

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 5

CX/GP 10/26/5-Part 2

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMITTEE ON GENERAL PRINCIPLES
Twenty-sixth Session
Paris, France, 12 -16 April 2010**

REVIEW OF THE RISK ANALYSIS POLICIES OF CODEX COMMITTEES

**COMMENTS IN REPLY TO CL 2010/01-GP
(India, Indonesia, Japan, Thailand, United States)**

INDIA

The overall general approach suggested for the revision of the Risk Analysis Policies of the Codex Committees generally appears to be acceptable.

However, we have some comments on some suggestions made in relation to the CCPR and CCFH.

Pesticide Residues

In relation to the 'Annex and Criteria', the Review Document suggests the Committee to consider if the Paragraph 35 in the Annex of the Policy Document should be shifted to the risk management section or alternatively to examine the need for its inclusion, citing a reason that the guidance in the paragraph is not systematically applied (eighth paragraph under the Section on Annex and Criteria on page 5). The Paragraph 35 indicates that if no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

This is a very useful and important guidance to the work of the CCPR. In the absence of the method of analysis for a compound, it would not be possible to ensure effective enforcement of the relevant MRL and this will make the MRL redundant. We, therefore, strongly support retention of the guidance provided in the Paragraph 35 and shifting it to the risk management section as suggested.

Food Hygiene:

The Committee has been invited to consider whether the Annex should be retained in the CCFH Risk Analysis Policy document (fourth paragraph under the section on CCFH on page 7).

The guidance in the Annex pertains to the process of the work undertaken by the CCFH and most of the relevant guidance on the same is included in the main document elaborated by the CCFH or the relevant sections in the Codex Alimentarius Procedural Manual. However, there are some guidance paragraphs (e.g. second sentence of the paragraph 5, paragraph 10, and last portion of the paragraph 11) which have not been included in the main policy document. These may be included at appropriate locations in the main document, and the Annex can then be deleted.

INDONESIA

General Comments

Indonesia would like to thank Codex Secretariat for preparing documents Review of the Risk Analysis Policies of Codex Committees.

Following the adoption of Working Principles for Risk Analysis for Application in the framework of the Codex Alimentarius, we are of the view that the risk analysis principles elaborated by the relevant Codex Committees should be consistent with the Working Principles. Structure of the Working Principles and the components of risk analysis should be followed when Codex Committees develop principles for risk analysis taking into account the nature of the specific risks concerned.

Additives and Contaminants

We agree with proposal from Codex Secretariat that *Section 2. CCFA/CCCF and JECFA* could be described as “risk analysis”, *Section 3. CCFA/CCCF* as “risk management”; and *Section 4. JECFA* as “risk assessment” to change Section 2.

As these documents were developed when Codex Committee on Food Additives and Contaminants was still in existence, Indonesia considers that two separate documents could be useful. Even though several provisions are common, but there must be some differences between CCFA and CCCF in nature.

Nutrition and Foods for Special Dietary Uses

Indonesia agrees to the review of Codex Secretariat that the *Nutritional Risk Analysis Principles* generally follow the structure of the *Working Principles* as regards the description of risk assessment and risk management. As there are no specific provisions regarding risk communication, this section should be further developed.

We also propose to transfer paragraph 33 and 34 to the section on *Nutritional Problem Formulation*

Food Hygiene

Indonesia is of the view that this document should not repeat the provision in the Procedural Manual, as described in several paragraph of the Annex. Therefore it is not necessary to describe how working group may be convened and operate as mentioned under *Process for Considering Proposals for New Work*. Paragraph 6 and 7 should also be deleted as proposal for new work has been clearly defined in the Procedural Manual. Paragraph 5 is already mentioned in main document and may not need to be repeated in the Annex.

With regard to the section *Obtaining Scientific Advice*, Indonesia agrees that it should be deleted and incorporated in the main document. In order to make it consistent with Working Principles, the interaction between CCFH and JEMRA in obtaining scientific advice should be included in the same document.

As most of the paragraph should be deleted, Indonesia proposes to delete Annex and transfer the rest paragraph to main document.

JAPAN

Japan appreciates the efforts of the Codex Secretariat in preparing a review of the Risk Analysis Policies of Codex Committees, which is presented in CL 2010/1-GP, for consideration by the forthcoming 26th Session of the Codex Committee on General Principle (CCGP).

Japan generally agrees to the review of the Codex Secretariat, which pointed out discrepancy, mostly regarding inconsistency in format and order of sections/subsections/paragraphs between the “*Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*” (hereinafter referred to as “Codex-wide-RA documents”) and risk analysis principles and policy documents elaborated by respective general subject committees (i.e. CCFA, CCCF, CCRVDF, CCPR, CCNFSU and CCFH) (hereinafter referred to as “Committee-specific RA documents”).

However, Japan is of the opinion that the most important point of this review by CCGP is to check whether all the essential components on risk analysis in Codex-wide-RA are not missing in the current Committee-specific-RA documents. Japan recognizes that the current Committee-specific-RA documents are well-written and easy to follow the procedures and practice by respective committees.

