

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

CX/GP 07/24/3-Add.1

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-fourth Session
Paris, France, 2 - 6 April 2007**

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

Comments At Step 3

(Australia, Colombia, Costa Rica, Japan, Norway, Panama, CRN, 49P)

Australia

Australia thanks Canada and Norway for their work in facilitating the development of this document.

Australia is generally supportive of the outcomes of the working group as presented in CX/GP 07/24/3 and acknowledges that significant efforts have been made by all those who participated in the working group to reach consensus on the text contained in Appendix III.

In view of the number of years this has been under discussion, we believe that the document as presented provides the necessary framework and principles to be of practical assistance to member governments in the application of risk analysis to food safety.

We would like to offer the following editorial comments on the document.

Paragraph 5

For clarity we would suggest that the word “regulatory” be inserted before “program”.
The sentence would therefore read:

“Implementation of risk management decisions at the national level should be supported by an adequately functioning food control/regulatory program”

Paragraph 19

We suggest that the last word of the second sentence should be changed from defined to articulated. The sentence would then read:

“The output form and possible alternative outputs of the risk assessment should be articulated.”

Paragraph 20

It is Australia’s view that the current paragraph 23 mixes two different issues, viz, conflict of interest, and public availability of identities. With regard to conflict of interest, we consider it is not always possible to fully ascertain, nor achieve, absolute absence of conflict of interest, especially at national level where resources may be limited. We suggest it may therefore be preferable to focus on and articulate the intent of

the provision i.e. an absence of influence from the conflict of interest, and have edited the sentence accordingly.

With regard to public availability of identities, Australia is subject to guidance at government level that provides direction on this matter, and determines in various circumstances the public availability of such information. It is likely that national requirements will vary between member governments and we therefore consider the document should be silent on this aspect, we recommend the respective sentence be deleted.

Within the context of national governments (rather than Codex) this paragraph is equally applicable to risk assessors, risk managers and risk communicators therefore we suggest that consideration be given to moving the paragraph to earlier in the document, i.e. under *General Aspects*.

With regard to the above comments, Australia proposes that the paragraph be amended as follows:

~~“Experts and/or Government officials, involved in risk assessment, risk management and risk communication, should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these government experts, their individual expertise and their professional experience should be publicly available, while taking into account the need to protect them from external influence during the risk assessment process. These experts from outside government involved in risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. Transparent procedures should be used to select these experts, including disclosure of conflicts of interest in connection with risk assessment.”~~

The revised paragraph would therefore read:

“Experts and/or Government officials, involved in risk assessment, risk management and risk communication, should be objective in their work and not be subject to any conflict of interest that may compromise the integrity of the assessment. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved.”

Paragraph 25

In the first sentence we suggest that the words ‘where necessary’ be inserted after exposure scenarios, as not all situations will require a full exposure scenario, e.g. for a chemical risk assessment a tiered hierarchical approach maybe used especially in circumstances of limited resources, where priority would be given to potential exceedances of reference health standards.

The first sentence would therefore read:

“Risk assessments should be based on realistic scenarios, where necessary, with consideration of different situations being defined by risk assessment policy.”

Paragraph 36

With regard to the third sentence, we consider that it is not common that there will be ‘equal’ options, and the sentence potentially overemphasises trade considerations. We propose the following minor edits to adjust the emphasis in the sentence:

~~When~~ If making a choice among different risk management options, ~~which~~ that are equally effective in protecting the health of the consumer, national governments should ~~seek and~~ take into consideration the potential impact of such measures on trade ~~among~~ and select measures that are no more trade-restrictive than necessary.

Paragraph 41

In the last sentence the reference to paragraph 26 is incorrect; it should reference paragraph 24.

Paragraph 43

We consider that a more consistent approach, as appropriate, is one of the intents/ benefits of regional coordination. We therefore suggest amending this paragraph by adding the words 'and, where appropriate more consistent' as follows:

“National governments should share information and experiences on risk analysis with other national governments (e.g., at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate broader and, where appropriate, more consistent implementation of risk analysis.”

Colombia

Paragraph 20

1. We propose that the second sentence of this paragraph be changed so as to read as follows:

Information on the identities of these governmental and non-governmental experts, their individual expertise and their professional experience should be publicly available, while taking into account the need to protect them from external influence during the risk assessment process.

