

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3

CX/GP 02/3-Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Seventeenth Session
Paris, France, 15 - 19 April 2002

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS GOVERNMENT COMMENTS AT STEP 3 (Colombia, Cuba Guatemala, Malaysia, CI, CRN, IADSA, ICGMA)

COLOMBIA

SCOPE

Paragraph 3: In the second line, in order to maintain consistency with the rest of the document, the words “and the joint and consultations” should be replaced by “and the joint FAO/WHO expert bodies and consultations”.

RISK ANALYSIS - GENERAL ASPECTS

Paragraph 7: It is essential to the document that the term *confidentiality* be defined. The frame of reference for this term should not contravene the principle of transparency that must be included in the “Working Principles for Risk Analysis”.

Paragraph 10: We propose that the version of Paragraph 40 included in the earlier document, CL 2001/24-GP of July 2001, be retained: “When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence”.

Paragraph 11: We propose that the text of Paragraph 10 of the earlier document CL 2001/24-GP, of July 2001, be retained: “Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.”

Paragraph 11a (new): We propose that most of Paragraph 11 of the earlier document CL 2001/24-GP of July 2001, be incorporated here: “ Many sources of uncertainty exist in the process of risk assessment of food borne hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process”.

Risk assessment policy

Paragraph 14: We agree that this Paragraph should be deleted, while leaving the concept of “risk assessment policy” in the definitions, if the term is new. Otherwise, refer to the Codex Procedural Manual, which includes “Definitions for the purposes of the Codex Alimentarius”.

RISK ASSESSMENT

Paragraph 21: The third line of this Paragraph refers to the “hazard identification” as one of the phases of risk assessment. Although we accept the term *identification*, both the document definitions and the Codex

Procedural Manual refer to “hazard determination” as a phase of risk assessment. Therefore, in order to avoid a variety of interpretations, we propose that only the term “hazard identification” be used.

RISK MANAGEMENT

Paragraph 38: Because consequences of an economic nature are not the only consequences to be considered in risk management, we propose that the expression “among other consequences” be incorporated into the text of the first line of the Paragraph, which shall then read as follows: “Risk management should take into account, among other consequences, the economic consequences and the feasibility of risk management options...”

RISK COMMUNICATION

Paragraph 41: In order to maintain consistency with the rest of the document, in the second line, the words “expert bodies and consultations...”, which is in parentheses, should be replaced by “expert bodies and consultations and risk managers...”

Paragraph 41a: In the first line of the Paragraph, we propose that the expression “mere” be changed to “Risk communication is not limited to the simple dissemination of information”.

DEFINITIONS (ANNEX 1)

We suggest that any new terms be incorporated in the Annex of definitions, and that other concepts be included in the Procedural Manual.

CUBA

TITLE

Title should read: “Draft Working Principles for Risk Analysis for application in the framework of the Codex” (this remark is only valid for the Spanish version)

SCOPE

Paragraphs 1, 3 and 4 OK.

Paragraph 2) should read: “The primary purpose of risk analysis in the *Codex Alimentarius* Commission is protecting the health of consumers. Even though it does not, in itself, guarantee equitable practices, it should facilitate such practices”.

RISK ANALYSIS

Paragraphs 5-12 OK.

RISK ASSESSMENT POLICY

Paragraphs 13-17 OK.

RISK ASSESSMENT

Paragraphs 18-29 OK.

RISK MANAGEMENT

In paragraph 30), omit “*riesgo*” after “*consumidor*” (this remark is only valid for the Spanish version).

Paragraphs 31-38 OK.

In paragraph 39), add, after “regularly”, the words “and whenever necessary” (as it might seem that “when necessary” excludes the established level of frequency) .

Paragraph 40 OK.

RISK COMMUNICATION

Paragraphs 41, 42, 43 and 45 OK.

In 41a) Replace “merely” by “solely”, thus giving: “Communication of risks is not limited solely to...”

In 43a) sub-para i), first line, replace the word “*concienciación*” by the word “*concientización*” [NB: both Spanish words mean “awareness-raising” in English. The word preferred by Cuba is used more commonly in Latin America – TRANSLATOR’S NOTE]

In paragraph 44), we suggest the following change in the Spanish: “In the risk communication, the strategy should originate out of the risk analysis process and shall include a plan which shall set out how information and opinions shall be exchanged and considered.

APPENDIX 1

In Annex 1, omit “risk evaluation”, since this in fact constitutes risk analysis, which appears in the corresponding section of the text on analysis.

