

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 4

CX/GP 04/20/4-Add.1

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

Twentieth Session
Paris, France, 3 - 7 May 2004

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY GOVERNMENT COMMENTS AT STEP 3

(Brazil, Canada, European Community, United States, CI, 49P)

BRAZIL

a) General Comments

As already mentioned in Annex 1, no consensus was reached during the last meeting of CCGP on this proposal.

Nevertheless, the proposed document for Governments maintains the same structure of the previous one and clearly duplicates the structure of the document for application by Codex, adapting paragraphs that do or do not apply for Governments.

It is Brazil view that this procedure is not appropriate and that, consequently, the whole structure of the document is ill-conceived. According to the mandate of CCGP clarified by the Commission, this Committee should, as it considered appropriate, try to develop a new document on Risk Analysis for governments; a different document, with general guidelines on the subject.

In Brazil's view, the document on Risk Analysis for member countries should aim at helping those countries to develop their own Risk Analysis program, providing them with practical information on the structure and the objectives of such a program. The way it is presented, the document repeats the majority of the content of the **Working Principles For Risk Analysis For Application in the Framework of The Codex Alimentarius Commission** leading us to the conclusion that, in the essence, there isn't necessity of a new document. As questioned in Annex 1, Brazil is of the opinion that the guidance provided by the FAO/WHO Consultations (1995, 1997 and 1998) is still applicable to define the basic principles of risk analysis when applied to governments.

In view of these considerations, Brazil is of the opinion that CCGP should not proceed on the development of risk analysis principles intended for governments and should consider carefully the guidance to be provided to member countries by the Manual on Risk Analysis, which is being developed by FAO and WHO.

b) Specific Comments:

As stated above, Brazil understands that the discussion of this document should be interrupted. However, since the issue of precaution is present in that text, Brazil must once again stress its objection to the way that specific issue is treated.

In Annex II, paragraphs 32 and 33 do not reflect what has been assigned by the Commission to be treated in the document. This subject has already been discussed in the last session of the Commission. (See Report of

the 24th Session of the Codex Alimentarius Commission July 2001 - page 12, paragraph 81), which decided that: “When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the 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.”

Moreover, Brazil would like to point out that there is no need to describe the situation as in paragraphs 32 and 33 since this situation has already been dealt with in the SPS agreement Article 5, Item 7.

Regarding paragraphs 18 and 25, Brazil would like to ask for clarification about the inclusion of the expression “**ecological and environmental conditions**” since these issues are not included in the mandate of Codex.

CANADA

Background:

The 18th Session of the CCGP considered a first draft of the Proposed Draft Principles for Risk Analysis for Food Safety prepared by the Codex Secretariat. The Committee had a general discussion on the approach to the development of the Principles and the issues that should be addressed but did not reach a consensus on how to proceed further.

The Committee requested the Secretariat¹ to redraft the present document on the basis of the following considerations:

- The points raised during the debate, including the written comments submitted;
- Additional comments to be submitted by governments and interested international organizations within a reasonable time frame;
- An analysis of existing work developed by Codex Committees and Task Forces that provided advice to governments on specific risk analysis issues, with a view to avoiding duplication of work and to identifying gaps; and
- An analysis of related work undertaken by FAO and WHO, including on the practical application of risk analysis.

The Committee is being asked to consider the proposed draft principles but also several questions posed by the Secretariat in the working paper CX/GP 04/20/4, namely:

- whether work should proceed on the development of risk analysis principles intended for governments;
- whether the format of the document as basic principles should be retained;
- whether the principles applicable within Codex can be used as a basis for discussion with the required changes to make them applicable to governments, or if another approach is preferable such as:
 - "referring only to the recommendations of FAO/WHO Expert Consultations
 - "additional guidance from FAO/WHO concerning general risk analysis principles for governments
- whether this document should include the section on risk management or separate it in a first stage in order to concentrate on areas where consensus appears more likely and to advance them to further steps

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¹ ALINORM 03/33A, Report of the 18th Session of the Codex Committee on General Principles, Para 40.

Canadian Position

General Comments

Canada would like to first acknowledge the work of the Codex Secretariat in putting together the revised version of these principles. We would agree with the Secretariat that the Committee will need to reach a consensus on whether to proceed with work on the Proposed Draft Principles and if so, what format should they take.

