



**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 1: Review and validation of Codex priority allergen list through risk assessment**

Virtual meeting, 30 November – 11 December 2020, 28 January 2021, 8 February 2021

SUMMARY AND CONCLUSIONS

Issued on 10 May 2021

The first in a series of three meetings of an ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens was held from 30 November to 11 December 2020, with an additional two days for the report finalization and adoption on 28 January and 8 February 2021. The main purpose of this first meeting was to validate and, if necessary, update the list of foods and ingredients listed in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods (GSLPF) based on risk assessment.

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 with two additional sessions on 28 January and 8 February 2021.

Dr Lauren Jackson served as Chairperson.

Dr Bert Pöpping served as rapporteur.

An Expert Committee, comprised of scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry were selected to participate in the first meeting of the FAO/WHO Expert Consultation on Risk assessment of Food Allergens. To achieve the validation of the allergen list, the committee first identified and agreed upon the criteria for assessing additions and exclusions to the foods and ingredients listed in section 4.2.1.4 of the GSLPF. Subsequently, the committee clarified the groupings of foods and ingredients on the list and determined whether certain foods and ingredients that are derived from the list of foods known to cause immune hypersensitivity can be exempted from mandatory declaration.

This document summarizes the conclusions of this meeting, and is made available to facilitate the deliberations of the upcoming Codex Committee on Food Labelling. The full report of the meeting will be published in the Food Safety and Quality Series, and will describe the scientific evidence available to the Committee and its deliberations during the meeting.

The participants are listed in Annex 1 to 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/>

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

Background

The labeling of food allergens in pre-packaged foods plays a key role in protecting food allergic individuals while no preventative clinical treatment is available. Although the latest developments in immunotherapy with food allergens have shown promising results, avoidance of the offending food remains as the only option to prevent allergic reactions.

Allergens in food have been considered by the Codex on a number of occasions since 1993. In 1995, FAO started a Technical Consultation (FAO, 1995) that resulted in the identification of eight foods or food groups causing IgE-mediated food allergy. They were incorporated in the General Standard for the Labelling of Prepacked Foods (GSLPF) in 1999 (section 4.2.1.4) (CAC, 1985). In 1999, following the FAO Technical Consultation, WHO convened an Ad hoc panel on Food Allergens. The panel recommended the criteria for the addition of foodstuffs/products to the list of the Codex Committee on Food Labelling (CCFL) (FAO/WHO, 2000).

The CCFL is currently reviewing provisions relevant to allergen labelling in the GSLPF as well as developing guidance on the use of precautionary allergen or advisory labelling (PAL) (CAC, 2019). The Codex Committee on Food Hygiene (CCFH) has developed the Code of Practice on Food Allergen Management for Food Business Operators (CoP), which was adopted in 2020. This CoP provides guidance on allergen management in food production, including controls to prevent cross-contact where an allergen is inadvertently transferred from a food containing an allergen to a food that does not contain the allergen (CAC, 2000). The General Principles of Food Hygiene (GPFH) has also been updated in 2020 and includes information on the control of allergens (CAC, 1969). The CoP is intended to complement the GPFH and the GSLPF and support industry compliance.

There have been many scientific developments in the understanding of food allergens and their management since the original drafting of the GSLPF. Thus, in response to the request from Codex for scientific advice, including current evidence of consumer understanding of allergens, FAO and WHO are convening a series of expert meetings to provide scientific advice on this subject (Annex 2).

Scope

The objectives of the meeting is to see whether the published criteria (FAO/WHO, 2000) for assessing additions and exclusions to the list is still current and appropriate.

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.

Conclusions

The Expert Committee determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF. Thus, it was recommended that foods or ingredients such as lactose, sulphite, and food additives which cause food intolerances rather than immune-mediated responses, should be excluded from this list.

The Committee identified prevalence of the immune-mediated hypersensitivity to a specific food, severity (i.e. proportion of severe objective reactions to a food/ingredient such as anaphylaxis), and the potency of food/ingredient (i.e. the amount of the food/ingredient required to cause objective symptoms) as the three key criteria that should be used to establish the priority allergen list. Subgroups of the Expert Committee were established to review the literature on the prevalence, severity and potency of immune-mediated hypersensitivity of each food currently on the GSLPF list (cereals containing gluten and products of these; crustacea and products of these; eggs and egg products; fish and fish products; peanuts, soybeans and products of these; milk and milk products; tree nuts and nut products;), as well as other foods found on priority allergen lists established in individual countries or regions (e.g. mollusks, mustard, celery, sesame, buckwheat, lupin, and others).

