

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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Report of the *ad hoc* Expert Consultation on Risk Assessment of Microbiological Hazards in Food and Related Matters

PROPOSAL FOR A PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE COULD UNDERTAKE ITS WORK IN MICROBIOLOGICAL RISK ASSESSMENT/RISK MANAGEMENT

Prepared by the United States of America

The text below was issued as the Conference Room Document 6 at the 33rd Session of CCFH. The Committee was unable to agree on a method or process of interaction between CCFH and the *ad hoc* Expert Consultation on Risk Assessment of Microbiological Hazards in Food. Since, this text was not made available to all member countries and INGO organizations in a timely manner before the last session of the CCFH, therefore it is being circulated to solicit comments. Governments and interested international organizations are invited to submit comments or information on the attached Proposal and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition, pages 21-22*) **to:** Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, 1400 Independence Avenue, S.W., Washington DC, 20250 USA, preferably by email: syed.ali@usda.gov or fax: 1 (202) 720-3157, with a copy **to:** Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, viale delle Terme di Caracalla, 00100 Rome, Italy, by email: Codex@fao.org or fax: +39 (06) 5705.4593 **before 15 September 2001.**

The work of CCFH in the area of microbiological risk assessment and risk management is very important to both protecting public health and facilitating trade. It is likely that the Committee will have significant work in this area for some time to come.

With this in mind, the United States suggests that it would be helpful for the Committee to consider a process by which it will undertake its work in microbiological risk assessment/risk management. This is particularly important if CCFH is to take full advantage of the resource that FAO and WHO have jointly provided through the establishment of their Joint Expert Group in Microbial Risk Assessment. There will be a need for the Committee to provide certain information to the Expert Group so that it can properly do its work. Similarly, there will be the need for the Expert Group to provide its advice back to the Committee in a form that can be evaluated and used to enhance the work of CCFH.

In this regard, the United States would suggest that one possible process that uses the traditional CCFH Discussion Paper/Codex Step Document approach might be the following.

1. A country (or countries) agrees to develop a Discussion Paper regarding the risk assessment/risk management of a specific microbial pathogen. In addition to recommending whether a risk assessment is needed, the Paper would present, for example, the nature of the problem, pertinent background on the microorganism, the objective of work to be undertaken and a proposal for work. It would also identify specific foci that a risk assessment should address. In the parlance of risk assessment/risk management, the Discussion Paper would serve as an initial Hazard Identification and Risk Profile for a subsequent risk assessment. Preferably, the Paper would also present resource information on available hazard characterization and exposure assessment data.
2. The Committee would review the Discussion Paper and agree or not agree with the proposal.
3. If there is agreement to undertake the work, the Committee would forward the proposal to WHO and FAO for their consideration. If WHO and FAO concur with the proposal, the work would be assigned to the Joint Expert Group.
4. The Joint Expert Group would undertake an initial evaluation of the risk assessment approach that should be undertaken, the availability and limitations of data needed to successfully conduct a hazard characterization and an exposure assessment, identification of key assumptions that may have to be made (in the absence of data), and specific information of a risk management nature that would be required to complete the assessment.
5. The Joint Expert Group would inform the Committee of its initial evaluation through a "framework" document and request the Committee to assist in providing the needed information. The Committee could, at this stage, recommend proceeding with the work or if, in its judgement (guided by the Expert Group) data would ultimately be insufficient to accomplish the purpose of the work, recommend discontinuing work on the area. This decision and the comments and recommendations of the CCFH member countries would be communicated to the Expert Group.
6. If agreement is reached by the Committee to proceed, a formal request for new work would be made to the Commission for the development within the Step process, of a guideline document in the risk management area being addressed by the risk assessment or a revision of a Codex Code of Hygienic Practice. Identified in that request for new work will be a lead country (who may be assisted, as appropriate, by other countries) that will work with the Expert Group to incorporate the findings of the risk assessment into the developing step

document. At the same time a request for specific information requested by the Joint Expert Group will be made by the Committee to member countries. This can take the form of a Circular Letter, the response to which will be directed to the Joint Expert Group.

A Joint Expert Group will complete the risk assessment and forward its results to CCFH for review and comment. They will also be available to the lead country in interpreting the findings as it develops the step document.

[An alternative approach could involve the establishment of microbiological risk management working group that would develop the risk management guidance document or recommend revisions to Codex codes of hygienic practice.]

7. The risk management guidance document/revisions to Codex codes of hygienic practice would then proceed through the Step procedure, with the Committee and the Expert Group working in a coordinated fashion to develop the final guidance document.

Please refer to the accompanying flow diagram to visualize the proposed process.

As the state of science related to the conduct of microbiological food safety risk assessments mature, it is becoming evident that the effectiveness of this tool is highly dependent on effective, timely communications between the risk assessors and risk managers. The United States recommends that CCFH, FAO, and WHO explore non-traditional means for facilitating this exchange of viewpoints among member countries and between member countries and the Joint Expert Group. For example, the establishment of Internet bulletin boards are proving very successful as a means of accelerating and improving the scope of discussions on the types of technical issues that would be likely to occur in the development of a microbial risk assessment.

The United States recommends that the Committee consider this and/or other possible approaches to facilitating its work in microbiological risk assessment/risk management and establish a process by which it will do its work in these fields.

Flow Diagram for Microbiological Risk Assessment/Risk Management Process

