacceptable level of risk? (Risk Characterization)

Guidance for Risk Assessment (June 2025)

- Food allergen risk assessments support informed decisions and communication through the supply chain.
- Consistent food allergen risk assessment and risk management will improve food safety & public health.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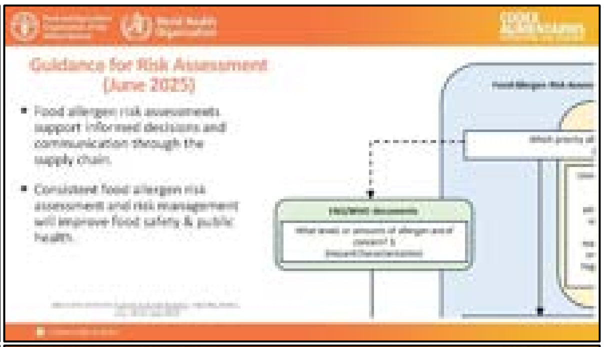
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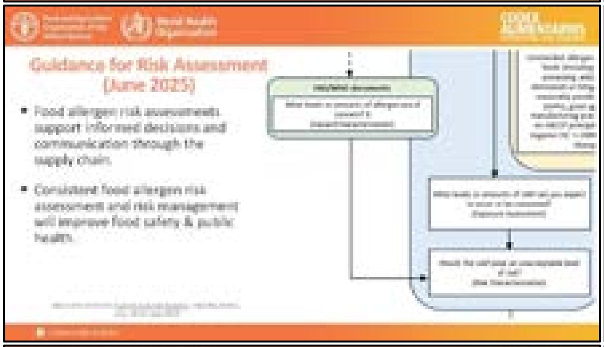
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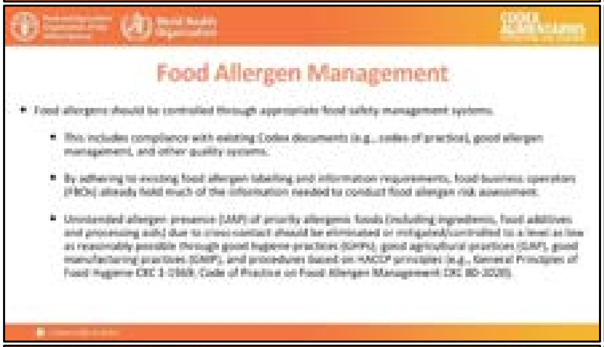
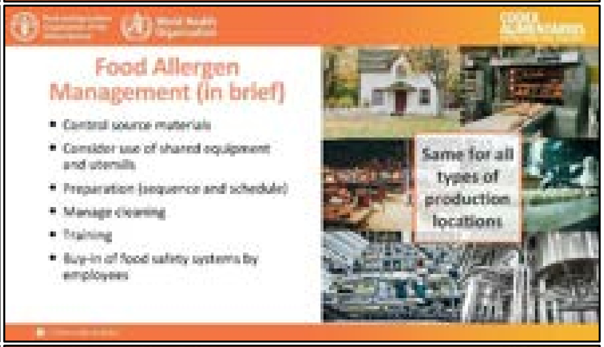
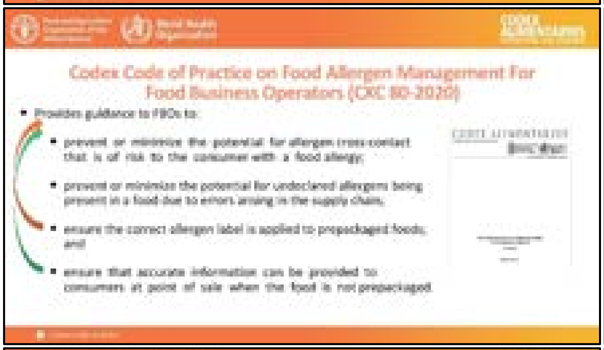
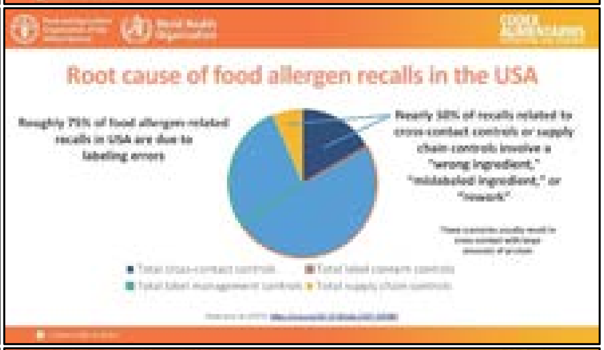
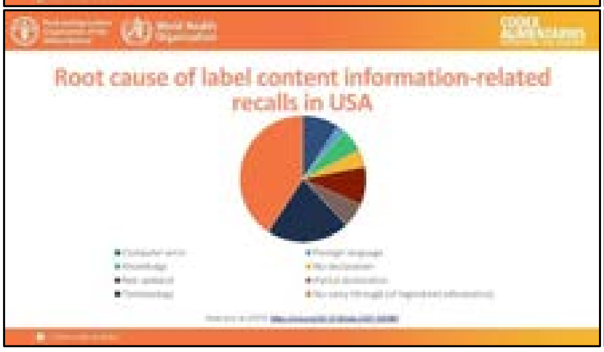
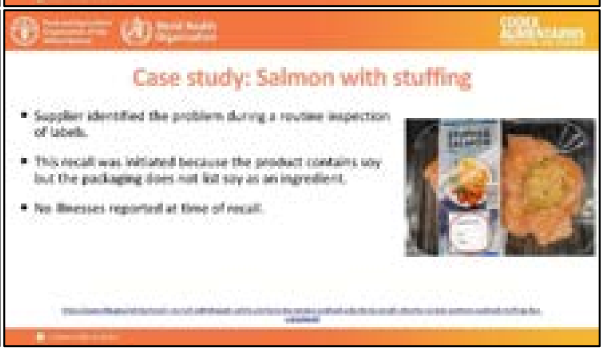

Food Allergen Management


Food Allergen Management (in brief)
Control source materials
Consider use of shared equipment and utensils
Preparation (sequence and schedule)
Manage cleaning
Training
Buy-in of food safety systems by employees
Same for all types of production locations


Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)


Root cause of food allergen recalls in the USA
Roughly 75% of food allergen-related recalls in USA are due to labeling errors


Root cause of label content information-related recalls in USA


Case study: Salmon with stuffing
Supplier identified the problem during a routine inspection of labels.
This recall was initiated because the product contains soy but the packaging does not list soy as an ingredient.
No illnesses reported at time of recall.

Case study: Imported snack rolls, biscuits, and wafers

- Recall due to undeclared wheat, egg and/or milk in the Ingredient List and/or Contains Statement on the product labels
- The issue originated from a supplier who inadvertently failed to fully disclose all allergens while translating the ingredient list.
- Mislabeling was discovered following receipt of a single consumer complaint involving an allergic reaction.

Case study: Holiday Cookie

- Limited product for the holiday season
- "Soy nuts" listed on ingredient statement
- Supplier had changed the recipe from soy nuts to **peanuts**
- Supplier claims to have updated company to change
- Company claims they were not notified of the change
- 25 year old woman died after eating a cookie
- **Visual review of product indicates 1-bite could possibly contain the e than 1 whole peanut**

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- SECTION I – OBJECTIVES
- SECTION II – SCOPE, USE AND DEFINITIONS
- SECTION III – PRIMARY PRODUCTION
- SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES
- SECTION V – CONTROL OF OPERATION
- SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION
- SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE
- SECTION VIII – TRANSPORTATION
- SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS
- SECTION X – TRAINING

- Refers to the General Principles of Food Hygiene (CXC 1-1969).
- The General Standard for the Labelling of Prepackaged Foods (CXS 1-1985) applies.

