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Agenda Item 4

CX/FH 09/41/11 Add.1

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-first Session

The Loews Coronado Bay Hotel, San Diego, California

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

COMMENTS SUBMITTED BY

**AUSTRALIA, COSTA RICA, CUBA, EUROPEAN COMMUNITY, JAPAN, UNITED STATES OF
AMERICA, INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS
FOR FOODS (ICMSF) AND INTERNATIONAL DAIRY FEDERATION (IDF)**

AUSTRALIA

General Comments

Australia would like to thank the Working group led by India for preparing a draft document and welcomes the opportunity to provide comments on CX/FH 09/41/11-Rev Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene.

Specific Comments

Australia provides the following wording for paragraph 18 to make it clearer what is needed before setting an MC:

18. CCFH shall consider establishing MC only for those pathogens food combinations for which JEMRA is able to provide an adequate quantitative microbiological risk assessment ~~appropriate scientific analysis & advice, and, where sufficient data are available, a risk analysis appropriate to the foodstuff and its use.~~ Recommendations by CCFH shall be based its recommendations on the dose response model and exposure assessment including the consumption patterns on a global basis when appropriate data are available. on the outcomes of the risk assessment including global consumption patterns where available. ~~The probability of exposure to certain dose(s) should take into account the normally used consumption pattern including serving size data and preparation practices provided by the members.~~ 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.

COSTA RICA

General Comments

Costa Rica is grateful for the opportunity to express our comments on this topic, and in general we agree with the document.

Specific Comments

In regards to the review of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues (CCPR), Costa Rica feels that a new paragraph could be included between paragraph 12 and 13, as indicated below.

12. Members, who wish to make a request for inclusion of new topics 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, 18th Edition, p. 30) and provide a preliminary risk profile, based on the template in the 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, 18th Edition, p. 42)*. The CCFH also identifies areas on which inputs from JEMRA are required and refers them, according to the identified priorities, to JEMRA for risk assessment.

CCFH must make an effort to identify priorities important for developing countries and for which said countries have risk analyses; and which are relevant to public health and the international food trade.

13. 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 the relevant uncertainties described by JEMRA.

CUBA

Cuba has the pleasure to support the document CX/FH09/41/11 beside It will be ratified at the next meeting.

EUROPEAN COMMUNITY**General Comments**

The European Community and its Member States (ECMS) would like to thank India for leading the work in developing the "Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene".

Specific Comments

The proposed text is generally acceptable to the ECMS. It only requires clarification regarding the status of the "Annexure" (pages 7-9 of the working document). If the intention is to retain it as an Annex to the draft document, as suggested in footnote 1 (p. 6), it is important not to repeat matters already addressed in the body of the document.

The possible Annex should focus on the process of considering proposals for new work. Therefore, the ECMS suggest deleting paragraphs 1, 2, 5, 9, 10, 11, 12, 13, 14 of the "Annexure" and insert it as an Annex to the "Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene" with the following heading: Process for Considering Proposals for New Work.

JAPAN**Scope**

Japan proposes the deletion of second and third sentences as they are already mentioned in paragraph 2.

II. RISK ASSESSMENT

Paragraphs 3 and 4 should be transferred to Section III as they are part of risk management.

III. RISK MANAGEMENT**Paragraph 12**

Delete the edition number of the procedural manual as it will become obsolete next year.

IV. RISK COMMUNICATION

Paragraph 24 should be deleted as it is not necessary.

UNITED STATES OF AMERICA

General Comments

The United States appreciates the work of India and members of the electronic working group to prepare the *Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene*. The United States believes the guidance in the document will be very helpful to the Codex Committee on Food Hygiene in carrying out its risk analysis work.

Specific Comments

Title: The United States notes that the title of the document would infer that the guidance provides principles for risk analysis activities undertaken by CCFH. However, the document is actually a process document that describes the policies and procedures by which CCFH should undertake its risk analysis activities, using risk analysis principles provided in other Codex texts. The United States suggests, therefore, that the title of the document be changed to the following: ***“Policies and Procedures to Implement Risk Analysis as Applied by the Codex Committee on Food Hygiene.”***

Scope: To better clarify the role that risk assessments conducted by national authorities have in the work of CCFH, the United States recommends the insertion of a new sentence immediately prior to the last sentence in the scope section of the document. The new sentence would read:

As part of the discussions and deliberations of CCFH and its working groups, relevant risk assessments and scientific evaluations performed at the national level should be taken into account, as appropriate.

