



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



**World Health
Organization**

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

Background

Allergens in food have been considered by the Codex on a number of occasions since 1993. The list of foods and ingredients known to cause hypersensitivity was included into the General Standard for the Labelling of Packaged Foods (GSLPF)¹ in 1999. Since then, a new paragraph relating to biotechnology (2001) and the insertion of 'Milk Protein' in the list of class names (2003) were updated within the GSLPF relating to the allergen.

The Codex Committee on Food Labelling is reviewing provisions relevant to allergen labelling in the GSLPF as well as developing guidance on the use of precautionary allergen or advisory labelling (PAL)². The Codex Committee on Food Hygiene (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. The scope of the CoP is allergen management throughout the supply chain including primary production, during manufacturing, and at retail and food service endpoints. The General Principles of Food Hygiene (GPFH) has also been recently updated and includes information on the control of allergens. The CoP is intended to complement the GPFH and the GSLPF and support industry compliance³.

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 an expert meeting to provide scientific advice on this subject.

¹ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXS%2B1-1985%252FCXS_001e.pdf

² 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%252FFREP19_FLe.pdf

³ Draft Code of Practice on Food Allergen Management for Food Business Operators accessible from the Report of CCFH50 meeting, at: <http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFH&session=50>

Scope and Objectives

The purpose of this project is to (i) validate and update the list of foods and ingredients in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods (GSLPF) based on risk assessment, (ii) establish threshold levels in foods of the priority allergens, and (iii) evaluate the evidence in support of precautionary labelling. Particular tasks may include:

1. GSLPF

- Whether the published criteria⁴ 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 on the list.
 - Whether certain foods and ingredients, such as highly refined foods (e.g. refined oils or hydrolyzed food proteins, etc) and ingredients, that are derived from the list of foods known to cause immune hypersensitivity but that are demonstrated to not contain allergens can be exempted from mandatory declaration.

2. Thresholds

- What are the threshold levels for the priority allergens (e.g. cereals containing gluten, crustaceans, eggs, fish; milk, peanuts, soybeans, and tree nuts) below which the majority of allergic consumers would not suffer an adverse reaction?
 - Are sufficient data available to establish threshold levels for (all) allergens? If not, what data are needed?
 - What are thresholds or levels associated with low, intermediate or high risk for allergic reactions or other adverse health consequences?
 - Is there an acceptable level of allergic reaction risk which does not negatively impact public health?
- How can thresholds be used by FBOs to determine:
 - Which cleaning procedures remove allergens 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.
- For the priority allergens, what are appropriate analytical methods for testing food and surfaces.
- What should be the minimum performance criteria for these different analytical methods?

3. Precautionary

- 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;

⁴ [WHO Technical Report Series 896 \(2000\)](#). 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.

- Whether allergen cross-contact is reasonably likely to occur from equipment used for foods with different allergen profiles and matrices; and
- The level of allergens in a food resulting from cross-contact, and need for modifying or improving preventive controls.
- 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. For example:
 - Should such labelling be restricted to those situations in which allergen cross-contact cannot be controlled to the extent that the product poses a potential risk to the allergic consumer?
 - Should such labelling only be applied following an assessment of the likelihood of allergen cross-contact identifying a risk to consumers?
 - Should such labelling not be used? Must a risk assessment be carried out identifying either a risk (allergen labelling) or no risk (no labelling) for the allergic consumers?
 - What are appropriate definitions of allergen, allergen cross-contact, and allergen profile? And in what way should allergy severity/class be taken into account for precautionary labelling?

CALL FOR EXPERTS

The assessment of potential experts will start on 29 February 2020

FAO and WHO are currently in the process of identifying experts to participate in future work of FAO and WHO in the area of food allergens. All applicants should meet the following general criteria:

- advanced University/College degree in food science, food technology, immunology, epidemiology, public health, or related fields
- experience in food safety/risk analysis related to food allergens
- at least five years of experience in relevant fields, including clinical experience on allergen, production and processing control for cereals containing gluten including wheat, crustaceans, eggs, fish, peanuts, soybeans, milk, tree nuts, and/or sulphite, assessment and application of relevant interventions in this sector, etc.
- scientific publications in peer-reviewed journals, in particular, relevant publications within the last 10 years
- good knowledge of the English language, both written and oral
- evidence of leadership or invited participation in national or international scientific bodies, committees, and other expert advisory bodies pertinent to the scope of this work

Selection of experts

Applicants' curricula vitae (CV) will be reviewed based on the criteria listed above by a selection panel appointed by FAO or WHO. A small number of accomplished individuals will be invited to participate in the proposed upcoming meeting on food allergens. Selected experts may be required to assist in the preparation of background papers and report drafts (in English). In selecting experts, FAO and WHO will consider, in addition to scientific and technical excellence, diversity and complementarities of scientific backgrounds, and balanced representation from geographic regions, including developing and developed countries, as well as gender. Unsuccessful candidates are not routinely notified.