This is because both governmental and non-governmental experts may be subject to outside influences and consequently the identity and the profile of both of them should be publicly known.

2. We propose that the second part of this paragraph be grouped together in one sentence, so as not to repeat the point in two separate sentences regarding the rigour of the transparent selection of non-governmental experts. The proposal is as follows:

“Experts from outside government involved in risk assessment should be selected on the basis of their expertise and their independence with regard to the interests involved, using transparent procedures, including disclosure of conflicts of interest in connection with risk assessment.”

Costa Rica

Costa Rica considers that the report of the working group which met in Brussels in September 2006 is very complete in terms of its mandate and reflects some simple and horizontal principles on the subject of the Proposed Draft Working Principles for Risk Analysis for Food Safety.

Costa Rica supports the continuation of work on the Proposed Draft in question, as attached in Appendix III of document CX/GP 07/42/3.

Japan

We are generally happy with the revised proposed draft text presented in CX/GP 07/24/3 and pleased to submit the following comments.

General Comments

Japan strongly supports the development of working principles on the application of risk analysis by governments.

Rationale

1. Article 5 of the SPS Agreement requires WTO members to ensure that their SPS measures are based on risk assessment taking into account risk assessment techniques developed by the relevant international organizations; in the area of food safety, Codex Alimentarius Commission. IPPC and OIE have already developed the risk analysis guidance documents for governments in the respective specializing areas. In

parallel with these international organizations, we think that Codex bears responsibility for preparing risk analysis guidance for governments in the area of food safety.

2. The 22nd Session of the CAC agreed to request the CCGP to develop working principles of risk analysis. As a consequence, it is clear that Codex bears responsibility for preparing working principles for governments.
3. Implementing risk analysis for food safety contributes to protecting the health of consumers, and the Working Principles for risk analysis will serve as a common basis for WTO members to introduce own risk analysis in their territories.
4. Codex has already adopted guidance documents on risk analysis for use in specific areas, such as microorganisms and foods derived from biotechnology. It will be useful to establish the Working Principles for risk analysis for governments as overarching principles, which can be referred when Codex develops new recommendations for governments on risk analysis in specific areas.

Specific comments

We propose to delete the words “, OIE and IPPC” from the following sentence:

“13. National governments should take into account relevant guidance, information and outputs obtained from risk analysis activities conducted by international organizations, with particular emphasis on the activities of Codex, FAO, WHO and their experts groups, ~~OIE and IPPC.~~”

Rationale

OIE and IPPC are international organizations carrying out risk analysis for other purposes than food safety. For this reason, we think it unnecessary to include specific reference to these two organizations in addition to Codex, FAO and WHO.

Norway

Norway is pleased to submit comments to **CX/GP 07/24/3 – Proposed Draft Working Principles for Risk Analysis for Food Safety.**

Norway is very pleased with the outcome of the working Group held in Brussels, Belgium September 26-28, 2006. We consider it very important that Codex is drafting this document for use for Governments and it is our hope that this document can be forwarded through the Codex Process in an effective manner.

Although we are very content with this draft proposal, we would like to propose some minor changes. In para 42 which reads “*With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective implementation of risk analysis principles and techniques in their food control systems.*” we suggest that “*food control systems*” be changed to “**food control management systems**” in order to underline that the risk analysis is performed at management level and not at food control level.

We also find it difficult to see that paras 42 and 43 concern **Implementation**. We therefore propose to move these two paras so that they follow para 13, as we look upon them as **General Aspects**.

Panama

The General Directorate of Industrial Standards and Technology of the Ministry of Trade and Industry of the Republic of Panama, as the Codex contact point, submitted for consideration and revision by the interested parties in the state and private sectors the Proposed Draft Working Principles for Risk Analysis for Food Safety (CX/GP 07/42/3), as a result of which the following observations were made on the above-mentioned document:

As a country we agree on the need to establish national principles for carrying out a risk assessment for the evaluation of food safety. However, each Member State must be given a time-limit or deadline for drawing up its regulations and manuals for the implementation of a system of risk assessment, taking into consideration their different elements (as defined by the Codex Alimentarius Commission) and the particular characteristics of each country (paragraph 16, report of the Working Group, page 4).

