

Joint FAO/WHO Food Standards Programme

CODEX ALIMENTARIUS COMMISSION

PROCEDURAL MANUAL

UPDATE TO THE 20TH EDITION



**World Health
Organization**



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

For further information on the activities of the Codex Alimentarius Commission, please contact:

Secretariat of the Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153 Rome, Italy

Telephone: +39 06 57051
Fax: +39 06 57053152/57054593
Telex: 625852 or 625853
E-mail (Internet): Codex@fao.org
Web site: www.codexalimentarius.net

Codex publications may be obtained through the worldwide Sales Agents of FAO or by writing to:

Sales and Marketing Group
Food and Agriculture Organization of the United Nations
Viale delle Terme di Caracalla
00153 Rome, Italy

Fax: +39 06 57053360
Email: publications-sales@fao.org

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WORLD HEALTH ORGANIZATION
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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UPDATE TO THE 20TH EDITION OF THE PROCEDURAL MANUAL OF THE CODEX ALIMENTARIUS COMMISSION

NOTE BY THE CODEX SECRETARIAT

THE FOLLOWING AMENDMENTS WILL UPDATE THE 20TH EDITION OF THE PROCEDURAL MANUAL TAKING INTO ACCOUNT SOME ERRORS AND OMISSIONS AND THE DECISIONS TAKEN AT THE 34TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION.

A CONSOLIDATED 21ST EDITION ALSO UPDATING SECTION V WITH SESSIONS HELD IN 2010/11 WILL BE PREPARED AS AN ONLINE VERSION ONLY.

SECTION II: ELABORATION OF CODEX STANDARDS AND RELATED TEXTS

IN THE “FORMAT FOR CODEX COMMODITY STANDARDS” AMEND THE SECTION ON FOOD ADDITIVES TO READ AS FOLLOWS¹:

“Food Additives

This section should contain a general reference to the corresponding sections of the General Standard for Food Additives which should take the following form:

“[Food Additive functional class] used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category x.x.x.x [food category name] or listed in Table 3 of the General Standard for Food Additives are acceptable for use in foods conforming to this standard.”

Exceptions from, or addition to, the General Standard for Food Additives that are necessary for its interpretation with respect to the product concerned should be justified fully, and should be restricted where possible. In cases where it is necessary to explicitly list food additives in a commodity standard, the names of the additives/functional classes permitted and, where appropriate, the maximum amount permitted in the food should be prepared in accordance with guidance given in the section on Food Additives in the *Relations between Commodity Committees and General Subject Committees*, and should follow a tabulation, viz:

“INS number, name of additive, maximum level (in percentage or mg/kg) grouped by functional classes.”

This section should contain the following reference to the *Guidelines for the use of flavourings* (CAC/GL 66-2008), as appropriate:

“The flavourings used in products covered by this standard should comply with the Guidelines for the use of flavourings (CAC/GL 66-2008).”

In this section, provisions for processing aids should also be included.”

¹ Adopted by the 33rd Session of the Commission, see ALINORM 10/33/REP, Appendix II

SECTION IV : RISK ANALYSIS

ADD THE FOLLOWING TEXT TO THIS SECTION² :

“RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE

I. SCOPE

1. This document addresses the respective applications of risk analysis principles and procedures by the Codex Committee on Food Hygiene (CCFH) as the risk management body and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) as the risk assessment body. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* to which these principles are supplemental.

II. PRELIMINARY RISK MANAGEMENT ACTIVITIES

2. The CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk based approach.
3. Members, who wish to make a request for inclusion of new item in the priority list of future work of CCFH, should prepare a project document in accordance with Part 2-1 of the Elaboration Procedure (Codex Procedural Manual) and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007). CCFH identifies the priority of all the new topics, submitted for its consideration, based on the *Criteria for the Establishment of Work Priorities* (Codex Procedural Manual). The CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA. Further details are provided in the Annex.

² Adopted by the 33rd Session of the Commission, see ALINORM 10/33/REP, Appendix II

4. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.
21. When referring pathogen-commodity combinations to JEMRA, the CCFH may also refer a range of MRM options, with a view to obtaining JEMRA's guidance on the attendant risks and the likely risk reductions associated with each option.

III. RISK ASSESSMENT

5. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base MRM options. For matters, which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.
6. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* and in accordance with the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999).
7. JEMRA should:
 - strive to base its risk assessments, on relevant data from different parts of the world, including that from developing countries;
 - identify and communicate to CCFH in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will, as far as possible, identify potential risks to populations of potentially enhanced vulnerability, e.g., infants, immuno-compromised population;
 - communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH with a description of the methodology and procedures by which JEMRA estimated any uncertainty in its risk assessment;
 - communicate to CCFH the basis for all assumptions and the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty in its risk assessment.