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Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)

- SECTION X – TRAINING (1 of 2)
- Training programs should include, as appropriate to the person's duties,
  - general allergen awareness, including the various nature and possible health consequences of the unintended or undeclared presence of allergens in products from a consumer perspective;
  - awareness of the likelihood of allergen cross-contact identified at each stage of the food supply chain, and the preventive measures and decontamination procedures applicable in the food business;
  - GHPs, for example, appropriate clothing, hand washing, and minimizing hand contact with foods to prevent or minimize allergen cross-contact;
  - hygienic design of facilities and equipment to prevent or minimize allergen cross-contact;
  - cleaning of premises, equipment and tools, including care between product cleaning instructions, and its importance in preventing or minimizing allergen cross-contact;
  - handling of rework materials to prevent or minimize unintended allergens from being incorporated into a food;
  - waste management, for example how waste should be handled to prevent or minimize allergen cross-contact;

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- SECTION X – TRAINING (2 of 2)
- Training programs should include, as appropriate to the person's duties,
  - situations where potential allergen cross-contact can occur between products, production lines or equipment, and prevention measures;
  - procedures for corrective actions when allergen cross-contact or labelling errors are suspected;
  - procedures for managing people traffic patterns around the site to prevent or minimize allergen transfer from one area to another, for example people changing production line or site, movement to the canteen/break room and of visitors;
  - equipment movement around the site, for example, maintenance tools, carts, food trays, etc. to prevent or minimize allergen transfer from one area to another;
  - labelling and the assessment of allergen presence in raw materials, semi-finished goods and finished products; and
  - sources of allergen information, e.g. supplier specifications, supplier audit records.

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- SECTION V – CONTROL OF OPERATION: Documentation and records (2 of 2)
- Could include:
  - suppliers' allergen management (e.g. questionnaire, survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including allergen cross-contact controls and cleaning schedules);
  - suppliers' allergen information / specification procedures for handling and storage of allergens;
  - label review;
  - label application;
  - scheduling;
  - batching (putting together the ingredients in a food);
  - rework;
  - cleaning (Standard Operating Procedures (SOPs)) and documentation that cleaning has been done);
  - line clearance procedures for label and packaging material removal at changeover;
  - packaging label and print manufacturing records.

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- SECTION V – CONTROL OF OPERATION: Documentation and records (2 of 2)
- Could include:
  - validation data for allergen cleaning efficacy;
  - verification activities (including any analytical test results for allergens);
  - corrective actions taken;
  - training (personnel trained, type of training, and date of training);
  - SOPs to minimize/prevent allergen cross-contact;
  - Allergen map; and
  - HACCP documentation.

Allergen Risk Review

The process of thoroughly investigating the allergen status of a food

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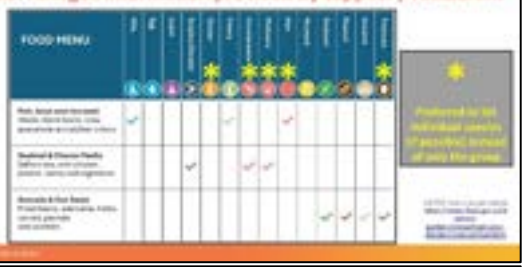
- SECTION III – PRIMARY PRODUCTION
  - Environmental hygiene
  - Hygienic production of food sources
  - Handling, storage and transport
  - Cleaning, maintenance and personnel hygiene at primary production

5.3 Incoming material requirements

- Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g. packaged foods that list all ingredients.
- Manufacturers should ensure that their suppliers have good allergen management practices to prevent or minimise the likelihood of allergen cross-contact between foods with different allergen profiles.
- Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information or on the label of the finished product (e.g. milk in a spice blend ingredient used in a food)
- Suppliers should have processes in place to manage allergen labelling.
- Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including allergen cross-contact controls and cleaning programs.

Example: Allergen information provided by supplier / restaurant



Example: Supplier Questionnaire

Case study: Ingredient and product information technology systems

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- SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES
- Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment.
- Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in all cases.
- Production sequencing (i.e. separation by time) should be considered as an option, especially for small businesses.
- An analysis of the process, including the equipment design, should be conducted to determine the likelihood of allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures are needed to prevent or minimise allergen cross-contact.

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- SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES
- FBOs producing food at more than one site should consider whether it is feasible to consolidate production, processing and storage of products containing specific allergens at one location. Although this may not always be feasible, particularly for small businesses, it could be used to limit allergen cross-contact.
- Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on the likelihood of allergen cross-contact resulting in a risk to the consumer with a food allergy, to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas, or use screens to set up temporary segregated areas, for foods with different allergen profiles.
- Equipment, tools, utensils and containers (other than single-use containers and packaging) in contact with foods that contain allergens should be designed and constructed to facilitate the effective removal of allergens during cleaning.

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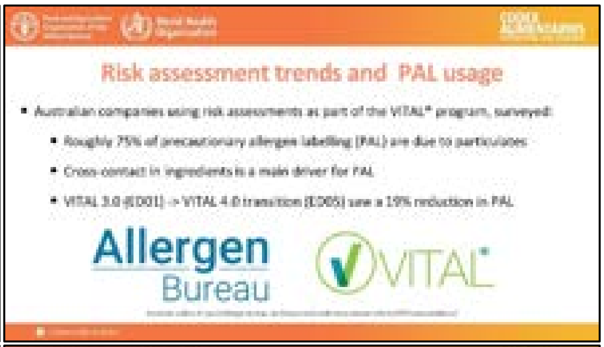
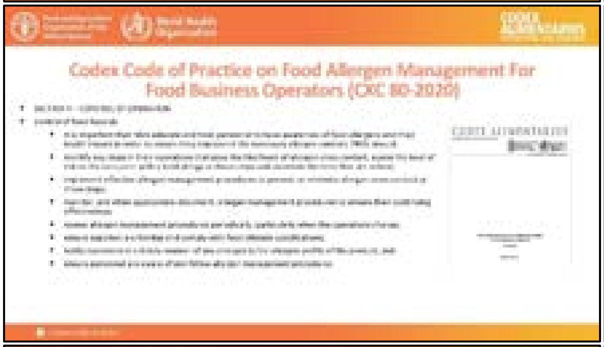
- SECTION V – CONTROL OF OPERATION
- Control of food hazards
- Key aspects of hygiene control systems
- Incoming material requirements
- Packaging
- Water
- Management and supervision
- Documentation and records
- Recall procedures (with traceability)

Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)

- SECTION V – CONTROL OF OPERATION
- Control of food hazards
- Information that may be helpful in assessing allergen cross-contact risk includes:
  - allergens present in the facility, allergens that share the same processing line;
  - the nature of the allergen (i.e. whether the food itself is an allergen, derived from an allergen, or the allergen is a component in an ingredient);
  - whether allergens are, or may be, present, as notified by the supplier;
  - whether the allergen is a particle, powder, liquid or paste;
  - the processing steps where the allergen is used;
  - ease of preventing allergen cross-contact between processing lines;
  - ease of cleaning the equipment used to process foods with different allergen profiles; and
  - the maximum amount of an allergen due to allergen cross-contact (if the information is available).


Allergen form
Is the allergen a…
Particle/pieces,
Powder/flour,
Liquid or
Paste/butter?
Visible at FAO/WHO Reference Dose (RfD) levels