Canada supports continued work on these principles for the following reasons:

The development of these principles falls within the mandate of the Codex Alimentarius as outlined in Article 1 of the Statutes of the Commission.

This work was endorsed by the 23rd Session of the Commission² when it adopted the Medium-Term Plan 1998 - 2002³. The mandate to CCGP was reconfirmed by the 24th Session of the Commission.⁴

The development of principles would complement the work of FAO and WHO in developing the implementation guidance in their manual on risk analysis "Food Safety Risk Analysis - An Overview and Framework Manual".

While acknowledging that work by some Codex Committees has resulted in risk analysis guidance, those texts tend to focus on a particular category of food (e.g. foods derived from biotechnology) or on a particular component of risk analysis (e.g. microbiological risk assessment). A set of broad risk analysis principles covering all foods and all components of risk analysis would contribute to a more consistent approach by countries in implementing their risk analysis procedures, whether they use their own methods or make use of the FAO/WHO Manual.

A more consistent and systematic approach to risk analysis contributes to enhancing the level of health protection afforded consumers.

Canada favours the "principles" format as we believe this approach contributes to consistency while allowing member governments the flexibility to implement the risk analysis process in a manner best suited to the particular needs of their country, whether through use of the FAO/WHO Manual or developing their own procedures.

We are also of the view that the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius Commission* would serve as a basis of discussion for risk analysis principles for use by governments.

With respect to the question regarding risk management, particularly the provisions on precaution, Canada supports their inclusion. We acknowledge that Article 5.7 of the SPS Agreement allows signatories to that Agreement to implement provisional measures in those circumstances where relevant scientific evidence is insufficient. However, it must be noted that it is the mandate of the Commission to develop food standards for its members, not all of whom are members of the WTO. Therefore, further guidance for all countries should be provided in the Codex documents on issues related to protecting the health of consumers rather than relying on a trade agreement to provide this guidance.

Specific Comments:

Title

² ALINORM 99/37 Report of the 23rd Session of the Codex Alimentarius Commission, Para 34.

³ Codex Medium Term Plan 1998 - 2002, paragraph 3.

⁴ ALINORM 01/41 Report of the 24th Session of the Codex Alimentarius Commission, para 75.

Canada would like to suggest that the title be changed to: *Working Principles for Risk Analysis for Application to Food Safety and Nutrition*.

Rationale: Canada recommends text within this document should be consistent with text that was agreed upon at the 18th Session of CCGP for the application of Risk Analysis in Codex. In that text, the title of the document and the paragraph concerning objectives were changed to reflect that these principles were designed to ensure that food safety and health standards are based on risk analysis. For consistency purposes, we suggest the title be changed to *Working Principles for Risk Analysis for Application to Food Safety and Nutrition*.

Paragraph 1

1. The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to protecting the health of consumers regarding food safety issues, as guidance to governments for food safety, in order to facilitate the application of risk analysis to food safety issues.

2.

Rationale: Canada suggests this modification to highlight that the application of risk analysis is broader than addressing the micro or chemical aspects of food safety. There are other aspects of food which have an impact on the health of the consumer and standards developed to address such risks should also be the result of the application of the risk analysis process. This change also makes this paragraph consistent with the suggested revised title.

Paragraph 2

Canada recommends that this paragraph be modified as follows and moved to the “Scope” section:

2. ~~The overall objective of risk analysis applied to food safety is to ensure public health protection.~~ The objective of these principles is to provide guidance to Codex members so that food safety and health related aspects of their measures are based on risk analysis.

Rationale: Canada feels the above changes better reflect the conclusion made at the 18th Session of the CCGP and is consistent with the Working Principles for Risk Analysis for Application in the Codex Framework. As concluded at the 18th Session, “risk analysis” itself does not ensure public health protection. What this document is meant to do is provide principles for the application of risk analysis so that various food safety measures are based on risk analysis. The above word set is more consistent with this conclusion.

Paragraph 18

18. Risk assessment should take into account relevant ecological and environmental conditions, production, transport, storage and handling practices which may have an impact on the safety and nutritional quality of the food, used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

Rationale: Addition of the text “which may have an impact on the safety and nutritional quality of the food” makes more explicit that the “relevant ecological and environmental conditions” are those which apply to the safety and nutritional quality of food and will thus enhance consistent interpretation of this paragraph.