As a general observation, we would recommend that the Spanish version of the circulated document be revised.

GUATEMALA

We are aware of the importance of implementing risk analysis. We recognize that this requires a commitment to begin obtaining the information necessary to conduct the risk-analysis study.

As a developing country, however, we recognize the need to work together with external consultants in the training of the staff, from the various sectors, who will make up the assessment, management, and communication teams at the national level.

We propose that, in Paragraph 13, a sentence should be added to the effect that guidelines or principles shall be provided, to help with preparation of the risk-analysis study (Implementation Procedures Manual).

We believe that, on this basis, all developing countries must be given the opportunity to participate, under the same regulations, and in an equitable manner, in the marketing of harmless foods.

At the end of Sub-paragraph 1, Paragraph 44, Annex 2, the following phrase should be added regarding the communication of risks to the public:

“care should be taken in the way in which the information is communicated to the public, so that it does not cause people to panic.”

MALAYSIA

Malaysia supports the Draft Working Principles For Risk Analysis for Application in the Framework of the Codex with the following minor amendments :

Paragraph 4

We propose that this paragraph which appears under “Scope” be amended to clarify the risk assessors and risk managers in the Codex framework :

“Within the framework of the Codex Alimentarius Commission” and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment normally lies with the joint FAO/WHO expert bodies and consultations (risk assessors).

Footnote 5 to Paragraph 7

We propose to amend the words “other interested parties” to “other relevant parties” as the words “other interested parties” do not provide further clarification of the term “interested parties”.

Paragraph 23

We suggest that this paragraph be amended to put more emphasis on science in line with the Second Statement of Principle Relating to the Role of Food Safety Risk Assessment:

“Risk assessment should be based on all available scientific data. It should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.”

Paragraphs 31 and 35

We notice that the words “legitimate factors” appear in both these paragraphs and reference to the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles is made only in paragraph 31.

For clarity purposes, we suggest that there should be a footnote to these words in both 31 and 35 paragraphs explaining that it should be in accordance to the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles.

Paragraph 41

In line with our suggestion to clarify the risk assessors and risk managers in the Codex framework in paragraph 4, we propose deletion of the words “expert bodies and consultations” and Codex Alimentarius Commission and its subsidiary bodies” in brackets. Hence this paragraph would read :

“Risk analysis should include clear, interactive and documented communication amongst risk assessors and risk managers, and communication with member countries and all interested parties in all aspects of the process.”

Paragraphs 41 bis and 42

We suggest that paragraph 41 bis be renumbered as paragraph 42 and vice-versa to ensure a smooth flow of thoughts.

CONSUMERS INTERNATIONAL

General comments

Consumers International welcomes the progress that was made on the draft working principles for risk analysis at the Working Group convened by France (5-7 December 2001) and welcomed the opportunity to participate in the important discussion.

We consider it essential that Codex makes progress on this issue. The working principles for risk analysis will make an important contribution to the development of standards which will ensure the health protection of consumers. At the moment the draft relates only to the application of risk analysis within Codex and we hope that a consensus can be achieved which will enable this work to be progressed at the next meeting of the Codex Committee on General Principles (CCGP) 15-19 April 2002.

We consider that there is now a great deal of agreement on the principles and it is important that the discussion focuses on resolving any major points of principle rather than reopening discussions on relatively minor drafting points as this will hold up the Principles further.

We hope that the CCGP can come to agreement on these working principles directed to Codex at the Seventeenth Session. Such agreement will facilitate the subsequent and urgently needed consideration of risk analysis principles directed to governments.

Specific comments

As we do not want to re-open discussion on principles where there is now a great deal of consensus and broadly agree with the draft that came out of the Working Group, we have tried to keep our comments brief.

Scope

We agree with the scope of the principles and the emphasis on protecting the health of consumers as the primary purpose of risk analysis.

Risk analysis - general aspects

We agree with the changes that have been proposed by the Working Group for paragraphs (5), (6), (9) and (9 bis).

(11) - We agree with this paragraph which reflects the compromises made by the Working Group in order to reach consensus on this difficult issue. We do however consider that the assumptions used for the risk assessment and the risk management options selected should also reflect the extent of the potential public health

consequences and therefore suggest that the last sentence of this paragraph is amended to read as follows: "Where there is sufficient evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty, [delete *and*] the characteristics of the hazard *and the potential public health consequences.*"

Risk assessment policy

We agree with the proposed amendments to paragraphs (14) and (15).

