

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 5 (e)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-fifth Session

Orlando, Florida, United States of America, 27 January – 1 February 2003

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

Comments submitted by: **Canada, Brazil, Mexico, and Consumers International**

GENERAL COMMENTS:

CANADA

Canada would like to thank the United States for drafting this document. It provides good information as to what should be the process by which the Committee could undertake its work in risk analysis. We are pleased to offer the following comments:

Canada would like to note that the document is about undertaking work in microbiological risk analysis, i.e. risk assessment, risk management **and risk communication**. There are a number of elements of risk communication that are referenced in the document but no reference is made in the title and appropriate sections. Specifically, bullet point four of the Proposed Process is a risk communication activity, i.e., the iterative communication between risk assessors and risk managers for the purpose of clarifying issues such as scope, assumptions, etc. Elements listed in the risk profile, for example in section 4 of Annex I, require the utilization of risk communication techniques to obtain such information. Canada suggests a consequential change throughout the text – where the phrase “microbiological risk assessment/risk management” occurs, it should be replaced with “microbiological risk analysis”.

MEXICO

Mexico is generally in agreement with the document; however we suggest carefully reviewing the translation in Spanish, since there are some points where there are differences between the versions, which causes confusion.

We believe the document should be integrated into the Procedures Manual; however, in order to do this, it should be summarized so that it is not repetitive. Its structure should also be evaluated, such that the complete names of the documents referred are cited only once.

CONSUMERS INTERNATIONAL

Consumers International appreciates the opportunity to comment on this draft process and commends the committee for developing such a strong proposal.

INTRODUCTION

CANADA

In addition, to reflect this concept, the **first paragraph** of the introduction should be amended as follows:

*The Codex Committee on Food Hygiene (CCFH) is moving towards a broad risk **analysis-management** based approach to developing recommendations on ensuring consumer protection and facilitating fair practices in food trade. This broad risk-**analysis management** approach may employ microbiological risk assessment, **may utilize risk communication techniques** and may utilize a spectrum of risk management tools including microbiological risk management guidance documents, codes of hygienic practice, food safety objectives and microbiological criteria.*

It is Canada's view that these changes will make the terminology and concepts in this paper more consistent with the definitions and terminology used in the Procedural Manual¹ and in the *Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

PROPOSED PROCESS

1.0 Proposal for Work

1.2

CANADA

As all listed criteria may not apply to all situations, we recommend amending the first sentence as follows:

The following criteria, **as appropriate**, should guide the development of a proposal for new work.

MEXICO

It is not clear to which case point 1.2 will apply and to which 1.3 will apply, especially when in 1.1 it says that the proposal of new work related to microbiological risk assessment and risk management may be made by the Commission and by CCFH, among others. Accordingly, the two points should not be separated, since the Codex expert groups will only conduct **international** risk assessments.

1.3

CANADA

For the same reason stated above, the first sentence of the paragraph should be amended as follows:

If the proposal for new work is going to include a recommendation for the conduct of an international risk assessment, additional criteria for that phase of the new work should include **the following as appropriate**:

CONSUMERS INTERNATIONAL

Our first comment concerns the third criterion listed in Section 1.3 which indicates that a risk assessment must first be initiated at the national level before a specific microbial pathogen/commodity combination can be considered for Codex review. For several reasons, we are concerned that this criterion could bias Codex towards prioritizing problems in developed countries more than those in developing countries. There have been few microbial risk assessments conducted thus far, and nearly all have been conducted by developed

¹ Procedural Manual, 12th Edition, pg 41- 44

countries. Further, it is quite possible that there might NOT be a risk assessment available at the national level even though there ARE sufficient data available to conduct a risk assessment (at either the national, regional, or international level). This is particularly likely for public health problems in developing countries. For these reasons, we would suggest eliminating this criterion.

1.4

MEXICO

For point 1.4, in reference to the new work that may be presented to the Committee orally, we propose that it be established that the request needs to be approved or confirmed in writing in order to be taken into consideration.

In point 1.4 it is not clear what the difference is between presenting the request in writing in compliance with certain requirements, including the risk profile and an output document, and presenting a discussion paper as described in point 2.3, whose characteristics coincide with those indicated in point 1.4.

1.7

CONSUMERS INTERNATIONAL

End of the paragraph, add the following: ", provided that the mandate, scope and purpose of the risk assessment has been clearly defined, and the necessary risk assessment policy developed."