Paragraph 23

23. Risk management should follow a structured approach including ~~risk evaluation~~, preliminary risk management activities, ~~assessment~~ evaluation of risk management options, ~~implementation of management decisions, monitoring and review of the decision taken~~ and, if needed, selecting appropriate prevention and control options. Implementation of the selected option [by member countries] should be followed by monitoring and review to ensure that public health objectives are being achieved

Rationale: As written, this paragraph is inconsistent with the Codex definition for “risk management”. The implementation and subsequent monitoring are not included in the Codex definition. In order to avoid confusion, Canada proposes the indicated revisions. Activities related to the implementation and review of risk management decisions are also addressed in paragraph 28.

Paragraph 24

24. Risk management decisions should be determined primarily by human health considerations^(New Footnote), and unjustified differences in the level of consumer health protection should be avoided. Consideration of other legitimate factors relevant to the risk management options may be appropriate, particularly in the determination of the measures to be taken. These considerations should not be arbitrary and should be made explicit.

The new footnote would read as follows: “Member countries may refer to the World Trade Organization’s *Guidelines to Further the Practical Implementation of Article 5.5 (G/SPS/15)* as the document provides useful guidelines on the application and practical implementation of the concept of appropriate level of consumer health protection”.

Rationale: Canada suggests adding the footnote to reference the WTO document “*Guidelines to Further the Practical Implementation of Article 5.5*” as that document provides useful guidance on avoidance of different levels of consumer health protection for similar risks. We suggest this footnote to generate discussion and we reiterate that the document which is referred in the footnote is not a legal document but rather be used in a guidance format.

Paragraph 25

25. In achieving agreed outcomes, the risk management should taken into account the impact on food safety and nutritional quality of relevant ecological and environmental conditions, production, transport, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

Rationale: Addition of the text “the impact on food safety and nutritional quality” will make it more explicit that the relevant ecological and environmental conditions are those conditions which impact on the safety and nutritional quality of the food and thus facilitate a more consistent interpretation of this paragraph.

Paragraph 32

32. *When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that serious or irreversible adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply ~~precaution through interim~~ provisional measures, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment. However, additional information should be sought, ~~a more complete risk assessment should be performed, and incorporated into a subsequent risk assessment,~~ and the measures taken reviewed, all in a reasonable time frame.*

Some Members refer to this concept as the "precautionary principle" while others refer to it as “the application of precaution”.

Rationale: This paragraph recognizes the obligation of governments to take action to protect the health of consumers in those instances where, in the absence of complete scientific information, there is reasonable evidence to suggest that exposure to a food poses a risk to its citizens. Paragraph 9 indicates that “precaution” is an inherent element of risk analysis. Paragraph 32 addresses the application of “precaution” in those special circumstances where the scientific data is incomplete. The revision to move the reference to “precaution” from the paragraph to the footnote places the emphasis on the actions allowed under these circumstances rather than the terminology which describes those actions. Furthermore, the suggested revision from “interim” to “provisional” makes this paragraph more consistent with the language used in Article 5.7 of the SPS Agreement which also acknowledges this obligation. The footnote acknowledges that some Member countries refer to these actions as applying “the precautionary principle” while others simply refer to it as the “application of precaution”.

Paragraph 33

33. ~~[In such situations]~~ The following considerations should be taken into account when deciding on the measures to be applied, especially as regards ~~interim~~ provisional measures:

Rationale: We suggest changing “interim” to “provisional” for consistency with our proposed amendment to paragraph 32 and with the terminology in Article 5.7 of the SPS Agreement.

- (a) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.
- (b) There should be a transparent explanation of the need for the measures and the procedures followed to establish them
- (c) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data
- (d) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.
- (e) The measures taken are the least trade restrictive to achieve the desired level of protection of the health of consumers.
- (f) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.
- (g) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.

Rationale: It is Canada’s opinion that the criteria identified in paragraph 33 are applicable to all risk management decisions since scientific information is never complete and is constantly changing. However, it is also acknowledged that the intent of paragraph 33 is to establish some disciplines around the application of “provisional measures” so that such actions are undertaken in a consistent manner. The suggested revisions acknowledge the general applicability of the identified criteria while recognizing their intent is to provide for a consistent application of paragraph 32. Furthermore, it must also be recognized that the list is not exhaustive and that other considerations may need to be taken into account, particularly by those Member countries who are also members of the WTO.