(17) - We suggest that this paragraph is moved to the section on risk management.

Risk assessment

(19) - The second sentence of this paragraph is currently unclear and should either be deleted or clarified.

(20) - It is also important for the transparency of the risk assessment that observers representing consumer interests are appointed to the relevant committees and consultations. We therefore suggest that the last sentence of this paragraph is reworded as follows: 'Where possible, expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from around the world *and observers representing consumer interests.*'

(23) - We suggest that the following wording is included at the end of the paragraph: '*including cumulative and interactive effects resulting from multiple exposures.*'

We agree with the proposed amendments to the rest of the paragraphs in this section.

Risk management

(30) - It may be appropriate to use different risk management approaches in different situations even if the risk is similar. We therefore suggest that the second sentence of paragraph 30 is deleted.

We agree with the proposed amendments to paragraphs (31).

(32) - We suggest that reference is made to '*level of compliance and enforceability*' after 'inspection' and that '*including cumulative and interactive effects resulting from multiple exposures*' is included at the end of the sentence after 'specific adverse health effects'.

We agree with the proposed amendments to paragraph (33).

(34) - We suggest that 'assessed' is changed to 'evaluated' in order to avoid confusion with risk assessment. The sentence would therefore read as follows: 'Risk management options should be *evaluated* in terms of the scope and purpose of risk analysis and the level of consumer protection they achieve.'

(37) - We suggest that the last sentence of this paragraph is deleted as the principles are directed at Codex rather than member governments. The issue of whether or not measures are more trade restrictive than necessary is an issue for the World Trade Organisation and not Codex.

We agree with the proposed amendments to paragraphs (38) and (39).

Risk communication

(41) - We suggest that the following worded is added at the end of this paragraph: '*from the initial framing of the questions to be addressed by the risk assessors.*'

(43) - We suggest that the first sentence is amended to read as follows: 'Risk communication with interested parties should include a transparent explanation of the risk assessment policy, [delete 'and of'] the assessment of risk, including the uncertainty, *and risk management options.*'

(44) - We suggest that after 'a plan', the following wording is inserted: '*developed with the participation of all interested parties.*'

We fully support the other changes that have been made which strengthen this section on risk communication.

CRN (COUNCIL FOR RESPONSIBLE NUTRITION)

Precaution in risk analysis has been a major issue for the Codex Committee on General Principles (CCGP) for several years. Strong differences of opinion have been voiced among governments and international organizations. Two consistent dominant questions have been identified: (1) is *precaution* an inherent part of risk analysis, and, if so, is this or is this not sufficient? If precaution is an inherent part of risk analysis, is it part of risk assessment, risk management, risk communication, or a combination of these? (2) Is the specific phrase “precautionary principle” either necessary or acceptable in describing precaution in risk analysis for foods.

In this continuing debate on precaution and the “precautionary principle,” two major viewpoints have developed:

1. Proponents of the “precautionary principle” in risk analysis for foods generally insist that this “principle” is essential for achieving adequate precaution is assuring food safety, that precaution itself is synonymous with the “precautionary principle,” that Paragraph 5.7 of the Sanitary and Phytosanitary Agreement (SPS Agreement) and Principle 15 of the Rio Declaration are equivalent, and that “consumer confidence” is an implicit aim of Codex that can be better achieved through adoption of the “precautionary principle.”
2. Opponents of the “precautionary principle” in risk analysis for foods point out that
 - a. Precaution is an inherent part of risk analysis (e.g., the conservatism in the methods and assumptions of risk assessment, the powers of regulatory officials to take temporary emergency actions in risk management, and usual practices of diverse interested parties in risk communication);
 - b. Adoption of a separate and additional “precautionary principle” would be redundant with existing precautionary measures and authorities;
 - c. SPS 5.7 and Rio Principle 15 are not equivalent because SPS 5.7 addresses uncertainty in the proof of **safety**, whereas Rio 15 allows risk management decisions without full scientific certainty of **harm**, and these are opposites with regard to logical feasibility;
 - d. Use of the specific phrase “precautionary principle” will be used to support unjustified technical barriers to trade;
 - e. The “precautionary principle” would not increase protection of the consumers’ health,
 - f. Consumers should not be misled into believing that the “precautionary principle” is essential or even useful to their protection; and
 - g. Consumer confidence should be inspired by achievement of the two official aims of Codex food standards (i.e., “protecting consumers’ health and ensuring fair practices in the food trade”), and with proper risk communication the “precautionary principle” is unnecessary.