Appointment of experts

Selected experts will be invited to contribute to the meeting only in their individual scientific capacity. An expert will not represent the government of country of which he or she is a citizen, or the institution with which he or she is associated. The experts designated will not receive any remuneration, however, where a physical expert meeting is held, travel costs, subsistence allowance and other related expenses will be the exclusive responsibility of FAO and WHO.

Applications

Interested applicants should submit their CV. The CV should include a description of education, relevant work experience, evidence of national or international expertise on the topic, including a list of peer-reviewed publications relevant to the factors indicated above (please do not include reprints in your submission unless specifically requested at a later date). Applicants must have a good working knowledge of English as correspondence and meetings will be in English only.

Before participating in any related activity, all the selected experts will be required to declare any potential interests associated with the subjects and substances that will be evaluated. Experts will be asked to indicate, in writing, all interests (financial and intellectual) on their part or that of their spouse that may affect, or be perceived to affect, their scientific independence as experts, including one or more of the

following conditions: employment (past or present) by any commercial enterprise or private or civil sector association; receipt of research or other study grants from such enterprises or associations; shareholdings in commercial enterprises active in fields related to food safety. Identification of an interest does not necessarily indicate a conflict nor automatically exclude an individual from participation. For example, as expert, it is expected that many, if not all, will be employed in some capacity related to the subject matter. These declarations must be completed and evaluated before a formal invitation will be issued. Declaration documents will be retained by the Joint Secretariat and a summary of declarations will be included in the report of the work. In addition, a confidentiality undertaking must also to be completed prior to appointment to ensure proper handling of dossiers and proprietary information.

Deadline

Please submit nominations and CVs at your earliest convenience, but no later than **29 February 2020**.

Data submissions in response to the call for experts should be sent to:

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CALL FOR DATA

Deadline: 31 May 2020

FAO and WHO desire that all relevant information and data about food allergens are considered in their assessment and are thus issuing this international call to raise awareness about data needs and invite all interested parties to provide any relevant information/data, particularly data that may not be readily available in the public domain.

Objectives

The data will serve as inputs to the development of scientific advice, which shall be provided through an expert consultation that will take place in 2020, and will guide the elaboration of appropriate Codex texts and advise Member States.

Request for relevant information

FAO and WHO want to ensure that all available and relevant information and data are collected, and are requesting governments, private sector, the food industry, academia, consumer groups, laboratories, and any other interested organizations and individuals to submit any available data on the specific areas indicated above. These data may be published or unpublished. Reference should be made to related published studies, where applicable.

List of data and information requirements

Data and information on the following aspects are requested:

1. Data on the prevalence and characteristics of food allergy cases and food allergens.

- Food allergy case studies:
 - time (year and month) and location (region, country, and city) of case occurrence;
 - age, sex and medical status;
 - case confirmed or suspected to have resulted from the exposure to food allergens;
 - implicated type of food allergen (if identified), and how this was determined (e.g. diagnosis, laboratory confirmation, investigation, etc.);
 - source attribution of the food allergen, including origin (e.g. local, imported);
 - clinical presentation, pathophysiology and outcome of the allergy;
- Epidemiological data on food allergies:
 - number and age and sex distribution of individuals with diagnosed food allergies, as well as acute cases, hospitalizations, and deaths associated with food allergens;
 - susceptibility characteristics and medical history of diagnosed food allergic individuals (e.g. pregnancy, nutrition, health and medication status, immune status and previous exposure history or any other risk factors identified);
- Clinical, chemical and biological data on food allergens, including clinical presentation of reactions to respective allergens (cutaneous, respiratory, gastrointestinal, cardiovascular, etc.); pathophysiology of food allergens; immunogenicity of food allergens; dose-response studies (in particular minimum eliciting dose); immunotoxicity studies;
- Occurrence data on food allergens in unrelated food commodities, including possible sources (formulation mistake, product reuse, inadequate clean, allergen cross-contact, etc.);
- Any other relevant data.

2. Analytical methods for food allergen detection along the value chain.

- DNA-based;
- protein-based;
- others.

3. Dietary exposure assessment data

- levels and patterns of human exposure from all relevant sources of identified food allergens;
- food consumption patterns and population groups.

4. Risk management measures

- current allergen monitoring and surveillance, as well as commodity-specific programmes;
- summary of risk management programs in place for food allergens, and evidence for their success or otherwise.

Data provider: Please provide name, title and full contact details of the contact person for follow-up and further details if needed.

Confidential and/or unpublished data

FAO and WHO recognize that some of the information and relevant data which are now required may be unpublished or of a confidential nature. With regard to unpublished information and data, this remains the property of the author for subsequent publication by the owner as original material. Unpublished confidential studies that are submitted will be safeguarded in so far as it is possible to do so without compromising the work of FAO and WHO. Specific issues relating to confidentiality should be discussed directly between the information and data owners and FAO/WHO. For these and other issues please contact FAO and WHO at the contacts provided.

Deadline

Please submit any relevant information electronically either via e-mail (if not too large) or on a USB stick, in any official United Nations language (English, French, Spanish, Arabic, Chinese, Russian), and with title and short description of the content in English, to the addresses below at your earliest convenience, but no later than **31 May 2020**.

Data submissions in response to the call for data should be sent to:

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