codex alimentarius commission

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Agenda Item 3 **CX/GP 05/22/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-second Session
Paris, France, 11 – 15 April 2005

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

CONCLUSIONS OF THE WORKING GROUP ON THE PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS
6 November 2004, Paris, France

1. In accordance with the decision of the 20th Session of the Codex Committee on General Principles, a Working Group was convened on Saturday, 6 November 2004 co-chaired by Argentina and Canada.[1] This meeting was attended by 29 delegations from 25 Members and 4 Observer Organizations[2]. A full list of participants is attached as Appendix 1 to this report.

2. The Working Group agreed to use the compilation of comments developed by Argentina and Canada as the reference document during its consideration of the Proposed Draft Principles of Risk Analysis for Food Safety **(Appendix III).**

3. In their opening remarks, the Co-Chairs recalled the mandate given to the Working Group which was to improve the text of the *Proposed Draft Working Principles for Risk Analysis*. Prior to engaging in a section by section review of the current document, the working group had a general discussion on several of the questions which were contained in Annex 1 of the Secretariat's paper.[3]

4. Taking into consideration the fact that the purpose of these principles is to provide guidance to countries on risk analysis, and the requests received for technical assistance in this area, some delegations questioned whether the document as currently drafted provided countries with what they needed. It was suggested that before work could progress, there was a need to determine what were the needs of countries, particularly developing countries. Some of these delegations also noted the guidance on risk analysis being developed by FAO and WHO, the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius* as well as the provisions of Article 5.7 of the SPS Agreement and expressed the view that there was no need for developing additional principles.

5. Other delegations supported continuing work on the draft principles. They recalled the decision of the Commission to develop two guidelines, one with respect to Codex for inclusion in the Codex Procedural Manual and the other for use by governments for publication in the *Codex Alimentarius*. They expressed the view that there was a need for the principles for governments because the proposed FAO/WHO

[1] ALINORM 04/27/33A, paragraph 43

[2] Argentina, Australia, Brazil, Canada, European Commission , France, Germany, India, Italy, Japan, Kazakhstan, Korea, Kyrgyzstan, Laos, Malaysia, Mexico, Nepal, Netherlands (The), New Zealand, Paraguay, Spain, Sweden, Thailand, United States of America, Zambia, 49P, Consumers International, CRN, ICGMA.

[3] CL 2004/34-GP

Manual consisted of a number of PowerPoint slides and case studies, and was intended as a training tool rather than guidance for governments. Delegations further noted that not all members of Codex were members of the WTO and that Codex had a responsibility to provide guidance to all its members. It was recalled that at the 20th Session of the CCGP the representative of the WTO supported Codex work on the preparation of principles for application by government since both OIE and IPPC had already developed similar principles. Several delegations expressed the view that circumstances for governments are different from Codex, particularly in light of insufficient scientific information, therefore the Codex principles would not be applicable to government.

6. While noting there was no consensus within the Working Group on the relevance or need for these working principles, the Chair reminded the Working Group that it had no mandate to make a decision regarding appropriateness or relevance of work on the principles, such a decision could only be made by the Committee. The mandate given to this Working Group by the Committee was to review the current document with a view to improving the text.

7. The Working Group considered the *Proposed Draft Working Principles for Risk Analysis* paragraph by paragraph.

Title

8. The Working Group agreed to add a reference to "food safety" and changed the title to *Proposed Draft Working Principles on Risk Analysis for Food Safety*. A suggestion to also make reference to "nutrition" in the title was not included as several delegations expressed concern with an expansion of the scope.

Scope

9. The Working Group agreed to amend paragraph 1 by adding at the end of the sentence "…in light of the purpose of the Codex Alimentarius Commission." A footnote referencing Article 1(a) of the Statutes of the Codex Alimentarius Commission was also added.

10. It further agreed to move paragraph 2 from under "General Aspects" to the Scope section to make the text more consistent with the Working Principles already adopted by Codex. The Working Group also agreed to revise the paragraph to read "The objective of these principles is to provide guidance to Codex members so that food safety and health related aspects of their decisions and recommendations are based on risk analysis." It was also agreed to place "health related" in square brackets as some delegations felt the term was too broad and undefined.

Risk Analysis – General Aspects

11. Paragraph 3 was revised to place "Health and" in square brackets as some delegation felt the reference to "health" was broader than reference in the title to "food safety". The word "analysis" was added after risk for clarity.

