



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



**World Health
Organization**

**Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens
Part 3: Review and establish precautionary labelling in foods of the priority allergens**

Virtual meeting, 18 – 29 October, 3 November 2021

SUMMARY AND CONCLUSIONS

Issued on 13 December 2021

The third in a series of three meetings of an ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens was held from 18 to 29 October 2021, with an additional day for the report finalization and adoption on 3 November 2021. The main purpose of this third meeting was to review and evaluate the evidence in support of precautionary labelling.

If conditions had permitted, this meeting would have been held at FAO headquarters in Rome, Italy. Because of the travel restrictions and lock-downs due to the COVID-19 pandemic in many countries, the joint FAO/WHO secretariat was unable to convene a physical meeting. Therefore, the meeting was held as a videoconference using a virtual online platform.

In view of the time differences in the countries of origin of the invited experts, the time for a videoconference was restricted to a 3-hour time slot (12:00–15:00 CET) each day. To make up for the usual daily length (8–10 hours) of a joint FAO/WHO scientific expert meeting and efficiencies associated with in-person meetings, virtual sessions were held daily over the course of three weeks.

Dr Stefano Luccioli served as Chairperson.

Dr N Alice Lee served as rapporteur.

An Expert Committee, comprising scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry were selected to participate in the series of meetings of the FAO/WHO Expert Consultation on Risk assessment of Food Allergens (FAO and WHO, 2020a).

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

The meeting participants are listed in Annex 1 of this summary report.

More information on this work is available at:

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

and

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

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Background and objective

At its 45th session in May 2019, the CCFL requested FAO and WHO to provide scientific advice to validate, and if necessary, update the list of foods and ingredients in section 4.2.1.4 of GSLPF (General standard for the labelling of prepackaged foods) (FAO and WHO, 2019). In December 2020, the initial meeting of the ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, addressed the request by first identifying and agreeing upon the criteria for assessing additions and exclusions to the priority food allergen list, then evaluating the available evidence for foods of concern (FAO and WHO, 2020b).

The CCFH has developed a code of practice (CoP) to provide guidance to food business operators and competent authorities on managing allergens in food production, including controls to prevent allergen cross-contact. In relation to this CoP, the 50th session of CCFH requested FAO and WHO to provide scientific advice with respect to the list of priority allergens and the use of allergen threshold levels to inform allergen risk management for foods (FAO and WHO, 2018). In March 2021, the Expert Consultation convened to establish threshold levels for priority allergenic foods and recommend analytical methods for detection in food and food processing environments. This second meeting addressed a part of the CCFH request by establishing recommended reference doses, based on health-based guidance values (FAO and WHO, 2021a).

The CCFL is also developing guidance on the use of precautionary allergen or advisory labelling (PAL) (FAO and WHO, 2021b). Following those two meetings, FAO and WHO convened the Expert Consultation for a third meeting to address the remaining requests from the CCFH, and also to support the ongoing work of CCFL.

The purpose of this third meeting was to evaluate the evidence in support of precautionary labelling (Annex 2).

Conclusions

- Precautionary allergen labelling (PAL) based on a comprehensive allergen risk management program and implemented using a single clear unambiguous advisory statement, supported by effective risk communication, is an effective strategy to protect consumers from unintended allergen presence (UAP).
- Current use of PAL is voluntary and often not part of a standardized risk assessment process. This leads to non-uniform and indiscriminate application of PAL (including a multitude of different phrases) and/or inappropriate absence of PAL. Consumers find the information currently provided by PAL to be confusing. This results in poor communication and misinterpretation of the risks posed by UAP, reducing consumer trust in allergen labelling, and proven health risk to the allergic consumer.
- The available evidence indicates that some manufacturers, consumers and other stakeholders do not understand current strategies to communicate precautionary messages relating to risks posed by UAP in products. Current data indicate a preference for wording which conveys that a food is “not suitable for” consumers with a particular allergy. Education of consumers, healthcare providers, food business operators, risk assessors and risk managers is critical to PAL management.

- Individual allergy management considerations:
 - The use of a PAL system based on risk-based reference doses (RfDs) would be protective for the vast majority of food-allergic individuals.
 - In this framework for PAL, it is recommended that all individuals with a particular food allergy avoid foods when a PAL to that food is present. However, this system may be overprotective/restrictive for some of the less sensitive individuals with food allergies.
 - Any deviations from this recommendation should be taken into consideration for individual allergy management advice, as discussed between an allergic individual and their healthcare providers.
- RfDs recommended in the 2nd meeting are not intended to be used for making a claim that a food is free from specified allergens.
- Risk assessment for considering ingredient exemptions from priority allergen labelling is proposed for a future meeting.

