

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 5

CX/FAC 04/36/4
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

Thirty-sixth Session

Rotterdam, The Netherlands, 22 -26 March 2004

DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

COMMENTS AT STEP 6

The following comments have been received from: Brazil, Japan, Mexico and Spain
in response to CL 2003/33-FAC

BRAZIL:

Brazil appreciates the opportunity to comment on the “Proposed Draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants”. Considering that not always a quantitative risk assessment follows the establishment of acceptable or tolerable intakes by JECFA (which is considered a safety assessment) for a better understanding and to be consistent along the document both risk assessment and safety assessment should be mentioned when referring to assessments performed by JECFA (see items s, w, q), as it is written in (g). Furthermore, a definition of safety assessment should be provided to clearly differentiate it from risk assessment. To be consistent with the definition of risk assessment provided in the Codex Manual, Brazil suggests the following definition : safety assessment – a scientifically based process consisting of the following steps: (i) hazard identification and (ii) hazard characterization.

- Item k: which are the legitimate factors to be considered? Has a list of legitimate factors been prepared by the Committee on General Principles?
- Item cc: the first part of the sentence needs clarification. What is the relationship between small and medium size enterprises and the use of global data by JECFA in its assessments? What is the role of small and medium size enterprises in providing data on epidemiological surveillance and exposure? How should it be done?
- Item ii: to which general risk analysis guidelines of Codex Alimentarius and CCFAC the statement refers? Is there a document available that could be referenced in text?
- Item kk: the statement seems not to be correct, to be consistent with the former paragraph, the last sentence should read “...internacional trade AND that present...”.

JAPAN:***Background***

1. The 26th Codex Alimentarius Commission adopted the Proposed Draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants (CCFAC) at Step 5 on a basis of the recommendation of the 35th CCFAC. The 35th CCFAC also agreed: 1) that a definition for “safety assessment” would be required in a future revision to the text; and 2) that future revisions to the text should not conflict with the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”. (ALINORM 03/12A, paras. 24 and 29)