12. Paragraph 4 was modified to add a third bullet "evaluated and reviewed as appropriate in the light of newly generated scientific data" to enhance consistency with the *Working Principles for Risk Analysis in the Framework of the Codex Alimentarius*. A proposal to include "systematic" in the paragraph was not accepted.

13. In order to strengthen the reference to the risk analysis process, the Working Group agreed to include a reference to "preliminary risk management activities" in paragraph 5.

14. No revisions were made to paragraphs 6, 7 and 8. The Working Group considered written comments from Iran and Chile but they were not incorporated into the document.

15. There was an extensive discussion on paragraph 9. Some delegations expressed the view that the first sentence should be deleted as "precaution" is an exceptional activity and not a principle and noted that the WTO allows countries to adopt measures to address exceptional circumstances.

16. Other delegations were of the opinion that the sentence was a reflection of actual practice and that the text in the first sentence was consistent with text already adopted by Codex. It was their opinion that the reference to precaution should be retained.

17. Several alternative words were suggested, including "prudence" and "caution". The Working Group decided to place all three words, "caution", "prudence" and "precaution" in square brackets. In the last sentence of paragraph 9, the Working Group also agreed to replace "reflect" with "take into

consideration", delete the phrase "and the characteristics of the hazard" and to add "and the degree of uncertainty" at the end of the sentence. It was agreed that the amended sentence would be moved to the section on Risk Management.

Risk Assessment Policy

18. In order to enhance the understanding of what "risk assessment policy" was, it was agreed to add a footnote to the title of the section outlining the elements of risk assessment policy.

19. Paragraphs 10, 11 and 12 were retained with no changes.

20. In paragraph 13 the phrase "Where necessary" was modified to "where appropriate" as suggested in the written comments submitted by Chile and the Working Group agreed the paragraph should be moved to the section on Risk Management.

Risk Assessment

21. Paragraphs 14 and 15 were retained with no revisions.

22. There was extensive discussion regarding paragraph 16 regarding the independence of the risk assessors. The Working Group agreed to a number of revisions to improve the clarity of the intent of the paragraph and to enhance the requirement for the risk assessment process to be objective, transparent and the need for disclosure of conflicts of interest.

23. The first sentence of paragraph 17 was amended by inserting the word "relevant" before "available". The sentence now reads "Risk assessment should be based on all *relevant* scientific data. The Working Group also agreed to add the phrase "where appropriate" at the end of the last sentence.

24. In paragraph 18, it was agreed that the reference to "ecological and environmental" conditions would be replaced with a reference to "factors relevant to food safety" as some delegations expressed concerns that the reference to ecological and environmental conditions was too broad and there was a need to keep the principles focussed on food safety. The Working Group also agreed to include "processing" as a separate function from production.

25. The last sentence of paragraph 19 was revised by deleting "where relevant" from the end of the sentence and inserting "if relevant" at the beginning. The Working Group also agreed there was a distinction between "chronic" and "long term" health effects and revised the last sentence to make this distinction more evident.

26. There were no revisions to paragraphs 20, 21 and 22.

27. The Working Group did not consider the remaining paragraphs of the document as there was insufficient time. **Appendix II** to this report contains the revised text for paragraphs 1 to 22 inclusive.

Appendix I

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Appendix II

REVISED
PROPOSED DRAFT PRINCIPLES OF RISK ANALYSIS FOR FOOD SAFETY[1]
(At Step 3 of the Procedure)

SCOPE

1. The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments**, in light of the purpose of the Codex alimentarius Commission**[(*)].

2. **The objective of these principles is to provide guidance to Codex members so that food safety [and health related] aspects of their decisions and recommendations are based on risk analysis**..

RISK ANALYSIS - GENERAL ASPECTS

3. **[**Health and**]** food safety decisions and recommendations should be based on risk **analysis and be** appropriate to the circumstances.

4. The risk analysis process should be

-applied consistently,

-open, transparent and documented**,**

-evaluated and reviewed as appropriate in the light of newly generated scientific data

5. The risk analysis process should follow a structured approach incorporating the three distinct but closely linked components of risk analysis (risk assessment, risk management **including preliminary risk management activities,** and risk communication), each being integral to the overall risk analysis process. The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage food related risks to human health.

6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties[4].

7. Effective communication and consultation with all interested parties should be established and maintained throughout the risk analysis process.