Recommendations

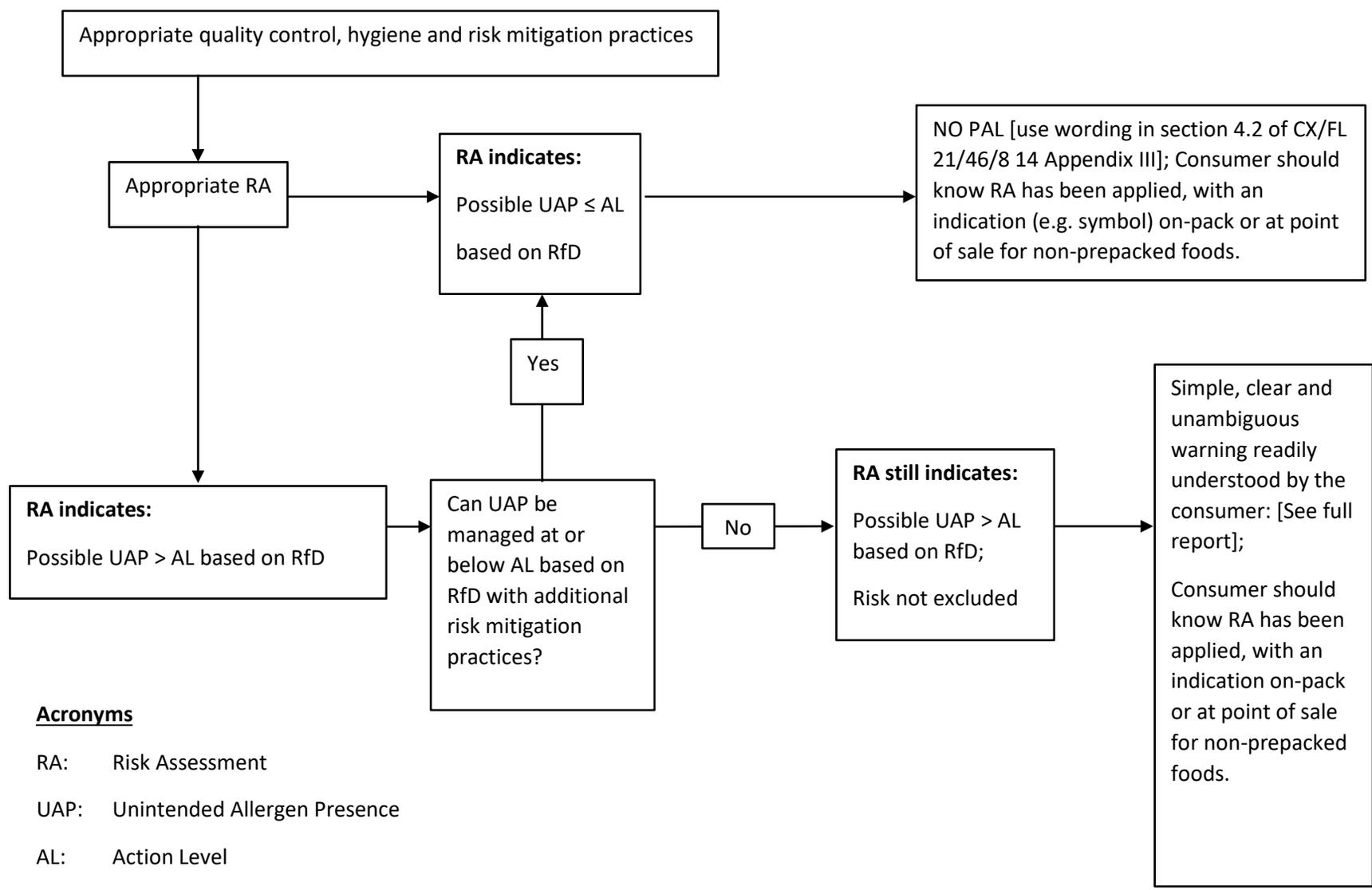
The safety of consumers with food allergies is a shared responsibility of all stakeholders including but not limited to consumers, food business operators (FBO), healthcare providers and regulatory bodies.