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)

General Comments

ICMSF would like the following comments on Appendix I to be considered in the discussion of the Committee:

Specific Comments

Section II. Risk Assessment, item 5.

The term “safety assessments” is used in the paragraph and it would be helpful when it would be explained what components make up a “safety assessment” and how these differ from “risk assessments” as defined by CAC. Notably, the term “safety assessments” is not used anymore in the remainder of the text.

Section II. Risk Assessment, item 10.

In addition to communicating the “basis for all assumptions used in a risk assessment” it would be appropriate to request JEMRA to communicate to CCFH “the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty”. This will then help CCFH to establish MRM options as described in Section III, Risk Management, item 13.

Section III, Risk Management, item 13.

In addition to taking account of “relevant uncertainties” it would be appropriate to take into account “all assumptions” communicated by JEMRA to CCFH as described in Section II. Risk Assessment, item 10.

Section III, Risk Management, item 16, 18, and 19

In these different paragraphs, the term MC (Microbiological Criterion) is sometimes used as an example of a MRM metric and sometimes as a separate concept from MRM metrics. Language would best amended to consequently consider MC as an example of a MRM metric. Some improvements in the language are proposed in the comments on items 16 and 18 as given below.

Section III, Risk Management, item 16.

In the last two sentences of this paragraph, MCs are proposed for “sensitive populations” while MRM metrics are proposed where “the tolerance for risk through foods is extremely low”. This is confusing language and should best be amended. It is proposed to amend the last two sentences to read:

“For certain products that are intended for consumption by sensitive sub-population (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immuno-compromised persons, etc.), it should be necessary for CCFH to establish specific MRM metrics such as MCs.”

Section III, Risk Management, item 18.

The use of MC as the single appropriate MRM metric in the situation described is confusing and not in line with the Principles and Guidelines for the Conduct of Microbiological Risk Management and in particular with its annex II on Guidance on Microbiological Risk Management Metrics (CAC/GL 63-2007). Also, as JEMRA focuses on providing “risk assessment” rather than “risk analysis” a rewording would be required. ICMSF requests that the first sentence be revised to read “CCFH shall consider establishing MRM metrics only for those pathogens for which JEMRA is able to provide appropriate scientific analysis & advice, and, where sufficient data are available, a risk assessment appropriate to the foodstuff and its use”.

Section III, Risk Management, item 19.

The first sentence of this paragraph should clarify that it relates to the establishment for MCs rather than for other MRM metrics, in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997) as it mentions the preference for validated methods. Since the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007) do not explicitly state a preference for validated methods nor for sampling plans for verifying compliance with other MRM metrics than MCs (i.e. FSO, PO and PC values) the second sentence is best deleted. It is proposed to reword this paragraph to read: “Where MRM metrics are proposed, methods of analysis and sampling plans would best be provided, preferably including validated reference methods.”

Section III, Risk Management, item 20.

The last part of the sentence in this item, i.e. “when pathogen-commodity combinations are identified for evaluation” seems superfluous as the sentence starts of referring to pathogen-commodity combinations apparently identified by CCFH for evaluation by JEMRA.

INTERNATIONAL DAIRY FEDERATION (IDF)

General Comments

The International Dairy Federation would like to commend the work of the electronic Working Group since the work has progressed well, and therefore IDF generally supports the document. The document references other detailed CCFH guidance and appears to provide appropriate overarching principles and procedures for the work of CCFH as requested by the CAC.

Specific Comments

However, the IDF would like to suggest the following modifications to the end of the Paragraph 16 of APPENDIX 1 page 5:

- The phrase “it should be necessary for the CCFH to establish MCs” could be softer such as “the CCFH may establish MCs.” (also punctuation is missing),
- The very last sentence “In cases, where the tolerance for risk through foods is extremely low, it might be appropriate for the CCFH to establish MRM metrics” might be deleted because MRM metrics are always useful for various purposes, including the design HACCP systems. If not deleted, at least the word “more” needs to be inserted prior to “appropriate” to put emphasis to the fact that the statement relates to the establishment of alternatives to Microbiological Criteria.