

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 2

CX/GP 12/27/2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-seventh Session

Paris, France, 2 – 6 April 2012

MATTERS ARISING FROM THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES ¹

I. MATTERS ARISING/REFERRED FROM THE CODEX ALIMENTARIUS COMMISSION

33rd Session of the Commission

Code of Ethics for International Trade in Foods including Concessional and Food Aid Transactions

The Commission adopted the Code at Step 8 of the Procedure².

Amendments to the Procedural Manual

The Commission adopted amendments to the following texts:³

- Section on Format for Codex commodity standards (Food Additives) in Section II “Elaboration of Codex texts”
- *Risk analysis principles and procedures applied by the Codex Committee on Food Hygiene*
- *Criteria for the establishment of work priorities* and inclusion of new *Guidelines on the application of the Criteria for the establishment of work priorities applicable to commodities*
- *Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces*
- *Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces*

34th Session of the Commission

Amendment to the Procedural Manual

The commission adopted an amendment to the terms of reference of the Committee on Processed Fruits and Vegetables.⁴

¹ This document contains: **Part I:** Matters arising/referred from the 33rd and 34th Session of the Codex Alimentarius Commission. **Part II:** Matters referred from other Codex Committees and Task Forces that require specific action by the Committee. The Codex Secretariat will report verbally on matters of horizontal nature as appropriate to the discussion of the Committee.

² ALINORM 10/33/REP, para 18 and Appendix III

³ ALINORM 10/33/REP, paras 11 – 17 and Appendix II

⁴ REP11/CAC, paras 16 - 20

II. MATTERS REFERRED BY OTHER COMMITTEES

1. Committee on Food Hygiene (CCFH)⁵

The CCFH agreed to forward the revised *Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* to the 35th Session of the Commission for adoption, through the Codex Committee on General Principles.

2. Coordinating Committee for Latin America and the Caribbean⁶

"Length and content of reports and simultaneous and timely availability of documents: Discussion paper on timely and simultaneous distribution of documents and length and content of reports"

26. The Committee recalled that the 32nd Session of the Commission had agreed⁷ that Chile, supported by other countries, would prepare a discussion paper for the Committee on General Principles that would include recommendations on ways to ensure the timely distribution of documents and on the length and content of reports. The 26th Session of the Committee on General Principles in 2010⁸ had briefly considered the paper and had agreed that it would be discussed at the CCLAC and submitted for information to the other FAO/WHO coordinating committees and that the item should remain on the agenda of the CCGP.

27. The delegation of Chile introduced the document containing proposals for the topics of timely and simultaneous availability of documents and length and content of reports. The Delegation indicated that timely availability should also imply simultaneous distribution, but it did not propose holding one language version back until the others were ready.

28. In regard to the timely availability of documents, the Delegation of Chile made the following proposals: (1) increase the availability of translation services by providing additional funds for such services, for example using the Trust Fund or SDTF; (2) strengthen the Codex Secretariat and; (3) use machine translation.

Simultaneous and timely distribution of documents

29. The Codex Secretariat indicated that the delay in document distribution was not so much a problem of funding but rather of timing and organization as the original working documents arrived late, sometimes because of delays in the Secretariat and sometimes because delivered late by working groups or members. Additional resources for translation would thus not solve the problem. The Secretariat further recalled that the translation of documents was the responsibility not only of the Secretariat, but also of the host governments in the case of all Codex committees, with the exception of the FAO/WHO coordinating committees, the Executive Committee and the Commission, and that the translation services provided by FAO were not for the exclusive use of Codex. They had been reduced over time with an increasing trend towards outsourcing. More funds for translation would need to be requested from the governing body of FAO. The Secretariat noted, concerning option (2), that this could speed up some documents, but only those under the Secretariat's direct responsibility, and possibly the finalization of certain reports.

30. Concerning proposal (3) on machine translation, the Chair of the CCLAC informed the Committee that, in line with the Executive Committee's proposal, part of the report of the current meeting would be machine translated and submitted to delegations for review alongside the document translated by translators.