IV. RISK MANAGEMENT

8. The MRM options recommended by the CCFH to the CAC should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.
9. Elaboration of 'Guidelines' or 'Codes of Hygienic Practices' could include Microbiological Criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g., FSO, PO, PC), as outlined in Annex II of the MRM document (CAC/GL 63-2007), to address a food safety risk.
10. In cases where JEMRA has performed a risk assessment and CCFH or the CAC determines that additional scientific guidance is necessary, CCFH or CAC may make a specific request to JEMRA to provide further scientific guidance necessary for deciding on an appropriate MRM option.
11. CCFH decides, on a case-by-case basis, the need to elaborate 'Guidelines' or 'Codes of Hygienic Practices', and/or to establish an 'MC', or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a 'Guideline' or a 'Code of Hygienic Practices' is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive sub-populations (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immuno-compromised persons, etc.), it may be necessary for the CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.
12. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by the CCFH, as described in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Codex Procedural Manual). When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.
13. Wherever possible, CCFH should consider establishing MCs for those pathogen – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment. Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption

patterns and dietary exposure. The applicable guidance provided in the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) shall be utilized by the CCFH for establishment of MCs.

14. Where MCs are established, methods of analysis and sampling plans shall be provided, including validated reference methods.

V. RISK COMMUNICATION

15. In accordance with the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCFH, in co-operation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the members in a timely manner. The CCFH recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, the CCFH and JEMRA should utilise the guidance on interaction provided in paras 18 through 23.
16. In order to ensure transparency of the risk assessment process in JEMRA, the CCFH may provide comments on the guidelines related to assessment procedures being drafted or published by JEMRA.

VI. INTERACTION BETWEEN RISK MANAGER (CCFH) AND RISK ASSESSOR (JEMRA)

18. The CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, a dialogue between the CCFH and JEMRA is desirable to thoroughly assess the feasibility of the risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.
17. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.
19. It is essential that communications between CCFH and JEMRA are timely and effective.
20. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, the

CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.

22. CCFH may recommend to the CAC to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.
23. CCFH and JEMRA should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members.

ANNEX: PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK

PURPOSE

1. The following guidelines are established to assist the CCFH to:
 - Identify, prioritize and efficiently carry out its work; and
 - Interact with FAO/WHO and their scientific bodies as the need arises.

SCOPE

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work; criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; and a process by which CCFH will obtain scientific advice from FAO/WHO.

PROCESS FOR CONSIDERING PROPOSALS FOR NEW WORK

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities (“*ad hoc* Working Group”) at each Session, in accordance with the Guidelines on Physical Working Groups.

4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work.

- i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.
- ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the *ad hoc* Working Group as well as the CCFH Host government and Codex Secretariats.
- iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.
- iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the

Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

- v. If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’³. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be “denied” or “returned for revision,” a justification for this recommendation will be provided.
- vi. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project document⁴, which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work..

PROPOSALS FOR NEW WORK

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile⁵, as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

6. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

7. The proposal for new work may also:

- address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- facilitate risk analysis activities; or

³ Codex Alimentarius Commission, *Procedural Manual*

⁴ The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*,

⁵ Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

- establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

PRIORITIZATION OF PROPOSALS FOR NEW WORK

8. The Committee will prioritize its proposals for new work at each CCFH meeting, if required. This will be carried out by the Committee after consideration of the recommendations from the *ad hoc* Working Group. The *ad hoc* Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

OBTAINING SCIENTIFIC ADVICE

9. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies (e.g. ICMSF). When undertaking such work, the Committee should follow the structured approach given in the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development) and the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*⁶.

10. In seeking an international risk assessment to be conducted by FAO/WHO (e.g., through JEMRA), CCFH should consider and seek advice on whether:

- i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)
- ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

⁶ Codex Alimentarius Commission, *Procedural Manual*.

- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

11. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document, a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work together with a scope of work to be undertaken. If FAO/WHO respond favourably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g., lack of data, lack of financial resources).

12. The Committee recognizes that an iterative process between risk managers and risk assessors is essential throughout the process described above and for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s).

13. The FAO/WHO will provide the results of the microbiological risk assessment(s) to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

14. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 30-1999)."

SECTION V

CODEX INTERGOVERNMENTAL STRUCTURE AND SESSION HISTORY

AMEND THE TERMS OF REFERENCE OF THE CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES AS FOLLOWS⁷:

“To elaborate worldwide standards and related texts for all types of processed fruits and vegetables, including but not limited to canned, dried and frozen products as well as fruit and vegetable juices and nectars.”

DELETE THE FIRST SENTENCE IN THE TERMS OF REFERENCE OF THE CODEX COMMITTEE ON VEGETABLE PROTEINS WHICH WILL THUS READ⁸:

“To elaborate definitions and worldwide standards for vegetable protein products deriving from any member of the plant kingdom as they come into use for human consumption, and to elaborate guidelines on utilization of such vegetable protein products in the food supply system, on nutritional requirements and safety, on labelling and on other aspects as may seem appropriate.”

⁷ Adopted by the 34th Session of the Commission, see REP11/CAC, Appendix II

⁸ Correction of error in the 20th edition.

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The Procedural Manual of the Codex Alimentarius Commission is intended to help Member Governments participate effectively in the work of the joint FAO/WHO Food Standards Programme. The manual is particularly useful for national delegations attending Codex meetings and for international organizations attending as observers. It sets out the basic Rules of Procedure, procedures for the elaboration of Codex standards and related texts, basic definitions and guidelines for the operation of Codex committees. It also gives the membership of the Codex Alimentarius Commission.

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