

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 5 (a)

**CX/FH 04/5 - Add.1
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

THIRTY-SIXTH SESSION

Washington, DC, USA, March 29 – April 3, 2004

PROPOSED DRAFT PROCESS BY WHICH THE COMMITTEE ON FOOD HYGIENE COULD UNDERTAKE ITS WORK IN MICROBIOLOGICAL RISK ASSESSMENT/RISK MANAGEMENT

Comments submitted by Argentina, Canada, and Ghana

GENERAL COMMENTS

ARGENTINA

As presented in the introduction to the CX/FH 04/05 Proposed Draft, it is through the proposed process that the Committee moves forward in developing a procedure that deals with the new Terms of Reference assigned to it by the Codex Alimentarius Commission at its 24th Session.

The proposed process presented in the Discussion Paper will allow the Committee to undertake its microbiological risk management activities by a process that, although having a defined structure, enables work order and development. Also, aspects of flexibility are taken into consideration within the process, which could introduce certain agility in such a manner as to obtain timely results.

In general terms, and considering that, in order for the document to be approved, it must undergo the normal steps of the Codex procedure, it could be said that it meets the Principle of “Transparency”. There are certain timely issues regarding the process that, in this sense, could require further analysis. These issues will be analyzed later in the document.

No objections are noted in the proposed process regarding the Principle of “Equivalence”. In item 5.5, it is envisioned that in the new risk analysis framework another document format that describes risk mitigation strategies may be required. And in title no. 5, “Risk Management Options”, the necessary framework is given to identify, present, and assess the potential alternatives. This item considers the need to identify multiple risk management options that make it possible to achieve the

desired level of risk mitigation, as well as the detailed presentation of these options. It is necessary to emphasize that, for the evaluation of these options, the process takes into account the specific needs and capabilities of developing countries. This aspect of the process is coherent with item no. 34 in the Working Principles for Risk Analysis (WPRa) found in the Procedural Manual.

Perhaps as a way to reinforce this aspect of the process, the adoption of this new document model proposed should be ensured.

Although it is stated in the introduction that the Committee is moving towards a broad risk management-based approach to ensure consumer protection and facilitate fair practices in food trade, the content of the document, and Annex I in particular, do not seem to sufficiently consider this second objective. This could be due to the fact that the problems associated with international trade are not the main focus of the document, although these are mentioned in the criteria under item 1.2.

One aspect to keep in mind is that, with an increased number of products whose trade conditions are risk-analysis based, the number of difficulties presented to developing countries for the international trade of their products will increase as well.

CANADA

Canada would like to thank the United States for the revision of this document. Changes made improve the document from last year and clarify the information regarding the process by which the Committee could undertake its work in risk assessment/risk management.

GHANA

The word “iterative” is used throughout the document. It is not clear if that was intended or the replacement with “interactive” would be more appropriate.

1. Proposal for Work

1.5

ARGENTINA

In regards to item 1.5 in the Discussion Paper, it would be important to ensure the effective participation of experts from developing countries in the FAO/WHO JEMRA, just as it is envisioned in the WPRa (Item 18) found in the Procedural Manual. Such an effective participation would be one way to ensure the independence of the group of experts and to avoid undesirable effects in the outcome of their work regarding conflicts of interest.

1.7

ARGENTINA

In order to speed up the process, item 1.7 raises the issue that the Committee could initiate the development process, but it does not consider the previous or subsequent approval of the Commission in this matter. In this sense, item 2.2 reasserts that when the Committee¹ considers the work suggested as appropriate, it will request the undertaking of a microbiological risk assessment by the JEMRA. However, in this regard, item 2.4 states that the CCFH will recommend to the Codex Alimentarius Commission the initiation of the new work. If one considers that JEMRA's

¹“...based on preliminary risk profile information submitted, request that FAO/WHO initiate appropriate microbiological risk assessment activities while still defining the specific risk management questions that will be evaluated by the risk assessment.”

participation implies the initiation of work development, it is not sufficiently clear what the intervention of the Commission regarding the approval of the new work item would be.

Additionally, in regards to item 1.7, it would be beneficial to study in depth and to clarify the specific risk-management questions that will be evaluated by the risk assessment, in such a manner as to ensure that risk managers do not interfere in the work of risk assessors, preventing the latter from maintaining their independence.

2. Development of a Risk Profile and Agreement to Proceed with the Work

2.1

ARGENTINA

An issue of document usage in item 2.1 is that it first states that the Risk Profile, as such, will be used at a single session of the CCFH, but later it indicates that the information provided within the Risk Profile will prove useful in subsequent development of the guidance document.

4 Iterative Process between CCFH and FAO/WHO Expert Joint Group for the Conduct of Microbiological Risk Assessments

ARGENTINA

It is necessary to emphasize that the iterative process between the CCFH and the FAO/WHO Expert Joint Group, which is described in item 4, could be useful for the process in terms of agility, and work precision. Nevertheless, it would be appropriate to study in depth, clarify, and define the questions that will be considered within this interaction in such a manner as to not overlook any possible loss of independence by the risk assessors. For instance, in the matters considered within this interaction, it is stated that, “the nature of the risk-management control options to be considered,” being that there should be a functional separation between assessors and managers, this would only be appropriate in cases where the managers requested a potential risk assessment of different risk management options.

4.2

GHANA

First sentence, the word facile seems to denote a negative impression and may be replaced with simple.

5. Development of CCFH Microbiological Risk Management Guidance Documents

5.5

Introduction and Background:

GHANA

Last sentence, end of the sentence, “....the effected populations” should read, “....the affected populations...”

Scope:

Risk Evaluation:

Consideration of the Risk Assessment:(Optional)

Risk Management Options:

GHANA

Second sentence should be corrected as follows ‘.....that articulates one or more “best practices”
that are widely accepted.....’