The European Community thanks the Codex Secretariat for having redrafted the Proposed Draft Principles, and wishes to express its broad support to the proposed text. The European Community is of the opinion that it is very important to have guidelines on risk analysis to help the governments to protect consumer health. These guidelines will also help Codex Members to fulfil their obligations vis-à-vis the WTO Agreements.

However, the European Community wishes to propose the following drafting amendments to the Proposed Draft Principles (Annex II):

- Paragraph 16: Add at the end of second sentence “*taking into account the need to protect them from external influence during the risk assessment process*”.

- Paragraph 23: Add the following new sentence consistent with paragraph 28 of the Codex Working Principles for Risk Analysis (13th edition of Procedural Manual, page 46): “*The decisions should be based on risk assessment, to the extent practicable, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade*”.

- Paragraph 25bis: Delete “*and, where appropriate, clearly identified in national standards and regulations*”. The inclusion of decisions and recommendations on risk management in national standards and regulations seems to be too prescriptive.

- Paragraphs 32 and 33: The European Community strongly supports retention of the text and deletion of square brackets.

The European Community considers that governments are fully responsible for the protection of their citizens’ health. They should therefore have the possibility to take interim measures pending new scientific information where a preliminary risk assessment suggests that adverse effects on human health may occur as foreseen in article 5.7 of the SPS Agreement. This possibility should be taken into account by the Codex guidelines intended for the governments.

- Paragraph 33, 2nd line: replace “*especially as regards*” by “*including*”.

The European Community is of the opinion that the considerations listed in paragraph 33 should apply to all kind of measures and not especially regarding interim measures.

- Paragraph 33(a): Add at the beginning “*Wherever possible*” and an additional sentence at the end of the sub-paragraph (a) : “*It is recognised that this may not always be possible in emergency situations*”

Under emergency situations, it might not be always possible to consult all stakeholders on potential advantages and disadvantages of alternative measures.

The European Community therefore supports the advancement of the proposed text at step 5.

UNITED STATES

General Comment

The United States believes that CCGP should carefully consider the best approach to developing appropriate risk analysis guidance for use by countries before proceeding further with the development of the current *Proposed Draft Working Principles for Risk Analysis for Food Safety*. The U.S. notes that, in Annex 1, the Secretariat reports that FAO and WHO are developing a Manual on risk analysis, which is in the process of finalization. This manual may be sufficient guidance for countries or there may continue to be the need of additional guidance in the form of an agreed upon set of over-arching principles, which Codex could develop. However, the next step cannot be determined until countries have an opportunity to study the FAO/WHO Manual. Given the number and importance of issues before CCGP, a more efficient use of Committee time might be to postpone debate on this issue until the Secretariat has circulated the completed Manual for review and comment. In any event, consistency between a Codex text and FAO/WHO guidance is crucial.

This issue should be addressed before CCGP initiates a “line-by-line review of Annex 2 to CX/GP 04/20/4, because once a line-by-line discussion is initiated, fundamental changes to the document in either content and/or format become much more difficult to accomplish.

Specific Comments

RISK ANALYSIS - GENERAL ASPECTS

Principle 3: The United States questions whether this paragraph is needed. It is a restatement of country obligations under the SPS Agreement. Further, the principle has been moved to the Risk Analysis section, yet continues to reference risk assessment, and as such is confusing. The U.S. would delete this principle.

Principle 8: The United States believes that a sentence should be added to this principle, to read:

Interaction between risk assessors and risk managers, which is needed to develop meaningful risk assessment, should be transparent.

Principle 9: The United States questions whether the reference to hazard characterization should not refer to risk characterization. The U.S. would rewrite the final sentence of this principle to read:

The risk management options selected should reflect the assumptions used for the risk assessment and should be consistent with the degree and characteristics of the risk to public health.

Risk Assessment Policy

This section, taken together with the definition of “risk assessment policy” provides very little guidance to countries on what should be considered within a risk assessment policy. Elements that could be further expanded in guidance to countries could include: priority setting for risk assessments, modes of interaction between risk assessors and risk managers, selection criteria for risk assessors, allocation of resources, and use of peer review, etc. This is the type of practical guidance countries, especially developing countries, would find more beneficial than a set of principles.