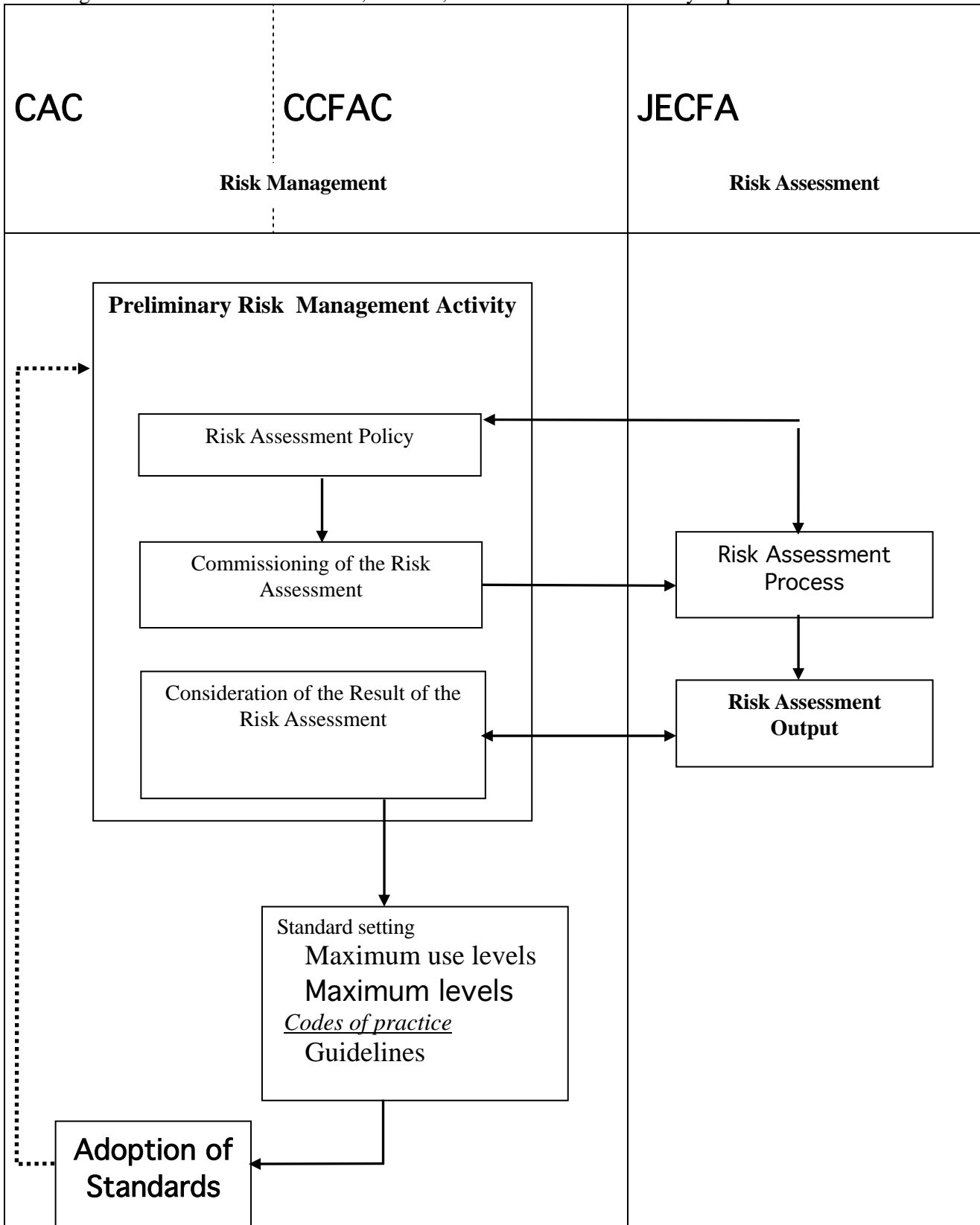
Comments

2. There are three different words in this draft relevant to risk assessment conducted by JECFA, “risk assessment”, “safety assessment” and “safety evaluation”. We agree that a definition for the term “safety assessment” should be included in the text. Despite that JECFA has not defined the term “safety assessment”, this word has been historically used by JECFA. In contrast, the term “safety evaluation” is seldom used in the CCFAC, so it seems better to replace “safety evaluation” with other appropriate words in consistency with the definitions of the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”.
3. We think that Figure 1 in this draft is intended to show the intuitive understanding of the iterative tasks between CAC, CCFAC and JECFA. The Committee needs to keep in mind that the term “preliminary risk management activity” was defined in the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” (ALINORM03/41, APPENDIX IV); also in the CAC Procedural Manual 13th Edition and replaced the other term “risk evaluation”.

Proposal of Japan

4. Japan wish to suggest that:
 - (1) The CCFAC should revise the Draft Risk Analysis Principles Applied by the Codex Committee on Food Additives and Contaminants (CCFAC) as follows:
 - The definition of “safety assessment” should be added. Our suggestion is “Safety assessment is a two-stage process. The first stage involves the collection of relevant data including the results of studies on experimental animals and, where possible, observations in human. The second stage involves the assessment of data to determine the acceptability of the intentionally used chemicals.” Despite that the proposed definition is taken from the recommendations of JECFA contained in the Principle for the Safety Assessment of Food Additives and Contaminants in Food published in 1987, it may be necessary to elaborate more appropriate expressions for the purpose of Codex; and
 - The term “safety evaluation” in paras. m) and n) should either be defined or be replaced with an appropriate term used in the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”.
 - (2) The CCFAC should revise Figure 1 in this draft in line with the components of the “preliminary risk management activity” in the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius”. Our suggestion is attached in the Annex to this paper.
 - (3) The following editorial modification should be made in this draft:
 - “Maximum Limits” in paras. r) and v) should read “Maximum Levels”; and
 - “MLs” in para. p) should read “Maximum Levels”.

Figure 1: The interactions of CAC, CCFAC, and JECFA in the risk analysis process



NB1: The preliminary risk management activity includes: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment in the “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” (ALINORM03/41, APPENDIX IV); also in the CAC Procedural Manual 13th Edition.

NB2: The dotted arrow represents the iterative exchange of information.

MEXICO:

It is proposed that paragraph z) be deleted, since it places emphasis on the quantitative risk assessment, which is not always possible especially for the long-term effects; moreover, this is embodied in paragraph y) which says that the risk assessment must be carried out with the best information available. Furthermore, in paragraph 5 of Appendix VIII it is recognized that it is necessary to continue working towards the most appropriate exposure assessment in respect of exposure to carcinogenic and genotoxic substances. If account is taken of the fact that in accordance with the Codex itself the assessment of the exposure forms part of the Risk Assessment, then it is highly improbable that with a situation of such great uncertainty emphasis can be placed on the use of the quantitative analysis.

SPAIN:

The following comments are submitted on the JECFA paragraph:

- The term “safety assessment” as used in paragraph y) in respect of the duties of the JECFA, should be defined.
- It is proposed that the wording of paragraph kk) be modified to read as follows:

“kk) When establishing the programme for a session of the JECFA, the Secretary of the JECFA shall grant priority to those substances which represent an imminent risk to public health or constitute a known or anticipated problem in international trade or which may give rise to emergency situations.”