CRN supports precaution in risk analysis but also has consistently opposed incorporation of the specific term “precautionary principle” on the grounds cited under No. 2, above. Hence, CRN commends the CCGP Working Group on Risk Analysis for the revision of the PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX, as distributed by the Codex Secretariat as CX/GP 02/3, Appendix 2. This current draft is an appropriate basis for further debate at the 17th Session of the CCGP in Paris, 15-19 April 2002. Nonetheless, CRN has certain recommendations for improving the draft, as describe below.

CRN Comments

CRN’s recommendations are provided on selected paragraphs, as incorporated into sections and enumerated in CX/GP 02/3, Appendix 2:

RISK ANALYSIS – GENERAL ASPECTS

§10

The following sentence should be added: *The functional separation of risk assessment and risk management will fully conform to the requirement, in paragraph 5 above, to be open, transparent, and documented.*

§11

Insert the word “credible” immediately preceding the word “evidence.” Delete the words “or incomplete.” The word “credible” is essential for an unbiased science-based analysis because otherwise the word “evidence” may be interpreted to include any plausible (i.e., mechanistically possible and not-disproved) adverse effect, no matter how remote the probability and regardless of a complete lack of any supporting evidence. The qualifier “incomplete” must be deleted because science is a continuous process and scientific data can always be considered “incomplete.” In contrast, the word “insufficient” is appropriate because scientific evaluation always includes a judgment about whether the currently available data are sufficient for a decision or whether additional data are required.

Risk Assessment Policy

§14

As described, risk assessment policy should be a component of risk management, but, equally important, risk managers must not readjust risk assessment policy to assure a politically motivated risk assessment outcome. The following phrase should be added to the current sentence, just before the period: “, but risk assessment policy must not be readjusted to assure a specific risk assessment outcome”. An acceptable alternative would be to add this thought as an additional sentence at the end of §16.

§16

If the recommendation for §14 is not accepted, the following sentence should be added at the end of this section: “Risk assessment policy must not be readjusted to modify a risk assessment to a predetermined outcome.”

§18

The word “necessary” should be replaced with “appropriate.” This change is appropriate because estimation of risk reduction is a risk assessment outcome, i.e., the reduction is the difference in the assessed risk under two specific circumstances.

RISK ASSESSMENT

§20

The word “possible” should be replaced with “reasonable” to eliminate speculative, conjectural and highly improbable outcomes of risk assessment.

§29

The paragraph needs an additional sentence such as: “Conversely, description of the possible impacts of uncertainty on risk management decisions requires the input of risk assessors, although the decision of how to resolve the impact lies with the risk manager.”

RISK MANAGEMENT

§31

The first sentence dilutes and corrupts the official aims of the Codex food standards described in the PROCEDURAL MANUAL, Eleventh Edition. The current draft of this paragraph assigns primacy to consumers’ health and a secondary role to fair practices in food trade. Indeed, the PROCEDURAL MANUAL requires “ensuring fair practices” whereas the current draft only requires “having regard to the promotion of fair practices.” There is no requirement in the current draft for appropriate or adequate regard to be given to ensuring fair practices. The paragraph should be edited to read:

Codex decision and recommendations on risk management should have two simultaneous objectives: protecting consumers’ health and ensuring fair practices in the food trade.

§35

The following phrase should be added at the end of the second sentence, immediately before the period: “, and the risk impacts of this decision should be described.”

§37

The second sentence should include a phrase to require examination of the risk management options in quantitative terms of risk modification or differences. The second sentence should have the following phrase added at the end, just before the period: “described in quantitative terms of risk modification”.

IADSA (INTERNATIONAL ALLIANCE OF DIETARY/FOOD SUPPLEMENT ASSOCIATIONS)

IADSA, the International Alliance of Dietary/Food Supplement Associations, welcomes the considerable improvements made by the Working Group to the Proposed Draft Working Principles for Risk Analysis.

IADSA still maintains significant reservations regarding five paragraphs of the draft text:

§10

IADSA considers that the development of a code of practice in cases where there is insufficient evidence to elaborate a Standard is in contradiction with the evidence-based approach to risk analysis elaborated in the Proposed Working Principles. IADSA seriously questions the value of a code of practice that is based on insufficient evidence. In such situations the Codex Alimentarius should simply communicate the results of risk assessment as defined in paragraphs §26-29.