Risk assessment trends and PAL usage
Australian companies using risk assessments as part of the VITAL® program, surveyed:
Roughly 75% of precautionary allergen labelling (PAL) are due to particulates
Cross-contact in ingredients is a main driver for PAL
VITAL 3.0 (2001) -> VITAL 4.0 transition (2005) saw a 19% reduction in PAL
Allergen Bureau
VITAL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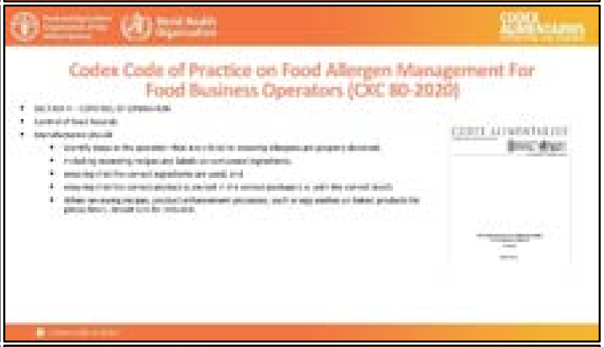
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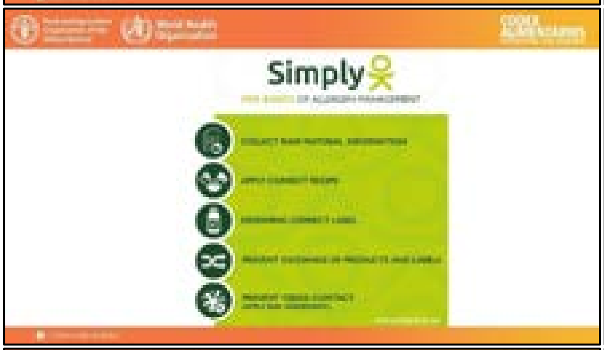
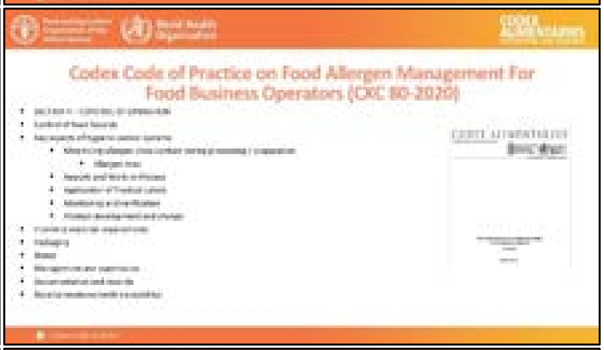

Simply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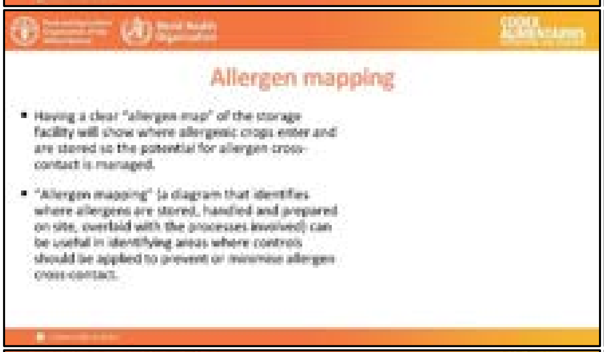
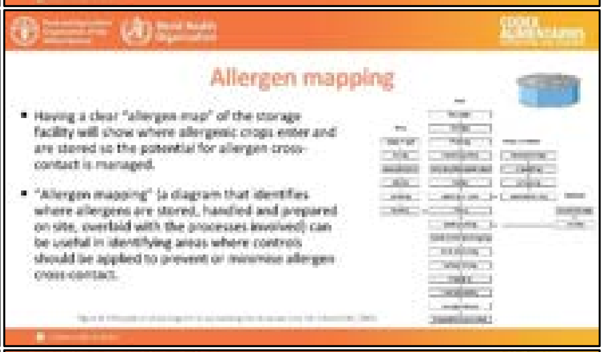

Allergen mapping
Having a clear "allergen map" of the storage facility will show where allergenic crops enter and are stored so the potential for allergen cross-contact is managed.
"Allergen mapping" (a diagram that identifies where allergens are stored, handled and prepared on site, overlaid with the processes involved) can be useful in identifying areas where controls should be applied to prevent or minimise allergen cross-contact.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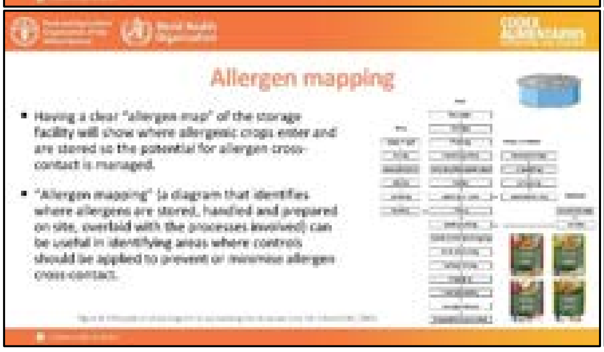
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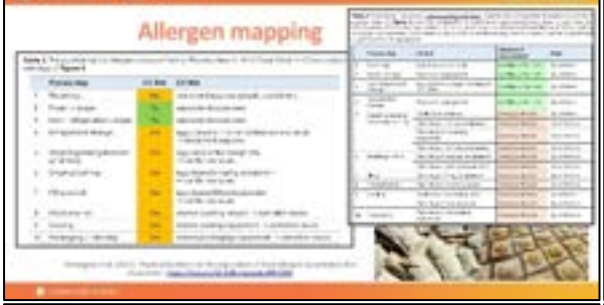

Minimising allergen cross-contact during processing / preparation

- If the same production area is used for foods with different allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles, e.g. process foods that do not contain allergens before foods with allergens.
- Where possible, allergenic ingredients should be added as late in the production process as possible, or as far downstream as possible in the processing line (e.g. closest to the filling and packaging equipment), to minimise the amount of equipment in the production area that comes in contact with the allergen.

Minimising allergen cross-contact during processing / preparation

- Manufacturers should consider a system to clearly identify personnel working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.
- Containers and utensils used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen.
- Where such dedication is not possible, effective cleaning procedures should be in place to clean containers and utensils before use for a food with a different allergen profile.
- Disposable liners can also be an effective strategy.

Rework and Work-in-Process

- Rework and Work-in-Process (WIP) that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas.
- The rework or WIP should be appropriately labelled with all food allergens specifically highlighted, and properly inventoried and accounted for during storage and when used, to prevent or minimise the potential for incorporation into the wrong product.
- "Same into same"
- Manufacturers should implement a policy for rework to be added back to the same product wherever feasible.

Application of Product Labels

- Manufacturers should:
  - Implement procedures to ensure that allergen information and labels are accurate
  - Verify that the correct product labels are used on the production line when packaging/labelling products.
  - Implement procedures to segregate and re-label food products that have been labelled incorrectly.
- If it is not possible to re-label such food, they should have a procedure to destroy the food.

Monitoring and verification

- Regular internal audits of production systems should be conducted to verify that:
  - the product formulation, including changes to product formulation, matches the records of allergenic ingredient use;
  - that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented; and
  - that line personnel are appropriately trained.
- There should be a regular review of suppliers.
- Occasional product testing for undeclared allergens may also be considered as appropriate for verification.

Product development and change (1 of 3)

- When developing new products, or changing formulations or ingredient suppliers, manufacturers should consider whether it is feasible to use a non-allergenic ingredient to provide the same functionality as an allergenic ingredient to avoid introducing a new allergen into the establishment or a processing line.
- Where the introduction of a new allergen into the establishment or a processing line is unavoidable e.g. during factory trials or consumer testing, care should be given to avoid allergen cross-contact with existing products.

Product development and change (2 of 3)

- Procedures for preventing or minimising allergen cross-contact, as well as relevant HACCP documents, operating procedures and associated personnel training, may need to be reviewed and revised to address a new product or formulation with a different allergen profile, especially when an allergen new to the production facility is involved.
- Product labels should be designed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed in a manner that prevents accidental use.

Product development and change (3 of 3)

- Where there is a change in the formulation which results in a change of allergen profile, manufacturers should consider indicating this on the packaging and on their websites for an appropriate period, with information such as "new formulation".
- Consideration could be given to changing packaging features such as colour when a new allergen is included in the formulation.

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- SECTION III – ESTABLISHMENT: MAINTENANCE AND SANITATION
- Maintenance and cleaning
- Cleaning programmes
- Pest control systems
- Waste management
- Monitoring effectiveness

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- SECTION III – ESTABLISHMENT: MAINTENANCE AND SANITATION
- Maintenance and cleaning
- Cleaning programmes
  - Cleaning procedures should be verified through visual observation (checking that equipment is visibly clean) and,
  - Where feasible and appropriate, (verified) through an analytical testing program
- Pest control systems
- Waste management
- Monitoring effectiveness

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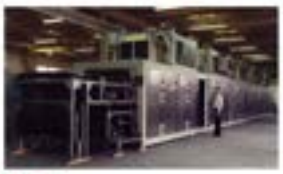
- SECTION III – ESTABLISHMENT: MAINTENANCE AND SANITATION
- Maintenance and cleaning
- Cleaning programmes
- Pest control systems
- Waste management
- Monitoring effectiveness
  - Manufacturers should periodically conduct tests to detect food residues that remain on surfaces after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective.
  - Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix).
  - Tests should be fit for purpose, i.e. appropriate for the targeted allergen, e.g. a casein (milk protein) test should not be used when whey (another milk protein) is the allergen of concern and the test should be validated to work with the matrix/food of concern.
  - FBOs should know the limit of detection of the test used and the test specificity.
  - If necessary, the FBO should obtain expert advice on interpretation of results (e.g. from the test kit supplier or an accredited testing laboratory).