Based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other *Triticum* species, rye and other *Secale* species, barley and other *Hordeum* species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut). Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens, such as buckwheat, celery, lupin, mustard, oats, soybean and tree nuts (Brazil nut, macadamia, pine nuts), should not be listed as global priority allergens but may be considered for inclusion on priority allergen lists in individual countries. Since current dietary trends include an increased consumption of plant-based foods and diets consisting of alternative protein sources, it was recommended that pulses, insects and other foods such as kiwi fruits be included in a “watch list” and evaluated for the priority allergen list when data on prevalence, severity and potency become available. Finally, the Expert Committee recommended that foods and ingredients derived from the list of foods known to cause immune-mediated hypersensitivities should be evaluated on a case-by-case basis for exclusion from declaration on ingredient lists and/or on food packaging.

References

CAC. 1969. *CAC/RCP 1-1969: General Principles of Food Hygiene (2020 Revision)*. Codex Alimentarius Commission.

CAC. 1985. *CXS-1-1985: General Standard for the Labelling of Prepackaged Foods (2018 Revised)*. Codex Alimentarius Commission (available at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B1-1985%252FCXS_001e.pdf)

CAC. 2019.

Report of the 45th Session of the Codex Committee on Food Labelling (CCFL). Ottawa, Ontario, Canada, Codex Alimentarius Commission. (available at http://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)

CAC. 2000. *CXC 80-2020: Code of Practice on Food Allergen Management for Food Business Operators.*

(available at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B80-2020%252FCXC_080e.pdf)

FAO.1995. *Report of the FAO technical consultation on food allergies.* 1995, Food and Agriculture Organization of the United Nations: Rome, Italy.

FAO/WHO. 2000. *Report of an ad hoc Panel on Food Allergens. Annex 4 of Evaluation of certain food additives and contaminants. Fifty-third report of the Joint FAO/WHO Expert Committee on Food*

Additives. WHO Technical Report Series 896 (available at https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf?sequence=1)

Annex 1. List of participants

EXPERTS

Dr Joseph Baumert, the United States of America

Dr Simon Brooke-Taylor, Australia

Dr Huilian Che, China

Dr Hongbing Chen, China

Dr René Crevel, the United Kingdom

Dr Geert Houben, the Netherlands

Dr Lauren Jackson, the United States of America

Dr Symeon Kyriakidis, Greece

Dr Sébastien La Vieille, Canada

Dr N Alice Lee, Australia

Dr María Cristina López, Argentine

Dr Stefano Luccioli, the United States of America

Dr Patrick O'Mahony, Ireland

Dr Gustavo Polenta, Argentina

Dr Bert Pöpping, Germany

Dr Benjamin Remington, the Netherlands

Dr Eva Södergren, Sweden

Dr Sirinrat Srikulnath, Thailand

Dr Stephen Taylor, the United States of America

Dr Paul Turner, the United Kingdom

RESOURCE PERSONS

Dr Simon Flanagan, Switzerland

Dr Markus Lacorn, Germany

Dr Clare Mills, the United Kingdom

Dr Emilio Esteban, the United States of America

Ms Kathy Twardek, Canada

Dr Douglas Balentine, the United States of America

Ms Verna Carolissen, Codex, Italy

Dr Sarah Cahill, Codex, Italy

Ms Lingping Zhang, Codex, Italy

Mr Patrick Sekitoleko, Codex, Italy

SECRETARIAT

Dr Markus Lipp, FAO, Italy

Dr Jeffrey LeJeune, FAO, Italy

Dr Vittorio Fattori, FAO, Italy

Dr Kang Zhou, FAO, Italy

Ms Christine Kopko, FAO, Italy

Ms Haruka Igarashi, WHO, Switzerland

Dr Stephan Walch, Germany

Dr Carmen Diaz-Amigo, Germany

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. 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?
- III. What are appropriate analytical methods for testing food and surfaces?

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.