§11

While uncertainty is an inherent element of risk analysis, precaution is not. Precaution reflects a deliberate decision to take a measure to prevent something undesirable from happening. Such a measure can only be taken by risk managers and not by risk assessors. Risk assessors are expected to take uncertainty fully into consideration (as specified in §25) and express this uncertainty transparently (as specified in §26), but their mandate does not include the consideration of precautionary measures. Even in the case of risk management, 'precaution' is customary practice, but it is not 'inherent': precaution reflects a deliberate choice of decision taken by the risk manager.

The first sentence of this paragraph should therefore be deleted.

§27

Risk assessors should always take potential cumulative or combined adverse effects into account. The 'where relevant' at the end of the paragraph is therefore unnecessary and should be deleted.

§37

For clarity, the final sentence of this paragraph should be amended as follows :

" When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the option that is the least restrictive to trade should be adopted. "

§38

For clarity, the first sentence of this paragraph should be amended as follows (consistent with paragraph §37)

"When making a choice among different risk management options, account should be taken of the economic consequences and feasibility of each option, in particular in developing countries."

ICGMA (INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATIONS)

The ICGMA would like to express our appreciation for the efforts of the Working Group members in the revision of the *Proposed Draft Working Principles for Risk Analysis* (Draft Document). We would also like to note the absence of members from developing countries at the Working Group meeting, but point out that we support the views of the few representative developing countries that did participate in the meeting.

ICGMA submits the following comments to the Draft Document as requested by your office.

Comments are provided to specific paragraphs, as numbered:

Title

The revised title accurately reflects the decision of the Commission that principles of risk analysis be applied to the framework of Codex. Accordingly, we support the revision.

Scope

3. We support the revisions to this paragraph as important clarifications that the principles contained within the document are intended to apply to the committees of Codex and the appropriate expert bodies in the conduct of risk assessment, management and communication. We support the acknowledgement that the Draft Document does not take as its goal the elaboration or implementation of risk analysis procedures for governments of member nations. This distinction is important in that it removes, in part, the relevance of national arguments regarding the essential factors forming the basis for risk analysis from any discussion of the guiding principles of an international standards-setting body such as Codex. The elimination of a discussion regarding national implementation of risk assessment, management, and communication from the scope of the documents permits the concept of scientific justification to once again move to the forefront of Codex decision-making.

Risk Analysis – General Aspects

9. We suggest revision of the last sentence to read, “However, it is recognized that risk management decisions are based on a risk assessment.” This wording strengthens the relationship of risk management and risk assessment and is in accordance with Article 5.1 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures Agreement.

10. We support the insertion of former paragraph 40 at paragraph 10.

11. The representatives from the few participating developing countries strongly urged the deletion of this paragraph. We support the deletion. Legitimate application of precaution in risk analysis and the right to take provisional measures in situations of uncertainty is defined in article 5.7 of the WTO SPS Agreement. ICGMA cautions on the elaboration of precaution in a Codex document which is not wholly in accordance with this article.

Risk Management

Although we support the modifications to the text of the Working Draft regarding risk management, we continue to request clarification of the role of Codex in risk management. Specifically, the Draft Document does not sufficiently clarify the fact that Codex does not implement risk management options or create risk management measures, as this role belongs properly to the governments of member nations. We believe that Codex’s role in generating guiding principles and recommendations for risk management to be used by the governments of member nations should be underscored.

31. We support the changes made to this paragraph. The addition of the reference to the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles* highlights the role of these criteria in underscoring the role of Codex as a science-based international standards-setting organization whose primary aim is to protect consumer health.

37. We support the revisions to this paragraph as consistent with our understanding of the definition of “fair practices in food trade” and the consideration of these practices in conjunction with the protection of consumer health.

Risk Communication

41 – 44: We support the changes made to paragraphs 41 through 44 regarding risk communication. In particular, we support the clarification in paragraph 41 of the two types of risk communication at issue within Codex: 1) communication amongst risk assessors (expert bodies and consultations) and risk managers (Codex Committees); and 2) communication amongst Codex and all interested parties (member governments, industry, citizens).

43. While the revisions to paragraph 43 are helpful in outlining the concrete goals of risk communication, and elaborating the importance of transparent, documented risk communication with all interested parties, this section still lacks any elaboration of suggested mechanisms for interactive risk communication between any of these groups. We would suggest that the Committee discuss in greater detail the currently available processes for risk communication between these three groups and make a determination as to whether new avenues for interactive risk communication, particularly with interested parties, should be developed.