Proper Cleaning of Shared Equipment is One Critical Step to Limit Allergen Cross-Contact

farrp

Proper Cleaning of Shared Equipment is One Critical Step to Limit Allergen Cross-Contact



farrp

Proper Cleaning of Shared Equipment is One Critical Step to Limit Allergen Cross-Contact

Why can't we use water in some production facilities?

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How Does Industry Ensure That Allergen Residue Has Been Removed?

Step 1: Visual Inspection

Step 2: Validation with Appropriate Analytical Tools

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Visual observation

Is it visibly clean?

Kitchen example

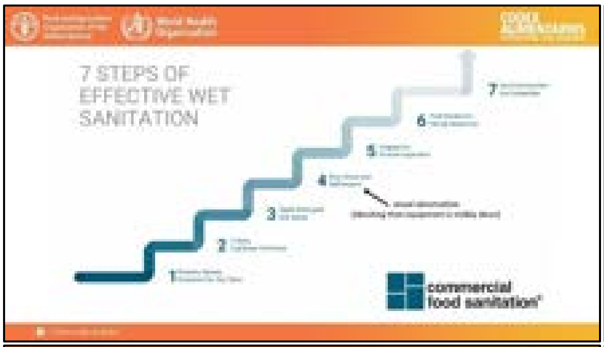
Visual observation

Is it visibly clean?

Kitchen example

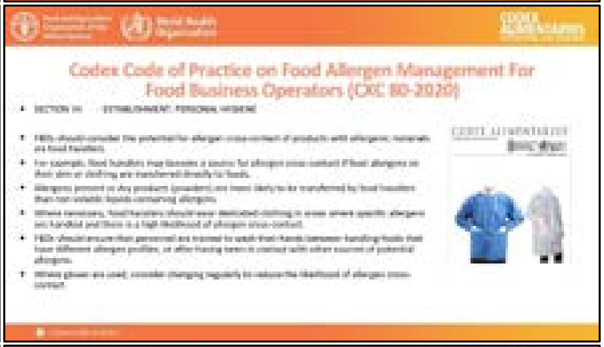
7 STEPS OF EFFECTIVE DRY SANITATION

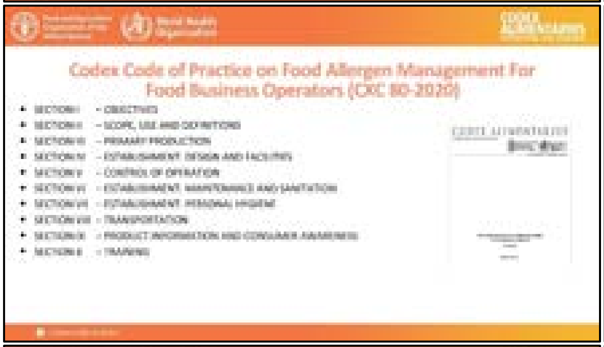
commercial food sanitation


7 STEPS OF
EFFECTIVE WET
SANITATION
commercial
food sanitation


Video - Scrubbing - CFS


Video - Overspray - CFS


Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)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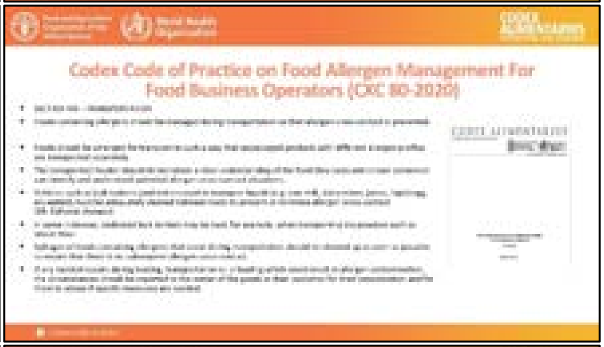
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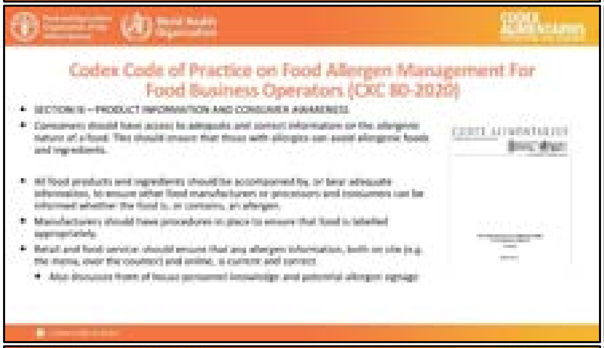
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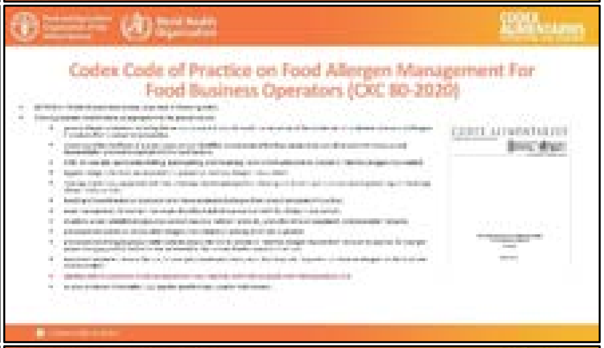
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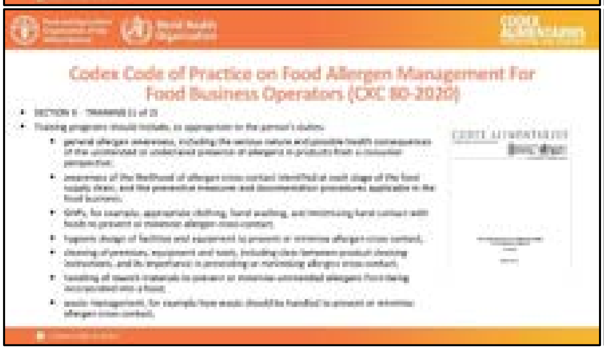
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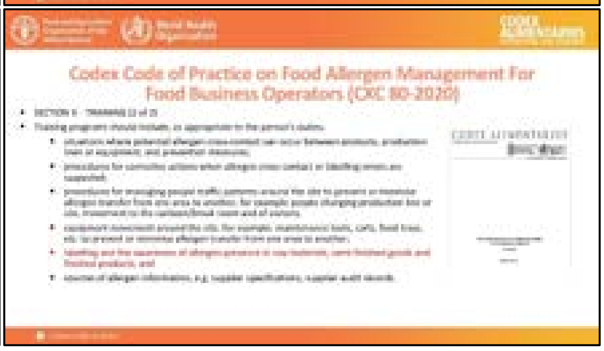
Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)

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Codex Code of Practice on Food Allergen Management For Food Business Operators (CXC 80-2020)

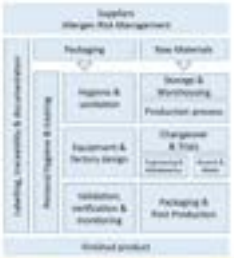
Allergen Risk Review

The process of thoroughly investigating the allergen status of a food

Updated Good Manufacturing Practices (GMPs) & Allergens

Allergen management

- The Good Manufacturing Practice (GMP) activities usually covered within food business operator's prerequisite programmes integrated in allergen management.