RISK ASSESSMENT

Principle 16: the United States is concerned that this principle is over broad and reflects unrealistic expectations. Having completely unbiased experts who understand the subject and associated science is probably impossible. The correct emphasis should be on transparency. For simplicity, the U.S. would delete the first two sentences of this principle, and have the principle refer to all experts. Therefore the U.S. would rewrite the principle, to read:

Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise and experience.

Principle 17: The use of qualitative information as presented in this principle is too open-ended. The United States believes that the word “relevant” should be inserted before “qualitative” and the phrase, “when appropriate” at the end of the sentence, to read:

17. Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account relevant qualitative information, when appropriate.

Principle 18: The phrase “ecological and environmental conditions” as it appears in the principle is too broad and vague. In some food safety risk assessments (e.g., pesticides, veterinary drugs) it may be appropriate to consider how the environment or ecology may affect the hazard. However, other types of effects on the environment or ecology would be considered in other risk assessments

that the risk manager would take into account when determining the risk management options to be selected. The United States calls for further discussion of the intent of this phrase. Preliminarily, the U.S. would qualify these considerations by adding the phrase “as they affect the hazard”, to read:

18. Risk assessment should take into account relevant ecological and environmental conditions as they effect the hazard, production, transport, 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.

Principle 19: The United States does not believe that the term “where relevant” in the last sentence is exactly accurate. The U.S. would rewrite this sentence to read:

Where necessary and feasible, Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment.

Principle 22: The United States believes that “results” is a better word than “conclusion” to describe the output from a risk assessment.

The results conclusion of the risk assessment including a risk estimate, if available, ...

RISK MANAGEMENT

Principle 23: The United States would insert the word “identification” before “evaluation”, to read:

23. Risk management should follow a structured approach including preliminary risk management activities, identification and evaluation of risk management options, implementation of management decisions, monitoring and review of the decision taken.

Principle 24: The United States finds the final two sentences of this principle to be misplaced. The primary consideration of risk management is human health. Just as economic consequences and feasibility may be considered, there may be other factors relevant to the risk management that could be considered in some cases. Therefore, the U.S. would delete the final two sentences of principle 24 and insert them as a new principle, Principle 27bis, after Principle 27 to read:

27bis. Consideration of other legitimate factors relevant to the risk management options may be appropriate, particularly in the determination of the measures to be taken. These considerations should not be arbitrary and should be made explicit.

Principle 25: The phrase “ecological and environmental conditions” should be deleted. In some cases environment and ecology could be other relevant factors and thus, they are subsumed with the new Principle 27bis.

25. In achieving agreed outcomes, risk management should take into account relevant production, transport, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

Principle 25bis: The meaning of the term “consistent” is unclear (consistent with what?). The United States would delete the word “consistent”.

Principle 26: The United States believes that a more logical flow to the principle would be to move the sentence “The option of not taking any action should also be considered.” to the end of the principle, to read:

26. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The outcome of the preliminary risk management activities should be combined with the evaluation of all available risk management options in order to reach a decision on management of the risk. The option of not taking any action should also be considered.

Principle 27: The United States is concerned that by requiring countries to select the least trade restrictive management option, Codex is, in effect, providing an interpretation of trade agreements. Codex should not attempt to paraphrase or elaborate upon the language of the SPS and TBT agreements. The U.S. is concerned that, no matter how carefully done, nuance will be lost and important SPS and TBT obligations inadequately reflected. The U.S. also believes that, in selecting risk management options, risk/benefit considerations should be considered. The U.S. would, therefore, delete the final sentence of this principle, to read:

27. Risk management should take into account the economic consequences (including risk/benefit considerations) and the feasibility of risk management options and recognize the need for alternative options.

Principle 29: The United States believes that it important to state the possible purposes of post market monitoring. Post Market monitoring for food safety reasons were agree upon by the Task Force on Foods derived through Biotechnology. Therefore the U.S. would add a sentence to this principle, to read:

29. Post-market monitoring may be an appropriate risk management measure in specific circumstances. The objective, need and utility of post market monitoring should be considered, on a case-by-case basis, during risk assessment and its practicability should be considered during risk management. Post-market monitoring for food safety risk management may be undertaken for the purpose of:

- a. Verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer health effects; and,*
- b. Monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human health impact.*

Principle 30: In addition to reference materials, reference standards may be an important tool in implementing risk management decisions. Therefore, the United States would insert the words “standards and” before the word “measures”, to read:

30. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference standards and materials; and, the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring as required according to the circumstances.