31. The Delegation of Mexico, as host country of the Committee on Fresh Fruits and Vegetables, informed the Committee that it was not always possible to have all documents in all languages at the same time, as some arrived at the last minute and translation costs were higher if the work was urgent. As regards the availability of committee reports, the delegations indicated that there was sometimes a delay between the dispatch of the finalized version by the host government and its posting on the Codex website.

32. A delegation noted that there had also been complaints from French-speaking countries about the late availability of documents. Host countries should adhere strictly to deadlines. More time could be scheduled between meetings to facilitate this. If one language version was missing, the other versions should not be distributed.

33. The Codex Secretariat indicated that the majority of Codex delegations had to work in languages that were not their national language and thus depended on the early availability of at least one version of the documents.

34. The PAHO/WHO Representative suggested that requests for a strengthening of CCLAC activities,

⁵ REP12/FH, para 129 and appendices V and VI (reprinted in the Annexes I and II to this document)

⁶ REP11/LA, paras 26 - 39

⁷ ALINORM 09/32/REP, para 194.

⁸ ALINORM 10/33/33, paras 99 – 103.

including the use of machine translation, should be forwarded to the annual meeting of the PAHO/WHO Directing Council through the Region's ministers of health.

35. The Committee agreed that translation software should be tested and that host governments and the Codex Secretariat should keep closely to deadlines.

Length and content of reports

36. With regard to the length of reports, the Delegation of Chile mentioned that its proposals took into account the fact that the reports were very useful for countries that were unable to attend meetings and that were interested not only in the outcome of those meetings, but also in the related discussions and negotiation process.

37. They thus proposed that while the main objective of reporting the results could be maintained, there should also be either: (1) a summary of the main aspects of the negotiation process or the relevant discussion points, including differing opinions (as well as minority opinions); or (2) an appendix providing a more detailed account of the content of the negotiation process with the positions of individual countries; or (3) expedited and facilitated access to recordings of members' contributions to the negotiating process at the relevant session in all languages.

38. The Codex Secretariat indicated that reports were prepared in accordance with Rule X.1 of the Codex Rules of Procedure and the guidance provided in the *Guidelines on the conduct of meetings of Codex committees and ad hoc intergovernmental task forces*. This was also in line with the decision adopted at the 62nd session⁹ of the Executive Committee and with Chile's proposal under option (1).

39. The Committee agreed that report drafting should continue to follow current practice, in line with proposal (1), as it was important that the debate be part of the report, and not an appendix, and audio-recordings might not be easy to make available."

3. Coordinating Committee for the Near East¹⁰

The Committee stressed the importance of having Codex documents and standards available in Arabic language in a timely manner to enable members to fully participate in the standards development and to send comments in time. The interest in concise reports and having the audio-recordings available in different languages was also mentioned.

⁹ ALINORM 09/32/3, para 140.

¹⁰ REP11/NEA, para 9

ANNEX I: reproduced from REP12/FH Appendix V**PROPOSED REVISION OF THE *RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE*****(for adoption)****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. PRIORITIZATION OF PROPOSALS FOR NEW WORK

2. The Committee prioritizes its proposals for new work at each CCFH meeting, when appropriate. This is usually carried out by the Committee after consideration of the recommendations from an *ad hoc* Working Group. This *ad hoc* Working Group considers 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.

III. PRELIMINARY RISK MANAGEMENT ACTIVITIES

3. 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.

4. Members, who wish to make a request for inclusion of a 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). 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). 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.

5. 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.

6. 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.

IV. RISK ASSESSMENT

7. 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.

8. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice.. When commissioning such work, the Committee should follow the structured approach given in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

9. 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 recommendations related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.
- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

10. 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 in 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).

11. 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).

12. 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.

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).

V. RISK MANAGEMENT

15. Risk management options may include provisions contained in Codex standards, guidelines, codes of practice or related texts.

16. 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.

17. 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.

18. 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 recommending on an appropriate MRM option.

19. 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, immunocompromised 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.

20. 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.

21. Wherever possible, CCFH should consider establishing MCs for those pathogens – 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.

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

VI. RISK COMMUNICATION

23. 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 24 through 29.

24. 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.

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

25. 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.

26. 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.

27. It is essential that communications between CCFH and JEMRA are timely and effective.

28. 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.

29. 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.

30. 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.