General Principles for Food Allergen Risk Assessment

- Which priority allergenic foods are or may be present? (Hazard Identification)
- What levels or amounts of allergen are of concern? (Hazard Characterization)
- What levels or amounts of UAP can you expect to occur or be (Exposure Assessment)
- Would the UAP pose an unacceptable level of risk? (Risk Characterization)

Would the UAP pose an unacceptable level of risk? (Risk Characterization)

- If doing calculations, FAO/WHO RfD-based Hazard Characterization most likely to be utilized

Exposure Dose ≤ Reference Dose* = range of exposure without appreciable health risk
Exposure Dose > Reference Dose* = range of exposure with appreciable health risk

(Concentration x Consumption)

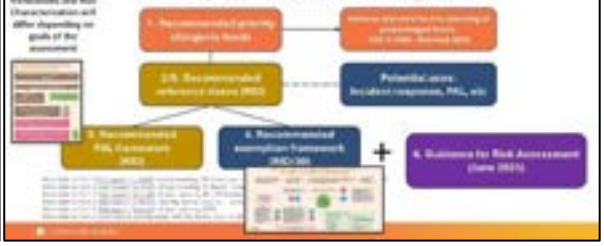
Point estimate (or analytical result) | Point estimate

Example exposure calculation

Concentration (mg/kg) × Consumption (kg) = mg food allergen protein exposure
10 mg peanut protein per kg food × 0.052 kg (50 g) = 1.8 mg peanut protein exposure

Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens



What levels or amounts of UAP can you expect to occur or be consumed? (Exposure Assessment)

- Amount consumed
- Level of cross-contact (composition, concentration)

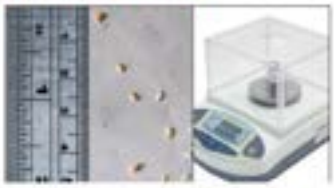
Factors to consider if assessing exposure: PARTICULATE

Size of PARTICULATE(S)

Cross-contact COMPOSITION

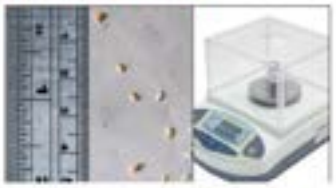
Particulate cross-contact, Simplicity is underappreciated

- Need to know / estimate
  - Mass or size
  - Composition
  - Number of particulates in package/amount eaten



Particulate cross-contact, Simplicity is underappreciated

- Need to know / estimate
  - Composition
    - Nut piece? What is protein content?
    - Dough piece? What is product formulation? What is protein content is allergen of concern?



Would the UAP pose an unacceptable level of risk? (Risk Characterization)

- For PARTICULATEs, the following calculation will likely to be utilized

Exposure Dose ≤ Reference Dose* =	range of exposure without appreciable health risk
Exposure Dose > Reference Dose* =	range of exposure with appreciable health risk

(Size/mass) x Composition)

Analytical data result or estimate — Usually nutrient analytical data

Example exposure calculation

Size / mass (mg)	x Composition (% ingredient in food, % protein in ingredient)	= Exposure
100 mg per particle	x 3% ingredient x 15% protein in ingredient	= 0.45 mg protein per particle
100 mg per particle	x 7% protein in food (peanut particle)	= 15 mg peanut protein per particle

Factors to consider if assessing PARTICULATE exposure and characterizing risk

Size of PARTICULATE(S)

Cross-contact COMPOSITION

What levels or amounts of allergen are of concern?

Reference Doses (RfDs): Milligrams total protein from the allergenic source

Example: Exposure calculation

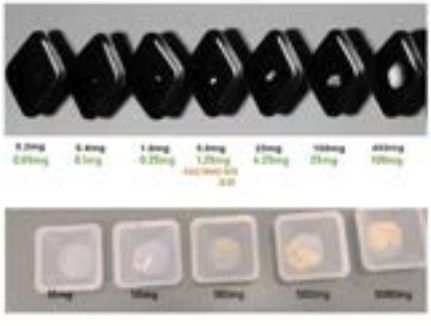
- On inspection, before cleaning, small peanut pieces (5-10) could be found in the dosing unit (final production step before packaging).
- Allergen management would require you clean before starting production on the following product, but this information could be very helpful for your food allergen risk assessment.
- What might be hidden in the equipment and potentially incorporated into the following product if not all equipment is able to be opened/visible to clean?

Example: Exposure calculation

- On inspection small peanut pieces (5-10) could be found in the dosing unit (final production step before packaging).
- The weight of a particle is 20-30 mg.
- Peanut is 25% protein

Size / Mass	x Composition	= Exposure
20-30 mg per particle	x 25% protein	= 5-7.5 mg peanut protein

- **Would the UAP pose an unacceptable level of risk? (Risk Characterization)**
  - Peanut protein exposure per particle is 5-7.5 mg
  - FAO-WHO Reference Dose for Peanut is 2 mg total protein from Peanut



FAO/WHO reference doses (RfDs) are visible amounts of food!

FAO/WHO reference doses (RfDs) are visible amounts of food!

- Upcoming FAO/WHO report will include visual representation of amounts of foods (e.g., as a photo) corresponding to the FAO/WHO reference doses (RfDs).
- These visualizations will benefit all stakeholders conducting a risk assessment, including competent authorities, FBOs, and primary producers.
  - Codex CoP: Cleaning processes should be verified through visual observation (checking equipment is visibly clean), [*and testing where feasible and appropriate*]
  - Many in food industry work to a "visibly clean" standard
- Additionally, consumers with food allergy and health care professionals can utilize these visualizations for food allergy management purposes.

Example: Exposure calculation

- On inspection, after cleaning, a limited number of dough particles (5-10) from the prior product formulation have been found across the pre-baking segment of a cookie production line.
- Could be "picked up" by following product
- Allergen management would require you clean further before starting production on the following product, but this information could be very helpful for your food allergen risk assessment.

Example: Exposure calculation

- On inspection, after cleaning, a limited number of dough particles (5-10) from the prior product formulation have been found across the pre-baking segment of a cookie production line.
- The weight of a dough piece is 70-110 mg
- Nonfat dry milk (NFDM) is 5.6% of the prior recipe
- NFDM is 36% protein

Size / mass	x Composition	= Exposure
60-120 mg per particle	x 5% NFDM x 36% protein in NFDM	= 1.1-2.2 mg milk protein per particle

- **Would the URP pose an unacceptable level of risk? (Risk Characterization)**
  - Milk protein exposure per particle is 1.1-2.2 mg.
  - FAO/WHO Reference Dose for Milk is 2 mg total protein from Milk

Consumption

Factors to consider if assessing exposure: POWDER, LIQUID, PASTE

Consumption AMOUNT

Grams of food being consumed per eating occasion

Cross-contact LEVEL or CONCENTRATION

Concentration of total protein from the allergenic source in food (mg/kg)

Exposure assessment: Consumption amount

- Food consumption estimates utilized for food allergen risk assessments and food allergen risk management programs should be:
  - Easy-to-use,
  - Conservative in nature,
  - Based on consumption at a single eating occasion,
  - Representative of consumption patterns of allergic individuals
- Should not be solely based on the serving size

Exposure assessment: Consumption amount

- Crucial to carefully consider the most appropriate food intake figure when performing an exposure assessment
- Example, in US FDA's Guidance for Industry Serving Sizes of Foods
  - Product is packaged and sold individually and contains less than 200 percent of the amount customarily consumed for that product?
  - The entire content of a single-serving container must be labeled as one serving

Questions about food intake data for exposure assessment

- Portion or serving size?
- Is the data provided in national food consumption databases?
- Can I use data from the acute daily intake for a single day?
- Can I use data from one country for another country?
- General population vs Population with food allergies?
- Frequency of consumption?

Example: Exposure calculation

- Peanut detected at 29 ppm (mg/kg) total peanut protein in a lot of 50g muesli bars

Concentration	x Consumption	= Exposure
29 mg peanut protein per kg	x ??? kg	= ??? mg peanut protein exposure

1 muesli bar	50 g
Average consumption (P50)	50 g
P90 consumption	100 g
Max consumption	250 g

Example: Exposure calculation

- Peanut detected at 29 ppm (mg/kg) total peanut protein in a lot of 50g muesli bars

Concentration	x Consumption	= Exposure
29 mg peanut protein per kg	x ??? kg	= ??? mg peanut protein exposure

1 muesli bar	50 g
Median consumption (P50)	50 g
P90 consumption	100 g
Max consumption	250 g

- Answers / Consumption amount used?
- 50g (0.05kg) = 1.45 mg peanut protein exposure (median)

Factors to consider if assessing exposure: POWDER, LIQUID, PASTE

Consumption AMOUNT

Grams of food being consumed per eating occasion

Cross-contact LEVEL or CONCENTRATION

Concentration of total protein from the allergen's source in food (mg/kg)

Concentration / Analysis / Other ways?