- The Expert Group recommends that the decision whether or not to use a PAL statement is part of a regulatory framework that requires FBOs to denote PAL when UAP exceeds the relevant RfD and to *not* use PAL when UAP does not exceed the relevant RfD. Moreover, FBO should/must provide an indication on the label (e.g., using a symbol) that a qualified RA to inform the need (or not) for PAL has been undertaken, irrespective of whether the RA outcome indicates that a PAL should be used or not.
- If an RfD is not established for a particular priority allergenic food, an estimated RfD can be used providing it is determined following the guiding principles elaborated by Meeting 2 of the FAO/WHO consultation.
- Compliance with existing Codex codes of practice, good allergen management and allergen control programs are a prerequisite for FBOs. The use of PAL is not appropriate where deviations from these programs may occur such as UAP due to production errors.
- Decisions about whether or not to use PAL should be based on hazard identification and risk characterization (refer to the diagram below). Adherence to the Code of Practice on Allergen Management for FBOs (FAO and WHO, 2020c), GMP (Good Manufacturing Practices), HACCP (Hazard Analysis and Critical Control Points) combined with an appropriate UAP risk assessment, should ensure that the level and frequency of UAP is minimized consistent with the principles elaborated for PAL. The use of PAL should be restricted and applied to those situations where UAP cannot be prevented and may result in an exposure above the RfD for a priority allergenic food.
- The presentation of PAL to the consumer should be simple, clear, unambiguous and not false or misleading:
 - A consistent and harmonized approach is the most effective use of PAL for communicating to consumers with food allergy about the risk from UAP.

- This includes use of a single unified and harmonized wording, which should convey to consumers that the product with PAL poses a risk to health for individuals with an allergy to that particular food, and thus “is not suitable” for them.
- The precise wording of the single phrase for PAL needs to be decided by CCFL in conjunction with all relevant stakeholders. Phraseology for PAL should consider taking local linguistic nuances into account.
- Education of allergic consumers (or those providing food for them, including FBOs) and other relevant stakeholders (e.g. risk assessors, risk managers, healthcare providers) is critical, to ensure understanding of the applied principles and the implications of the chosen phraseology.

FBOs should retain documented evidence of compliance with COP/ HACCP and their UAP risk assessment if such an indicator is used on the label.

- Analytical methods used to inform the risk assessment process and validate/verify cleaning processes should have a demonstrated fitness-for-purpose (including e.g. matrix-matched assay validation with a limit of quantification at least 3-fold below the action level for the specific food being analysed) and report in units of mg total protein from the allergenic source/Kg food analysed (ppm total protein from the allergenic source).



Acronyms

- RA: Risk Assessment
- UAP: Unintended Allergen Presence
- AL: Action Level
- RfD: Reference Dose

References

- FAO and WHO.** 2018. Codex Alimentarius Commission. Report of the 50th Session of the Codex Committee on Food Hygiene (CCFH). FAO, Rome. (available at https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-50%252FReport%252FREP19_FHe.pdf)
- FAO and WHO.** 2019. Codex Alimentarius Commission. Report of the 45th Session of the Codex Committee on Food Labelling (CCFL). FAO, Rome. (also available at https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-714-45%252FFinal%252520Report%252FREP19_FLe.pdf)
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- FAO and WHO.** 2020b. Summary report of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 1: Review and validation of Codex priority allergen list through risk assessment (available at <https://www.fao.org/3/cb4653en/cb4653en.pdf>)
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Annex 1. List of participants

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Annex 2. Meeting plan of the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens

Meeting 1: Review and validation of Codex priority allergen list through risk assessment (November – December 2020)

- I. Whether the published criteria for assessing additions and exclusions to the list is still current and appropriate.
- II. Subject to the advice on the criteria above:
 - Whether there are foods and ingredients that should be added to or deleted from the list.
 - Clarification of the groupings of foods and ingredients in the list.
 - Whether certain foods and ingredients, such as highly refined foods and ingredients, that are derived from the list of foods known to cause hypersensitivity can be exempted from mandatory declaration.

Meeting 2: Review and establish threshold levels in foods of the priority allergens (March – April 2021)

- I. What are the threshold levels for the priority allergens below which the majority of allergic consumers would not suffer an adverse reaction?
- II. For the priority allergens, what are appropriate analytical methods for testing food and surfaces?
- III. What should be the minimum performance criteria for these different analytical methods?

Meeting 3: Review and evaluate the evidence in support of precautionary labelling (October 2021)

- I. What methods/tools are available for FBOs to determine:
 - whether allergen cross-contact is reasonably likely to occur in a food after a cleaning procedure;
 - whether allergen cross-contact is reasonably likely to occur from equipment used for foods with different allergen profiles; and
 - the level of allergen in a food resulting from cross-contact?
- II. Guidance on precautionary labelling.
 - The use of scientifically based threshold levels to evaluate risk for consumers with food allergies.
 - Determine the conditions for using the precautionary allergen labelling.
- III. How can thresholds be used by FBOs to determine:
 - the extent to which a cleaning procedure removes an allergen to a level that prevents or minimises the risk to the majority of allergic consumers from allergen cross-contact; and
 - whether an ingredient that contains a low level of an allergen (e.g. an ingredient with a precautionary allergen label) warrants control of its use to prevent or minimise allergen cross-contact?