We consider that the problem of confidentiality is a very technical and “very legal” one. Each state – and ours in particular – will need to consider the levels of confidentiality and where the limits of such confidentiality lie. Accordingly, as it is drafted in paragraph 8 of Appendix III it sounds very simple, and will need to be expanded.

Council for Responsible Nutrition (CRN)

In CS/GP 07/24/3, the Codex Committee on General Principles (CCGP) requested comments on Appendix III, Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments (At Step 3 of the Procedure). The CCGP also provided a brief report on the meeting of the Working Group on the Working Principles for Risk Analysis for Food Safety, which convened in Brussels September 26-28-2006, as well as Appendix II the Background Paper for that meeting

Since the Brussels meeting on September 26-28, 2006 and subsequent to the release of CX/GP 07/24/3, the Food and Agriculture Organization has released a highly relevant and authoritative document—Food Safety Risk Analysis: A guide for national food safety authorities (FAO Food and Nutrition Paper 87 (FAO, Rome 2006).

In the context of the FAO Paper 87, the Brussels Working Group meeting on September 26-28, 2006, and Appendix III, CRN offers the following comments.

Contextual Comments

The CCGP should carefully consider the FAO Food and Nutrition Paper 87. This document is an authoritative statement by one of Codex’s parent organizations. It specifically focuses on advice to Governments—the same scope as the current CCGP works on risk analysis. Paper 87 may provide somewhat more detail (it is self-described as a “guide”) than is included in the current CCGP draft (which is positioned as “working principles”). There is no need for CCGP to “reinvent this wheel” because Paper 87 is highly relevant and appropriate. Moreover, Paper 87 does an admirable job of focusing on scientific issues and avoiding political considerations on risk analysis.

Comments on Appendix III—Proposed Draft Working Principles....

Scope

The scope appropriately considers risk assessment, risk management, and risk communication. In developing a document under this scope, the CCGP should focus on the scientific aspects of all three of these major elements of risk analysis. Without the scientific basis, the principles in one or all of these elements could become so non-objective as to be subject to various political interpretations.

General Aspects

Paragraph 2 should recognize that the Codex Alimentarius has two fundamental aims—ensuring health protection, and promoting fair practices in food trade, as is recognized in the next paragraph.

Paragraph 4 should find a less nebulous way of saying “to the extent possible.” It might further specify that national interpretations of “the extent possible” should not be abused to erect non-tariff trade barriers that may have to meet World Trade Organization arbitration scrutiny.

Risk Assessment

Paragraph 26 is correct that the responsibility for resolving the impact of uncertainty should lie with the risk manager. This paragraph should specify that the responsibility for identifying the impact of uncertainty

should lie with the risk assessor—and that should be requested by the risk manager as part of Risk Assessment Policy (in current Paragraph 17).

Paragraph 27 should specify that the risk assessment should be made available to outside risk assessors for their review before the risk managers made decisions based on it.

Risk Management

Paragraph 28 appropriately states that health protection is the primary objective, but it also should recognize that promoting fair practices in food trade is a critically important goal.

Paragraph 34 should state that the decision should be objective.

Paragraph 35 should require that if two management options are equally protective of consumer health, the one least inhibitory of food trade should be selected. This is better in the same paragraph, rather than being relegated to a subsequent paragraph—number 36 in the current draft.

Paragraph 37 should state that decisions should be reviewed as appropriate, rather than as “necessary.”

Risk Communication

A new paragraph should be added, perhaps as number 42, to state that risk communication should not support irrational fear of specific foods by exaggerating potential risks, i.e., by demanding essentially no uncertainty about their safety.

49th Parallel Biotechnology Consortium (49P)

We were pleased to be able to participate in the very productive Working Group meeting in Brussels last September. We support the text reported by the WG to the full Committee, with one added suggestion.

The “Implementation” language was discussed only very generally by the Working Group, and the report text does not accord with our notes of the full elements of the discussion. Of the items on the list of factors left at the end of the day, neither paras 42 nor 43 include, for example, “monitoring”—an essential aspect of implementing risk analysis which was discussed at the Brussels meeting. We suggest it be included as a para 43 *bis* along the lines of the following:

“Effective implementation of risk analysis should include measures to monitor any occurrence of the identified hazards, the appearance of any unexpected hazards, and the effectiveness and costs of the risk management measures which have been adopted. Periodically, there should be opportunities for updating the risk assessment and management measures on the basis of new information which is obtained.”