Japan is afraid that there may be disadvantages in aligning the inconsistent format and order of the text, due to potential loss of their better readability. Japan suggests that certain range of flexibility should remain in the format of the Committee-specific-RA documents noting that the Committee-specific-RA documents are always read in conjunction with the Codex-wide-RA documents.

Japan would like to highlight that Activity 2.1 of the Codex Strategic Plan 2008-2013 is designed to achieve Goal 2 “Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis” in Codex. The scientific basis is essential in decision-making by the Codex as stated in the Codex important statement in the Procedural Manual. In this context, appropriate scientific advice should be timely provided by risk assessors (e.g. JECFA, JMPR and JEMRA) to risk manager (Codex). Japan finds that this point, particularly relation between JECFA and JMPR and CCFA, CCCF, CCPR and CCRVDR, is appropriately addressed by the present Committee-specific-RA documents.

Suggestions from Japan are as follows;

1. CCGP, as the responsible party for Activity 2.1, should review the RA-documents primarily to see whether there is inconsistent **application** of the Risk analysis principle in relevant subsidiary bodies.
2. In doing the point 1 above, the CCGP may need inputs from relevant subsidiary bodies regarding technical matters because the Committee-specific-RA documents contain requirements and criteria applied to technical aspects. Therefore CCGP should seek view of each Committee concerned regarding possible inconsistencies between Codex-wide-RA and the Committee-specific-RA particularly in provisions related to technical matters, prior to the conclusion of the review in 2011.
3. CCGP should seek views of FAO and WHO, which organaize scientific expert meetings, such as JECFA and JMPR because they may have their view on better interaction between Codex and these risk assessment bodies.

Japan reiterates its opinion that alignment of the inconsistency in format and structure may possibly lead to less readability of the Committee-specific-RA documents. However, if the CCGP is intended to make recommendations on elimination of discrepancy in their formats and structures Japan would like to suggest that the CCGP should attempt to provide common working instruction, without giving specific proposals to individual Committee-specific-RA documents, in order to allow flexibility for relevant general subject committee in reviewing at the following step.

THAILAND

Thailand has considered the review prepared by Codex Secretariat in document CL2010/01-GP together with various documents on risk analysis policies and procedures applied by different Committees. We would like to comment on the following points:

1. We agree with the recommendations that the format of the principles for risk analysis developed by Codex committees should be amended to follow the structure of the Working Principles for risk analysis as much as possible. Also, the section on risk assessment policy should be in a separate section. This section may be taken from the existing text that have several elements of such policy appear throughout.
2. Thailand is of the opinion that it might be useful to separate the document on risk analysis principles for additives and for contaminants because of the differences and specificities between additives and contaminants.
3. Thailand recognises the Section on Prioritization of Proposal for New Work is included in some risk analysis document. Even though this Section is related to risk analysis, it is separately presented in the Codex Procedural Manual as the Section on Criteria for Establishment of Work Priorities. Codex Secretariat can work with the related Committees' Chairs to rearrange the Section in each document or move them to the relevant place in the Codex Procedural Manual.

UNITED STATES

General Comments

In general, the United States is in agreement with the Secretariat's analysis regarding the committees' risk analysis policies. We concur that, when feasible, for the purpose of achieving consistency, committees could undertake a review of their risk analysis policies in light of general recommendations regarding the structures of the documents. However, we do believe that the content of these documents is most important. As pointed out, committee-specific risk assessment policies are developed due to the nature of the specific risks considered, and we believe it is most important that flexibility be maintained to ensure these documents contain the necessary information. While we can agree that some restructuring may be needed in some documents, we do not believe this exercise should be used as an opportunity to revise the content of these documents. (However, if new information becomes available that would necessitate a revision, we would support such revising the documents.)

Specific Comments

Codex Committee on Food Hygiene (CCFH)

The United States agrees with some of the editing suggestions for this committee's policy on risk analysis, such as eliminating paragraphs 6-7 of the Annex based on the fact that the same information is present in the main document. Part of the texts in paragraphs 9 and 10 could be moved to the main document, thereby eliminating the need for the section on Obtaining Scientific Advice.

However, we do not concur with the recommendations to eliminate the Annex. The charge to CCFH was to "develop a document explaining policies in the application of risk analysis." The title of the Annex is "Process by which CCFH will undertake its work." This is specific to CCFH and we recommend the Annex be retained.

Codex Committee on Pesticide Residues (CCPR)

With respect to the Committee on Pesticide Residues (CCPR), the Circular Letter notes the CCPR Risk Analysis Principles are currently under revision and that the comments and suggestions included in the CL are not based on the current draft [(which will be considered by CCPR the week following the meeting of the Codex Committee on General Principles (CCGP)]. While we do not object in principle to a number of the suggestions, we believe that CCGP should not make recommendations regarding the CCPR risk analysis document, pending the outcome of deliberations at the upcoming CCPR meeting. However, the United States strongly objects to the suggestion to delete the section "Utilization of Steps 5/8 for elaboration of MRLs" from the principles document. These provisions resulted from years of careful review and evaluation and represent substantial reforms that have made it possible for CCPR to function efficiently. While they may appear procedural in nature, they are key to the risk management process in CCPR. We do not believe they are repetitive of other sections of the Procedural Manual. They should remain codified in the CCPR Risk Analysis Principles.