Concentration / Product formulation

- Inclusion rate for ingredient in question?
- Subingredient inclusion rate?
  - If ingredient is part of a formulation included as part of another final formulation
  - Example: Ingredient in a seasoning mixture used in a ready-to-eat meal
- Approximate protein content in ingredient (%)

Concentration / Analytical Considerations

- Need to Know the Targets, Calibrants, and Reporting Units

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Concentration / Analytical Considerations

- What do you want to measure?
  - Select appropriate detection system according to major components in the product
    - Example: Milk
      - Total Milk
      - β-lactoglobulin (BLG)
      - Casein
      - Hydrolyzed protein
- What protein source is used as the standard in the method?
- What units are the results reported in?
  - Example: ppm casein, ppm BLG, ppm NFDM, ppm total milk protein

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Food Allergen Detection Methods

- Immunoassays
  - Enzyme-Linked Immunosorbent Assays (ELISAs)
  - Lateral Flow Devices (LFDs)
- Polymerase Chain Reaction (PCR)
- Mass Spectrometry (MS)
- General Protein Tests
- ATP/Bioluminescence

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Food Allergen Detection Methods

- Some methods work better in certain matrices, and are less suitable for others.
- Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix).

Factors to consider if assessing POWDER, LIQUID, PASTE exposure and characterizing risk

Consumption AMOUNT

Grams of food being consumed per eating occasion

Cross-contact LEVEL or CONCENTRATION

Concentration of total protein from the allergen's source in food (mg/kg)

What levels or amounts of allergen are of concern?

Reference Doses (RfDs)

Milligrams total protein from the allergenic source

Example: Ingredient levels

Generalized

	Percentage of inclusion (%)	ppm (mg/kg) equivalents
Ingredient Levels	100%	1 000 000 ppm
	10%	100 000 ppm
	1%	10 000 ppm
	0.1%	1000 ppm
Cross-contact levels	0.01%	100 ppm
	0.001%	10 ppm
	0.0001%	1 ppm
	0.00001%	0.1 ppm

Visualizing a Part Per Million (ppm)

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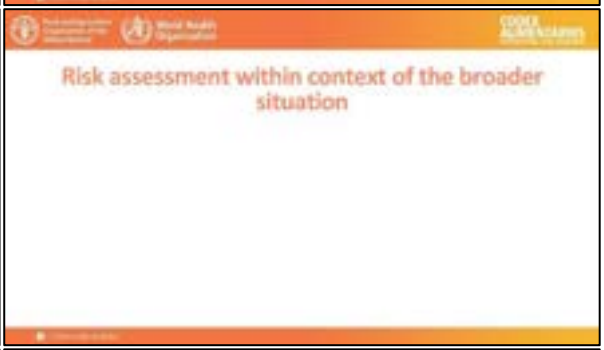
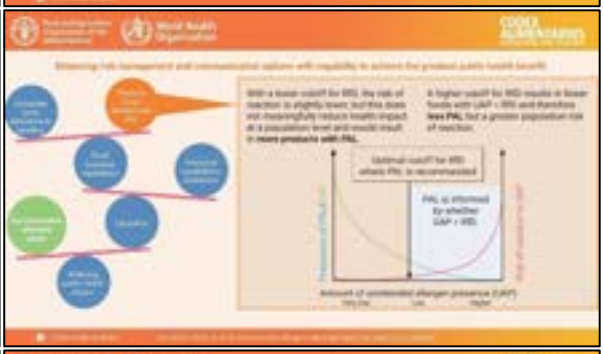
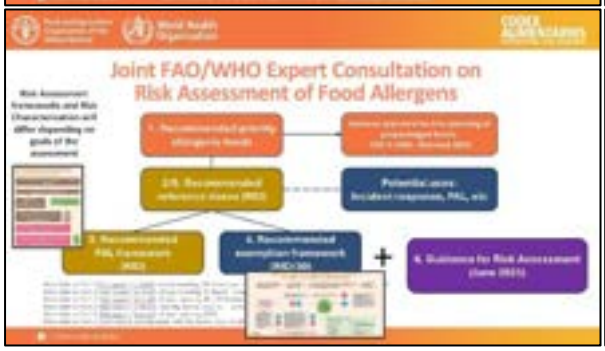
Quick reference: table milligram (mg) exposure per of grams (g) consumed.


Breakout session
Exposure calculation examples and/or weigh 5 particulates


Breakout session


Risk assessment within context of the broader situation




Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens


Logistics tonight and tomorrow
Dinner
Bring your ticket for dinner
Tonight
Homework
Factory visit
08:00 in the hotel lobby
Bring "homework" and product information forms

A4.5 Company slides on the factory.


生产过程防止交叉污染
The line which produced the product of "Peanut and walnut milk" must completely cleaning immediately to prevent cross
生产过程控制 Control during processing
To prevent walnut powder flying during tipping to avoid it spreading in the air. The allergens package should be compressed and sterilized.


配料区域分区标识 T
花生酱peanut
Based on the label and card to select peanut jam and walnut powder to remove surface cover, then move to tipping platform


投料 T
B14配料缸 Mixing tank
Topping peanut jam and walnut powder into B14 mixing tank, to prevent wal nut powder spreading contimination to othe area.


混料 T
物料管道 Materials
Pump the dissovled and even mixed peanut jam and walnut powder to B13 mixing tank, and mixed with raw milk for standardiztion.


储料
物料泵 Materials pump
Pump the mixed materials to M14 storage tank after materials mixed.


灭菌 S
物料管 Materials pipeline
Pump the semi finished product into UHT(sterilizer)


均质机，无菌罐储存待装 H
均质机 Homogenizer
After Homo. the materials goes into aseptic tank for filling


灌装
22快机 TTPK
Filling with TTPK filler, check the sealing during filling and throw the waste packaging materials into waste drum.


入库 S
码垛机 Palletizer
The finished produt is storaged into intellect warehous


清洗验证
After finished processing, perform CIP program, then dismantle pipeline and visual check the cleaning effect, check if has residual with test paper.

05

信息透明：标签管理

06

总结与承诺

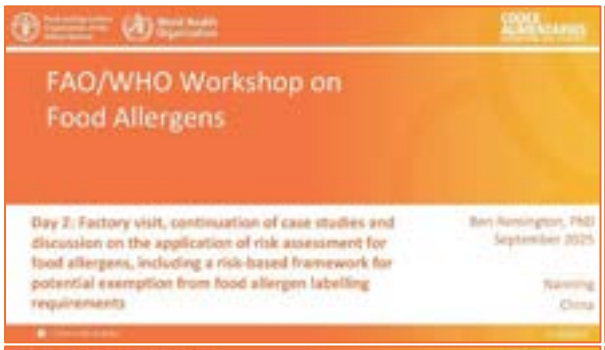
Summary and commitment

体系运行有效：持续改进接受监督

THANKS

感谢您的聆听

A4.6 Continuation of case studies and applications of risk assessment (Ben Remington)




Muesli bar / granola bar
Concentration
Consumption
Exposure


Noodle
Concentration
Consumption
Exposure


Cashew particle
Size / Mass
Composition
Exposure

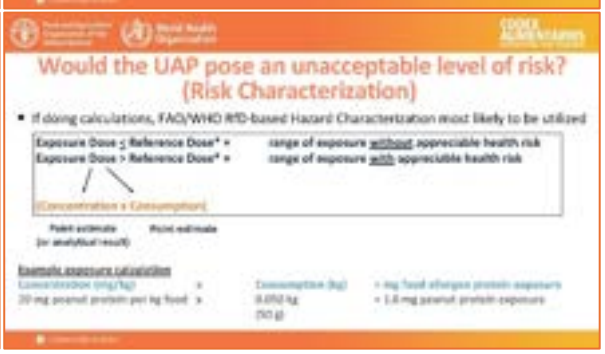

Dough particle
Size / Mass
Composition
Exposure


Continuation of allergen risk assessment


General Principles for Food Allergen Risk Assessment
Which priority allergenic foods are or may be present? (Hazard Identification)
What levels or amounts of allergen are of concern? (Hazard Characterization)
What levels or amounts of UAP can you expect to occur or be consumed? (Exposure Assessment)
Would the UAP pose an unacceptable level of risk? (Risk Characterization)


Guidance for Risk Assessment (June 2025)
Food allergen risk assessments support informed decisions and communication through the supply chain.
Consistent food allergen risk assessment and risk management will improve food safety & public health.