Rationale:

Our remaining comments relate to the overall need, in our view, for risk managers to clarify the mandate and scope of the risk assessment to the risk assessors. We feel this step is critical to ensure that the risk assessment is helpful to the risk manager and answers the questions they need answered. Defining the scope is necessary to focus the risk assessment on the part(s) of the production-to-consumption continuum that should be addressed, and on the relevant populations and exposure pathways. Also, the process should ensure that risk managers develop a risk assessment policy. This is consistent with the CCGP document, "Proposed Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" which says:

Risk Assessment Policy

- 13) Determination of risk assessment policy should be included as a specific component of risk management.
- 14) Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.
- 15) The mandate given by risk managers to risk assessors should be as clear as possible.
- 16) Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT

- 17) The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined.

The importance of clearly defining the scope was also emphasized at the Kiel Consultation referenced above, and was also recognized in the last report from CCFH, which states, "The FAO and WHO Representatives outlined the lessons learned to date, including ... the importance of clearly defining the scope of a risk assessment ...". We suggest the following changes to incorporate and strengthen this concept in the text.

2.0 Development of a Discussion Paper Including a Risk Profile and Agreement to Proceed with the Work

2.2

CANADA

We recommend deleting this paragraph as it is redundant with 2.3.

2.3**CONSUMERS INTERNATIONAL**

Add the following new text under new numbers 2 and 3 and renumber old 2 as number 4:

"2) the scope, and purpose of the risk assessment, 3) the applicable risk assessment policy."

Rationale: See the rationale provided under 1.7.

3. Involvement of the FAO/WHO Joint Expert Group on Microbiological Risk Assessment**3.2****CONSUMERS INTERNATIONAL**

First sentence, after "... (or preliminary documents..." add the following, "outlining the purpose and scope of the risk assessment, the relevant risk assessment policy, and other information) ..."

Rationale: See the rationale provided under 1.7.

4 Iterative Process between CCFH and FAO/WHO Expert Group on Microbiological Risk Assessment**4.3****CANADA**

We recommend deleting this paragraph as the information is already provided in paragraph 3.2.

4.4**CANADA**

To improve clarity, we recommend amending the **first sentence** as follows:

The Committee and/or its Working Group will receive ~~from and respond to~~ questions from the Joint Expert Group relating to the microbiological risk assessment(s) **and will provide the appropriate responses.**

5. Development of CCFH Output Document(s)**5.4****MEXICO**

Point 5.4, which describes the sections of the guidance document, states that in the introduction and in the background, as well as in the scope of application, a brief statement should be included about the combination of bacterial pathogen(s) and product(s), which would be repetitive in the long run. Thus, we suggest that the combination that will be referenced in the document be stated only in the scope of application.

**Implementation:
Monitoring and Review**

CANADA

It is unclear as to what is meant to be monitored and reviewed. We recommend a clarification to that effect.

ANNEX 1

SUGGESTED ELEMENTS TO INCLUDE IN A MICROBIOLOGICAL RISK MANAGEMENT DISCUSSION PAPER/RISK PROFILE**GENERAL COMMENT****CONSUMERS INTERNATIONAL**

We are concerned that the proposed format for the risk profile may be significantly lengthier and more detailed than necessary, which could delay progress. Initially, the risk profile should generally be rather brief, as appropriate to the circumstances early in the process, and then a more detailed one may be developed later as required. We suggest that this section be reviewed in light of the recent Joint FAO/WHO Expert Consultation on the Elaboration of Principles and Guidelines for Incorporating Quantitative Risk Assessment in the Development of Microbiological Food Hygiene Standards, Guidelines and Related Texts that was held in Kiel, Germany 18 - 22 March 2002.

RISK PROFILE ELEMENTS**MEXICO**

The section on “Risk Profile Elements” says “present, to the extent possible about the following points”; however, it does not ask for a definition of the minimum amount of essential data, which would give any country the chance, regardless of how limited its infrastructure is, of presenting some data, especially considering that both the risk assessment and management will have an impact on international trade.

BRAZIL

In Annex 1, subtitle “Risk Profile Elements”, it was suggested the inclusion of a new paragraph establishing that the country should inform about the sources used for the conception of the document, as well as the criteria for the acceptance or rejection of the data.

4 Other Risk Profile Elements**MEXICO**

In Annex 1, point 4, 1st bullet, we suggest changing the reading to the following: “Regional differences in the incidence *and prevalence* of foodborne illnesses due to the pathogen.

6. Available Information and Major Knowledge Gaps**MEXICO**

We suggest changing the title to: “Available Information”.

Mexico suggests studying document *CX/FH 01/15 August 2001: Guidelines for the Obtaining of Data for Risk Assessment*, prepared by Brazil and INPPAZ, as the activities proposed in the document would contribute to strengthening the systems in those countries that do not currently have all the data needed for risk assessment in order to achieve this.