8. There should be a functional separation of risk assessment and risk management, to the extent practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

9. **[[Precaution] [Prudence] [Caution]** is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process.**]** The risk management options selected should ~~**reflect**~~ **take into consideration** the assumptions used for the risk assessment~~,~~ **and** the degree of uncertainty~~ and the characteristics of the hazard~~. **♣**

Risk Assessment Policy[5]

10. Determination of risk assessment policy should be included as a specific component of risk management.

(*) Reference to Article 1 a), Statutes of the Codex alimentarius Commission, Procedural Manual – 13th edition.

[4] For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication").

♣ There is agreement to move the last sentence of this paragraph, as amended, to the section on "Risk Management"

[5] **[Elements of risk assessment policy include, among others: 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.]**

11. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.

12. The mandate given by risk managers to risk assessors should be as clear as possible.

13. Where ~~**necessary**~~ **appropriate**, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.[**]

RISK ASSESSMENT

14. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization, and should be documented in a transparent manner.

15. The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined

16. **Government officials involved in risk assessment should be objective in their scientific work and not be subject to any conflict of interest.** 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**. Experts from outside government ~~**responsible for**~~ **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**.

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

18. Risk assessment should take into account **factors** relevant **to food safety, e. g.** ~~**ecological and environmental conditions,**~~ production, **processing,** 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.

19. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups, as appropriate. **If relevant,** acute, chronic, ~~**(including**~~ long-term~~)~~, cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment~~, where relevant~~.

20. Constraints, uncertainties and assumptions and their impact on the risk assessment should be explicitly considered at each step in the risk assessment process and documented in a transparent manner. Expression of uncertainty or of variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

21. The report of the risk assessment should include the scope and purpose of the risk assessment carried out, the background of the request, the information considered, the scientific reasoning and the conclusions of the risk assessors. The report should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

22. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

[**] **There is agreement to move this amended paragraph to the section on "Risk Management"**

APPENDIX III

PROPOSED DRAFT PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY [6]

(At Step 3 of the Procedure)

This document contains Governments' and Observers' comments on CCGP 04/20/4 and CL 2004/34-GP. For inclusion of comments, we have considered, directly from drafting group members, documents CCGP 04/20/4-Add.1 and CCGP 04/20/4-Add. 2, verbal comments made during discussion at CCGP and responses in writing to CL 2004/34-GP.

The document should be read considering the following:

- 1st column. It contains the Full Text of document CCGP 04/20/4 considered by CCGP, May 2004. The underlined parts of the text are changes suggested in May 2004 at CCGP for inclusion in the document. Other parts have been struck out because their removal was suggested at the meeting. Some paragraphs are in brackets because no consensus was reached on whether they should be retained.
- 2nd column. It contains Governments' and Observers' comments on CCGP 04/20/4 and CL 2004/34-GP. The comments have been ordered under General Comments and then on a paragraph-by-paragraph basis. Within each of them, Governments' comments are presented in alphabetical order, according to the countries in English, and then Observers' comments. After the name of the country, the document on which comments are made is indicated [e.g. **Argentina** (CCGP 04/20/4-Add.2)]. Where a country makes comments on both documents, the views on CCGP 04/20/4 are presented first and then those on CL 2004/34-GP.
- 3rd column. It contains Changes suggested by Governments and Observers. Changes suggested without specified drafting have been included in this column without distinctive marks. Suggested changes for which Governments or Observers have proposed redrafting have been included highlighted; proposed added text is underlined and proposed removed text is ~~struck-out~~. The same criteria as those adopted in the 2nd column have been adopted here for the purposes of order and identification.
- 3rd column: in response to CL2004/34-GP, the United States redrafted (and renumbered) the "Proposed Draft Principles for Risk Analysis for Food Safety". The full text of this redraft has been included as Annex 1 of this document. Its inclusion in the chart was not possible due to its different numbering; also, some paragraphs of previous drafts have been removed and new paragraphs have been added. Including the US redraft in the chart would make it difficult to read.

[6] These principles are intended for governments and will be incorporated into the Codex Alimentarius.