Principle 32: The United States believes that principle 32 should be deleted. The rights and obligations of countries are adequately covered in the SPS agreement. Codex should not try to interpret or restate the trade agreements.

Principle 33: The United States believes that this principle should be deleted. Elements of this principle are not necessarily restricted to interim measures. Sub-elements (a), (b), (e), (f) and (g) are adequately addressed in other principles. Sub-elements (c) relating to proportionality and (d) relating to decisions/measures taken in similar circumstances are elements of risk assessment policy.

CONSUMERS INTERNATIONAL

Introduction

Consumers International (CI) welcomes the opportunity to submit comments on the approach that should be taken to the development of working principles for risk analysis for application by governments. We consider that this work is of prime importance for consumer protection and welcome the Secretariat’s efforts to find a way forward

and to provide a revised document. Our comments on the general approach and specific questions raised by the Secretariat (Annex 1) are set out below, followed by specific comments on the revised ‘proposed draft principles for risk analysis’ (Annex 2).

General Approach and possible options

Our comments on the options proposed in Annex 1 are as follows:

Whether work should proceed on the development of risk analysis principles intended for governments

We feel strongly that this work is essential for consumer protection. The adoption of robust working principles for risk analysis by national governments could help to reduce food-related illness and therefore CI fully supports Codex work in this area. Uniform principles generated by Codex would help ensure a harmonised approach among different countries.

Whether the format of the basic principles should be retained.

We consider that the format is still appropriate. It clearly sets out the principles relevant to each of the three stages in the risk analysis process while recognising that some general aspects apply and that there is a need for interaction.

Whether the principles applicable within Codex can be used as basis for discussion with the required changes to make them applicable to governments, or if another approach is preferable such as referring only to the recommendations of FAO/WHO Expert Consultations or additional guidance from FAO/WHO concerning general risk analysis principles for governments.

CI welcomed the adoption of the working principles at the last Codex Alimentarius Commission meeting. These principles reflect current consensus and understanding of risk analysis and reflect the conclusions and recommendations of relevant FAO/WHO expert consultations while recognising developments since the consultations were convened. We therefore consider that it is appropriate to use the principles applicable within Codex as the basis for these principles directed to governments while recognising that different circumstances may apply at a national level compared with application specifically within the context of Codex.

We are concerned that many of the points of disagreement at the last meeting of the Committee focused around concerns about the implications of the working principles for trade and the extent to which trade interests were prioritised relative to public health. This tension needs to be resolved if progress is to be made. We are concerned therefore that reference to relevant FAO/WHO consultations will not resolve this issue. However, if consensus cannot be achieved at this session of the Committee, we consider that there may be merit in requesting further clarification and examples of how the principles could apply in different situations at the national level. While FAO/WHO experts could assist with this process, practical experience drawn from member governments and observer organisations would also be important.

If principles for governments are to be developed, the Committee may consider including only a reference to the sections that are already included in the adopted working principles and retaining the sections that are specifically intended to governments.

We are concerned that by cross-referencing to the working principles within the context of Codex, these principles directed to governments would not be very user-friendly, could be confusing, lacking in clarity and will be inaccessible. We therefore prefer that the document retains its current format in the interests of transparency and ease of comprehension.

Whether this document should include the section on risk management or separate it in a first stage in order to concentrate on the areas where consensus appears more likely and to advance them to further steps.

We do not consider that it is feasible or appropriate to deal with the rest of the document without including risk management. Ultimately the whole objective of the risk analysis process is to reach decisions about the most appropriate way to manage food safety hazards. Risk management is clearly the most contentious section of the document and differences of approach need to be resolved in this area if Codex work on risk analysis is to be of value.

If the section on risk management is retained whether it should include the section on precaution in risk management, with the understanding that a general reference to precaution in risk analysis is retained in paragraph 9.

We consider it essential that precaution is referred to within the section on risk management as well as within the general aspects section. While precaution should be an inherent element of risk analysis in general, it is imperative

that principles for its application within the specific context of risk management are elaborated within the document. Further comments are provided on paragraphs 32 and 33 below.