General Principles for Food Allergen Risk Assessment
Which priority allergenic foods are or may be present? (Hazard Identification)
What levels or amounts of allergen are of concern? (Hazard Characterization)
What levels or amounts of UAP can you expect to occur or be (Exposure Assessment)
Would the UAP pose an unacceptable level of risk? (Risk Characterization)


Would the UAP pose an unacceptable level of risk? (Risk Characterization)
If doing calculations, FAO/WHO RfD-based Hazard Characterization most likely to be utilized
Exposure Dose < Reference Dose* =
range of exposure without appreciable health risk
Exposure Dose > Reference Dose* =
range of exposure with appreciable health risk
(Concentration x Consumption)
Point estimate
(or distributional result)
Point estimate
Example exposure calculation
Concentration (mg/kg)
Consumption (kg)
= mg food allergen protein exposure
10 mg peanut protein per kg food
0.052 kg
(50 g)
= 1.8 mg peanut protein exposure

What about Action Levels?

What about Action Levels?

Exposure Dose = Reference Dose* = range of exposure without appreciable health risk

ACTION LEVEL — Concentration (mg/kg, ppm) at transition point

Exposure Dose = Reference Dose* = range of exposure with appreciable health risk

(Concentration x Consumption)

What about Action Levels?

$$\text{AL (in mg total protein from the allergenic food/kg food)} = \frac{\text{RfD (in mg total protein from the allergenic food)}}{\text{Amount of food consumed (in kg)}}$$

$$\text{AL (in mg total protein from the allergenic food/kg food)} = \frac{\text{RfD (in mg total protein from the allergenic food)}}{\text{Amount of food consumed (in kg)}}$$

- Proposed definition in the DRAFT CCFL GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

  Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg).

  The amount of food should be established based on the quantity that can reasonably be expected to be consumed on a single eating occasion preferably using the 50th percentile.

- PAL [shall / should] [only] be used when it is demonstrated that unintended food allergen presence cannot be mitigated to a level at or below the action level for a food allergen based on the reference doses in the table at 4.3.1.

FAO-WHO risk-based framework for PAL

TABLE 1 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RfD (in mg)	CRUSTACEA	FISH	EGG	MILK	TREE NUTS	SOY	FISH	PEANUT	CEREALS	SESAME
RfA (in g)										
600 (in g)	200	5	3	3	3	3	3	3	1	1
30										

TABLE 1 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RfD (in mg)	CRUSTACEA	FISH	EGG	MILK	TREE NUTS	SOY	FISH	PEANUT	CEREALS	SESAME
RfA (in g)										
600 (in g)	200	5	3	3	3	3	3	3	1	1
30	6 000*									

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

TABLE 1 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RfD (in mg)	CRUSTACEA	FISH	EGG	MILK	TREE NUTS	SOY	FISH	PEANUT	CEREALS	SESAME
RfA (in g)										
600 (in g)	200	5	3	3	3	3	3	3	1	1
30	6 000*	150	100	100	60	60	60	60	30	30

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

TABLE 1 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RfD (in mg)	CRUSTACEA	FISH	EGG	MILK	TREE NUTS	SOY	FISH	PEANUT	CEREALS	SESAME
RfA (in g)										
600 (in g)	200	5	3	3	3	3	3	3	1	1
30	6 000*	150	100	100	60	60	60	60	30	30
60	4 000	100	100	60	40	40	40	40	20	20
100	2 000	50	50	30	20	20	20	20	10	10

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

TABLE 4 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RFD in mg	AL*
100 in g	1
10	0.1
1	0.01
0.1	0.001

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

TABLE 4 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RFD in mg	AL*
100 in g	1
10	0.1
1	0.01
0.1	0.001

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

Some EU/CH AILs express results as ppm 'NFDM or skimmed milk powder' *98% protein

TABLE 4 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RFD in mg	AL*
100 in g	1
10	0.1
1	0.01
0.1	0.001

Some EU/CH AILs express results as ppm 'NFDM or skimmed milk powder' *98% protein

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

*126 ppm NFDM

*130 ppm NFDM

*91 ppm NFDM

TABLE 4 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RFD in mg	AL*
100 in g	1
10	0.1
1	0.01
0.1	0.001

Some EU/CH AILs express results as ppm 'NFDM or skimmed milk powder' *98% protein

*126 ppm NFDM

*130 ppm NFDM

*91 ppm NFDM

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

Milk proteins are:
~80% caseins
~10% β-lactoglobulin

*12 ppm casein *1.1 ppm β-lactoglobulin

*13 ppm casein *1.3 ppm β-lactoglobulin

*10 ppm casein *1 ppm β-lactoglobulin

TABLE 4 ACTION LEVELS (ALS) BASED ON REFERENCE DOSES (RFDS) AND REFERENCE AMOUNT (RFA) CATEGORIES, ROUNDED DOWN FOR EASIER REFERENCE

RFD in mg	AL*
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Some EU/CH AILs express results as ppm 'NFDM or skimmed milk powder' *98% protein

*126 ppm NFDM

*130 ppm NFDM

*91 ppm NFDM

* mg/kg, ppm total protein from the allergenic source

Many analytical methods express results in whole food, or in other units

FAO/WHO Report 2, Table 10
Analytical methods found to be applicable at Action Levels corresponding to FAO/WHO RfDs, and not applicable in all cases when investigating other (utterly) more sensitive RfDs.

Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

Risk Assessment frameworks and Risk Characterization will differ depending on goals of the assessment

1. Recommended priority allergens for Canada

2/3. Recommended reference doses (RfD)

Potential uses: Incident responses, PAL, etc

4. Recommended PAL framework (ARC)

5. Recommended exemption framework (RAC) (AE)

+

6. Guidance for Risk Assessment (Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens)

FAO-WHO risk-based framework for PAL

FAO-WHO risk-based framework for PAL

- **Almond flour used in prior product**
  - 9% (90,000 mg/kg)
  - 21.4% protein in ingredient information
- **RfD: 1 mg almond protein**
- **Almond Cake**
  (USA Reference amounts customarily consumed per eating occasion, cake, medium weight 80g, others report 75g, expected consumption, consumption for AL after rounding 100g, 0.100 kg)
- **Action Level (AL): 10 mg/kg almond protein**
  (1 mg protein / 0.100 kg consumption)
- **Risk assessment finds up to 11 mg/kg almond protein, due to cross-contact during ingredient dosing and mixing.**
- **What next?**

FAO-WHO risk-based framework for PAL

- **Are the addition risk mitigation practices / cleaning options for the dosing and mixing area?**
  - Yes! More aggressive scraping and brushing, plus wiping is an option
- **Is the cross-contact with almond now below the AL?**
  - Occasional almond cross-contact
  - At most 2 mg/kg almond protein (BELOW AL)
- **No PAL**

Can I look from a different direction?

Quick reference: kilograms (kg) of carry-over from prior recipe in a mixer into the following product required to reach an IMD exposure per of grams (g) consumed.

"Backward" calculation

Case study from Import / Border Control

Case study from Import / Border Control

- Traces of peanut in mild curry powder from India
- 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder*)
- 0.25 [mg peanut protein / kg curry powder] x 0.040 kg curry powder in a single jar
  = 0.01 mg peanut protein per jar of curry powder
- FAO/WHO Reference Dose: 2.0 mg peanut protein
- RASFF Alert – **Measures taken by UK – Relabelling**
  - Is that measure really necessary?
  - This was not a risk-based decision

jar of curry powder ~40g

Case study from Import / Border Control

- Traces of peanut in mild curry powder from India
- 1 mg/kg - ppm (0.25 mg peanut protein/kg curry powder*)
- 0.01 mg peanut protein per jar of curry powder
- Recommended risk-based measures: No relabelling needed, no PAL needed
- Consumption of 200 jars leads to predicted exposure of 2.0 mg peanut protein (FAO-WHO Reference Dose)

Case study spices from Import / Border Control

–

We saw this example from the government point of view.

What could change from producer point-of-view?

–

How much more information might they be expected to have?

Risk Assessment for Exemptions from required allergen labelling

Risk Assessment for Exemptions from required allergen labelling

- Foods and ingredients in GSLPF 4.2.1.4 are known to trigger food allergy or coeliac disease and shall always be declared as allergenic foods using the specified name in addition to or as part of the ingredient name when intentionally present in the food.
- GSLPF 4.2.1.6: Regional or national competent authorities may exempt ingredients derived from foods listed in Section 4.2.1.4, and where applicable Section 4.2.1.5, from being declared as allergenic foods. Such exemptions shall be subject to a risk assessment[*] to establish the safety of the allergenic food derivative.
- Footnote * refers to Report 4 from the FAO-WHO expert consultation for the risk assessment of food allergens, which provides guidance for a risk-based framework for assessing whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of priority food allergens can be exempted from mandatory food allergen labelling.

Part 4: Framework for exemption from mandatory allergen declaration

- Framework was developed for consideration of labelling exemptions for foods and ingredients derived from priority allergenic sources
- Tested against previously granted exemptions in various countries or regions

Part 4: Framework for exemption from mandatory allergen declaration

- Characterization of the derivative, includes source and composition, existing uses, safety and reported adverse events.
- Exposure assessment from proposed exempt uses for verification against an acceptable marker of safety.
- Possibly analysis of specific proteins from allergenic source.

Part 4: Framework for exemption from mandatory allergen declaration

- Quantification of total protein → * Small and unreadable on purpose
- *Exposure less than RfD/307
- Assessments of potential alterations in the allergenicity of the protein(s) in the derivative

Part 4: Framework for exemption from mandatory allergen declaration

- Quantification of total protein → * Small and unreadable on purpose
- A number of considerations (e.g. hydrolyzed, very low protein, difficult matrix for protein recovery) which could render different allergen-specific methods to be not fit-for-purpose.

Part 4: Framework for exemption from mandatory allergen declaration

- Quantification of total protein → * Small and unreadable on purpose
- Non-specific methods, such as general protein or amino acid analysis will likely be required to complete a potential exemption assessment.

Part 4: Framework for exemption from mandatory allergen declaration

- Quantification of total protein → * Small and unreadable on purpose
- Existing non-specific methods might (will likely) need to be modified/extended to ensure applicability.

Part 4: Framework for exemption from mandatory allergen declaration

- Quantification of total protein → * Small and unreadable on purpose
- For total protein quantification, it is recommended to use more than one test method, each based on different principles, that are fit for purpose.

Part 4: Framework for exemption from mandatory allergen declaration

Case studies examined in the report

- Glucose syrups
- Alcohol distillates
- Peanut oil
- Soybean oil
- Soy lecithin
- Soy phytosterols/ tocopherols
- Fish gelatine
- Ice structuring protein (ISP)
- Wheat-based maltodextrins
- Isinglass
- Lactitol
- Extensively hydrolysed infant formula

Example: Soybean derivatives

- A simplified illustration of the production process for neutralized/refined bleached and deodorized (N/RBD) soybean oil
- In some instances, certain fractions created during production of N/ RBD soybean oil have undergone additional processing to create derivatives which have also been granted exemptions in a number of countries.
- Such examples include the phospholipids* (lecithins) and distillates* (tocopherols, phytosterols, sterols) fractions.

Example: Soybean derivatives

- Quantification of total protein → * Small and unreadable on purpose
- How would you go about quantification of total protein in highly refined (N/RBD) soybean oil?

Example: N/RBD soybean oil

- *Quantification of total protein in highly refined (N/RBD) soybean oil? → * Small and unreadable on purpose
- *Rigby et al 2011
  - *Tested multiple modified extraction methods
  - *Multiple protein content methods, based on different principles
  - *Explained reasoning for preferred combination of methods

Example: N/RBD soybean oil

- Quantification of total protein in highly refined (N/RBD) soybean oil?
- Exposure less than RfD/30?

Example: N/RBD soybean oil

- Quantification of total protein in highly refined (N/RBD) soybean oil?
- Rigby et al 2011
  - N/RBD oils protein content 62-265 ng/g (µg/kg)
  - Crude un-degummed oils protein content 86000-87900 ng/g (µg/kg)

Example: N/RBD soybean oil

- Quantification of total protein in highly refined (N/RBD) soybean oil?
- FAO/WHO 2022
  - Estimated 97.5th percentile eating occasion containing: Margarine, Salad dressing, French fries, and Mayonnaise
  - Range of exposures to soybean protein in N/RBD: 10.5–57.4 µg soy protein

Example: N/RBD soybean oil

- Quantification of total protein in highly refined (N/RBD) soybean oil?
- FAO/WHO 2022
  - Exposure to soybean protein in N/RBD would be less than the RfD/30 (333 µg soybean protein)
  - In the range of the RfD/175 (57 µg soybean protein) to the RfD/950 (10.5 µg soybean protein)

Example: N/RBD soybean oil

- Local outcomes: Recommended to exempt highly refined (N/RBD) soybean oil from required food allergen labelling
- No exemption list from CCFL/Codex

N/RBD Soybean Oil Conclusions

- Is the Rigby method going to be the new default method for determining general protein amounts?
  - NO
- Similar to allergen-specific methods for day-to-day risk assessments, the specific recommendation or general protein method used to support an exemption petition should be tailored on a case-by-case basis.

Case studies in Report 4

- **Exposure estimated < RfD/30**
  - Soy Phytosterols/Tocopherols
  - Soybean Oil
  - Peanut Oil (most cases)
  - Soy Lecithin
  - Fish Gelatine & Isinglass
- **Exposure estimated between RfD/10 and RfD/30 but history of safe use**
  - Whey derived ethanol
- **Exposure estimated between RfD/5 and RfD/10 but history of safe use**
  - Wheat-based glucose syrups (including dextrose)
- **Exposure estimated to exceed RfD (also exceeds RfD/30). Clinical studies required**
  - Extensively hydrolysed casein (EHC) (Milk, sole source nutrition [illegible] RfD)
  - Ice-structuring protein (ISP) (Fish 10 mg non-allergenic protein vs RfD of 5 mg protein)

Summary and final remarks for the risk assessment workshop

- What have we covered in these two days?
- Full spectrum of risk assessment
- Disease of food allergy, food allergen risk assessment and risk management
- From theory to practical application
- Observed industry best practice during factory visit
- Shared learnings and growth of knowledge as a group

Summary and final remarks for the risk assessment workshop

- This is just the beginning.
- Trainings, education and workshops for food allergen risk assessment will continue to be needed.
- You will be a trusted resource for others in your community.
- Please bring others along the food allergen journey.
- We are always open for delivering more workshops if it is desired in your country/region.

Thank you for your time and participation in this workshop!

- Please feel free to contact us with any questions in the future.
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FAO/WHO workshop on risk assessment of food allergens

Workshop report

This FAO/WHO workshop in China, held in September 2025, brought together over 60 experts from 11 countries across Asia, Africa, and Latin America to address and learn more about the growing challenge of food allergens. The primary goals were to:

- enhance the capacity of Member Countries in conducting food allergen risk assessments;
- reinforce the importance of moving from hazard to risk for food allergen assessment and management; and
- ensure alignment with the latest international standards.

AGRIFOOD SYSTEMS AND FOOD SAFETY
https://www.fao.org/food-safety/en/
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
ROME, ITALY

DEPARTMENT OF NUTRITION AND FOOD SAFETY
https://www.who.int/health-topics/food-safety
WORLD HEALTH ORGANIZATION, GENEVA, SWITZERLAND