Replacing the section on risk management with a reference to the recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety.

The section on risk management must be retained in the document. The principles will be of most use and are likely to make the greatest contribution towards improving food safety and protecting public health if they can be as clear as possible. The purpose of this document should be to explain how risk analysis principles should be applied by member governments within a national context and be based on current understanding. The FAO/WHO expert consultation established generic principles for risk management for Codex as well as for application by member governments and which, while still very relevant and valuable, may not reflect more recent developments in this area.

Proposal for a working group

CI would like to suggest an alternative approach if progress cannot be made at this session. We would like to propose that a working group is established to meet prior to the next meeting of the CCGP focusing on this document with the aim of achieving consensus on the most difficult areas including the use of precaution. This approach was successful in making progress and achieving greater understanding of different perspectives when developing the principles for risk analysis for application within Codex.

Proposed draft principles for risk analysis – redrafted version

In general, we support the principles as redrafted. Our comments focus on those aspects where we have concerns or specific points to raise.

Risk analysis – general aspects

(3) We do not consider it appropriate to include a paragraph dealing specifically with risk assessment in the ‘general aspects’ section. This paragraph is the first paragraph of the Codex ‘Statements of Principle Relating to the Role of Food safety Risk Assessment’ and therefore more appropriately fits in the ‘risk assessment’ section of the document. It also fails to recognise the need to have regard to other legitimate factors that are relevant. We therefore suggest that it is amended as follows: ‘Health and food safety decisions and recommendations should be based on a risk assessment *and other legitimate factors* as appropriate to the circumstances.’

(4) It is useful to clarify here that ‘all components’ of the risk analysis process should be applied consistently and be open, transparent and documented. We therefore do not consider it appropriate to delete the words ‘and all of its components.’ We suggest that the paragraph be redrafted as:

‘All components of the risk analysis process should be

- applied consistently
- open, transparent and documented.

Risk assessment

(16) We fully support the principle established within this paragraph that government officials involved in risk assessments should have no personal interests or biases with regard to the subjects of their risk assessments and that information on the identities of these government experts, their individual expertise and their professional experience should be made publicly available. We consider that this should also extend to any financial interests and therefore propose that the second sentence is re-worded to include this as follows:

‘Information on the identities of these government experts, their individual expertise, their professional experience and any other personal or financial interests should be made publicly available’.

We also agree that experts from outside government should be selected in a transparent manner and that there should be a public declaration of any potential conflict of interest, and that this should also identify and detail their individual expertise and experience.

Risk management

(23) While we appreciate that the term ‘preliminary risk management activities’ has been used in order to avoid using the potentially confusing term ‘risk evaluation’, we are concerned that it still sounds confusing. For the sake of clarity, we suggest that the elements of the ‘preliminary risk management activities’ are included in the body of the document as they are essential to effectively understanding and practicing risk management as set out in the

FAO/WHO Expert Consultation on Risk Management and Food Safety. We therefore suggest that this paragraph is restructured as follows:

Risk management should follow a structured approach including

- preliminary risk management activities (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 the conduct of risk assessment; commissioning of the risk assessment and consideration of the result of the risk assessment)
- evaluation of risk management options
- implementation of management decisions
- monitoring and review of the decision taken

(27) We do not consider that it is the role of Codex to specify the extent to which member governments should take into account trade concerns. This does not fall within Codex's remit and is dealt with under the World Trade Organisation's agreements of which the majority of Codex members are also members.

(29) We do not agree that consideration of the objective, need and utility of post-market monitoring is necessarily a risk assessment function. Risk managers may decide that as a result of assumptions and uncertainties inherent within the risk assessment that such monitoring is necessary. We therefore suggest that the second sentence of this paragraph is re-worded as follows:

'The objective, need, *practicality* and utility of post-market monitoring should be considered, on a case by case basis. [delete the rest of the sentence].'

(32) The inclusion of this paragraph under this section on risk management is essential for consumer protection. There will be, and have been, situations where failure by risk managers to act when scientific uncertainty makes it impossible to conduct a full risk assessment would put consumer safety at risk. In such circumstances it is appropriate that precaution is applied.

(33)(a) We agree that an examination of the full range of risk management options should be undertaken with all stakeholders and that this should include an assessment of the potential advantages and disadvantages of the alternative measures, including where appropriate, flexibility and cost-effectiveness considerations. It is also important that this assessment considers the implications of failing to take any action and therefore we suggest that the following wording is added to the end of 33 (a) '*taking into account potential costs of failing to act.*'

33(c) We agree that decisions/ measures taken should be proportional to the potential extent of the health risk and based on the available scientific data. However, it will always be easier to quantify the economic impact of introducing a measure compared to the long-term public health and economic implications of failing to take action. Care should also be taken that there isn't over-reliance on limited data when faced with scientific uncertainty which could prove to be misleading. This was for example the case when Bovine Spongiform Encephalopathy (BSE) was first discovered in the UK. Decisions/ measures should also take into account other legitimate factors. Many factors will impact on the acceptability of a particular risk, including for example whether it is voluntary or involuntary and whether or not there are any benefits.

We therefore suggest that the following wording is included at the end of 33 (c) '*while acknowledging its potential limitations*' and that '*other legitimate factors*' are acknowledged. The sentence would therefore read as follows:

'The decisions/ measures taken are proportional to the potential extent of the health risk, based on the available scientific data *while acknowledging any potential limitations, and taking into account other legitimate factors.*'

Risk communication

We generally support this section on risk communication. It is essential that risk communication is seen as a two-way exchange of information that can help to ensure the quality and robustness of the risk analysis by ensuring that the process incorporates the views, experiences and attitudes of all interested parties as well as enhancing transparency and dissemination of information.

49P (49th PARALLEL BIOTECHNOLOGY CONSORTIUM)

The decision to divide the subject of Risk Analysis into two documents—one for Codex and one for governments—was made by the Committee on General Principles and approved at the 50th meeting of the Executive Committee. CCGP finished its work expeditiously on the document for Codex, and now should

move ahead on the current document. This work should be coordinated with other relevant activities, such as the work on the FAO/WHO Manual on “Food safety Risk Analysis”.

We support including ecological conditions and other legitimate factors (Principles 16, 24, 25) when relevant to a risk assessment. For example, as a subunit of WHO has found, human health may be affected *indirectly* by environmental factors as regards genetically engineered foods:

Potential effects on human health of the consumption of foods derived from biotechnology and of the release of GMOs (especially plants) in the environment are generally recognized as public concerns.

* * * *

Responses to the second concern have so far been very scarce: the traditional framework for risk assessment and management involves a methodological progression through a rigorous sequence of analytical steps that does not fit the type of phenomena involved in this case. In addition, Environmental Risk Assessment usually identifies direct and indirect environmental effects but makes limited references to human health.

To fill this gap, WHO organized the seminar "Release of Genetically Modified Organisms in the Environment: is it a Human Health Hazard?". The category of hazards associated with the release of GMOs in the environment . . . dealt with by the seminar participants and for which human health effects should be identified or excluded, [was] restricted to 1) gene transfer; 2) alteration of ecosystem structure and function; and 3) development of resistances.

Release of Genetically Modified Organisms in the Environment: is it a Health Hazard? (7-9 September 2000)

Report of a Joint WHO/Europe – ANPA (Italian National Agency for Environmental Protection) Seminar, <http://www.euro.who.int/foodsafety/Otherissues/20020402_5>

In discussing the hazards that need to be assessed, “the seminar recognize[d] that the hazards discussed are not all unique to GMOs but may also apply to other organisms.” Thus, post-marketing monitoring (Principle 29) might have to include keeping track of some environmental indicators.

The 49 P organization strongly supports inclusion of the bracketed Principle 32. This language is an expression of a precautionary approach, as found in numerous laws of Codex members (for example, the Precautionary Principle is included in over 40 US statutes). We understand that some delegations suggest that the points made here are adequately covered in the WTO/SPS agreement. However, (1) not all Codex members are signatories of the SPS, (2) Codex principles should be integral and complete, standing on their own, and (3) the WTO has decided to follow Codex norms—Codex has *not* decided to abdicate its responsibilities to the WTO.

In regard to Principle 33, we see that some provisions appear to duplicate language in other parts of the Proposed Draft.

We think that Principles 34-37, on Risk Communication, are satisfactory, providing for transparency and recognizing that affected communities often have important information to transit *to* assessors.