PROPOSED DRAFT PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY[7] (At Step 3 of the Procedure)

Full Text of document CCGP 04/20/4 considered by CCGP, May 2004.[8]	COMMENTS: Direct from drafting group members; written comment made to CCGP (CCGP 04/20/4-Add.1); (CCGP 04/20/4-Add.2); CRDs circulated at CCGP; verbal comment made during discussion at CCGP; CL 2004/34- GP.[9]	**Suggested Changes** [10]
GENERAL COMMENTS	**Argentina** (CCGP 04/20/4-Add.2) After close examination, it can be said that the document has retained the structure of the project approved at the 26th session of the Codex Alimentarius Commission for the Application of Working Principles for Risk Analysis for Food Safety in the framework of Codex, with differences in those paragraphs which either are not applicable to governments or might be, but are approached in a different way. As stated in the mandate received by the Codex Committee on General Principles, the committee should, if deemed appropriate, develop a new document on risk analysis for governments, supposing that it was different than the previous one, which would provide guidance on this matter to assist Members to develop their own risk analysis programs. However, in the light of the new proposal, such guidance can be found in the text already approved by the Commission on the Application of Working Principles for Risk Analysis for Food Safety in the framework of Codex Alimentarius. This similarity between the texts would thus make evident that it would not be necessary to duplicate efforts and repeat discussions to achieve similar results, particularly taking into account that this draft includes specific provisions which have been widely discussed and questioned in their treatment by a number of developing countries at the 16th session of the Codex Committee on General Principles and the following session of the Commission. In our opinion, the scientific principles recommended by FAO/WHO Expert Groups on which the development of documents on the Application of Working Principles for Risk Analysis for Food Safety in the framework of Codex Alimentarius still in force. The approved document can therefore provide a basis for governments, without the need of developing a new text. In this respect, it remains unclear which the current gap is, taking into account the existence of a standard for the Application of Working Principles for Risk Analysis for Food Safety in Codex and	**Argentina** (CCGP 04/20/4-Add.2)**:** The scientific principles recommended by FAO/WHO Expert Groups on which the development of documents on the Application of Working Principles for Risk Analysis for Food Safety in the framework of Codex Alimentarius still in force. The approved document can therefore provide a basis for governments, without the need of developing a new text.

[7] These principles are intended for governments and will be incorporated into the Codex Alimentarius.
[8] The underlined parts of the text are changes suggested in May 2004 at CCGP for inclusion in the document. Other parts have been struck out because their removal was suggested at the meeting are changes suggested.
[9] The Government or Observer making each comment is identified. Next, the document on which comments are made is indicated.
[10] Suggested changes for which Governments or Observers have proposed redrafting have been included highlighted; proposed added text is underlined and proposed removed text is struck-out. Suggested Governments or Observers have proposed redrafting have been included highlighted.

	the virtually completed task by FAO/WHO for edition of the Manuals on Risk Analysis. **AUSTRALIA** (CL 2004/34-GP) In framing our response, we have endeavored to provide comment in relation to the options outlined in the Circular Letter, page 4 "Summary of Possible Options". Australia does not consider that the format of the current document should be retained. However, should the Committee decide on this as the preferred approach, Australia would agree to an amendment of the current Working Principles. *Whether work should proceed on the development of risk analysis principles intended for governments?* Australia agrees that work should proceed on the elaboration of a set of working principles for risk analysis, specifically for use by governments of member countries. Australia considers that a set of principles will assist in providing consistency across Codex members and will provide more specific guidance than is currently offered by the more generic and overarching *Working Principles for Risk Analysis for Use in the Framework of Codex*. Australia would envisage that working principles for use by member governments would be a practical guidance document that sits effectively between the higher order principles outlined in the adopted *Working Principles*, and the very applied risk analysis manual, that is currently under development by FAO. It is noted that the risk analysis manual whilst providing valuable guidance, will have no legal status, whereas working principles for use by member governments would be applicable to member countries under the World Trade Organization and would assist members of the WTO in meeting their obligations under the Sanitary and Phytosanitary Agreement (SPS Agreement). *Whether the format of the document as basic principles should be retained.* Australia does not consider that the format of the current document should be retained. However, should the Committee decide on this as the preferred approach, Australia would agree to an amendment of the current *Working Principles*. Australia considers the current document is too similar to the adopted *Working Principles* in both its content and structure, and as such, does not lend itself to more specific and applied guidance to member countries. Australia proposes development of a document that introduces a smaller number (e.g. 6-7) of higher order principles. This document would then further articulate guidelines explaining how those principles should be implemented at country level. There are a number of documents within Codex that contain overarching principles and then move on to elaborate further guidance. For example, the structure adopted with respect to Foods derived from Biotechnology provides an example of a similar format: *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC –GL 30-1999); Guidelines of the Conduct of*	**AUSTRALIA (CL 2004/34-GP)** PROPOSES DEVELOPMENT OF A DOCUMENT THAT INTRODUCES A SMALLER NUMBER (EG 6-7) OF HIGHER ORDER PRINCIPLES. THIS DOCUMENT WOULD THEN FURTHER ARTICULATE GUIDELINES EXPLAINING HOW THOSE PRINCIPLES SHOULD BE IMPLEMENTED AT COUNTRY LEVEL.

	Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003); Guidelines for the Conduct of Food Safety Assessment of Food Produced using Recombinant-DNA Microorganisms (CAC/GL 46-2003) *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:* **a.** *Referring only to the recommendations of the FAO/WHO Expert Consultations.* Australia agrees the working principles applicable within Codex could serve as a useful basis for developing more specific principles. However, we consider it would not be appropriate to refer only to the FAO/WHO Expert Consultations. Whilst the scope of these documents includes member countries, this is not their primary focus and they are not specifically directed toward regulatory implementation at a national level. Also, as these 3 documents were printed in 1995, 1997 and 1998 respectively, it may be appropriate to consider provision of more up-to-date information. **b.** *Additional guidance for governments from FAO/WHO concerning general risk analysis principles for governments* If Codex does not elaborate additional guidance specifically for governments, an alternate approach would be for FAO/WHO to provide such guidance, noting however, this approach would require additional resources from FAO/WHO. *If principles intended 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.* Australia acknowledges cross-reference to the *Working Principles* as a possible approach. However, given the *Working Principles* (published in the Procedural Manual) and the specific information for governments would ultimately be in two separate publications (refer Footnote 2, Annex 2: "These principles… will be incorporated into the Codex Alimentarius"), Australia considers a single document would be easier to reference and thereby more practical. AS IT MAY BE DIFFICULT TO REACH CONSENSUS ON SOME ASPECTS OF RISK MANAGEMENT, THE COMMITTEE MAY CONSIDER **c.** 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. Australia considers the section on risk management can be progressed and the document as a whole will be better developed and more internally consistent if all components are considered at the outset. **Brazil** (CCGP 04/20/4-Add.1) As already mentioned in Annex 1, no consensus was reached during the last meeting of CCGP on	**Brazil** (CCGP 04/20/4-Add.1)**:** CCGP should not proceed on the development of risk analysis principles intended for governments and should consider carefully the

	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. **Brazil** (CL 2004/34-GP) During the last CCGP meeting there was opposition to proceed on the elaboration of this document. Brazil was among those countries that considered this work should be interrupted due to the following reasons: Brazil needs some clarification regarding the objective of this document, since the Commission has already approved a document on Risk Analysis to the Codex system. This document, in Brazil's view, presents the principles on that issue, which applies also to governments; 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. 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, a new document is not necessary, with this format. So, before proceeding on this work, it should be clarified what is the purpose of this document. According to the mandate of CCGP clarified by the Commission, this Committee should, as it considered appropriate, try to develop a <u>new</u> document on Risk Analysis for governments; a different document, with general guidelines on the subject.	guidance to be provided to member countries by the Manual on Risk Analysis, which is being developed by FAO and WHO.

	Brazil considers that one possible option to proceed with that work and to eliminate the source of potential conflicts would be to suppress the chapter on Risk Management and make reference to the Recommendations of FAO/WHO on Risk Management. 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. 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. **Canada** (CCGP 04/20/4-Add.1) 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. • 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*	**Chile** (CL 2004/34-GP) Some concepts, such as "uncertainty" and "precaution", which are

	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. **Chile** (CL 2004/34-GP) We believe it is important to develop a document like this as it may act as a guide for governments in consistency with, *inter alia*, the provisions of the SPS Agreement. We do not object to this format but, if other proposals are submitted, we are open to study them. We believe that all risk analysis stages, including management, should be included without exception. Some concepts, such as "uncertainty" and "precaution", which are used but undefined in the context of Codex should be defined in order to improve the understanding of their scope in the text and to facilitate discussion. In our opinion, "precaution" should be included so as to set limits and provide a framework for its eventual use, which should be clearly exceptional and those who make use of it should have a scientific justification for its decision. It should be mentioned that Art. 7.5 of the WTO SPS Agreement refers to it. Therefore, we consider that its application should be regulated by developing practical principles, among which these should be taken into account: The application grounded on science-based objective facts that affect human health; that the plausibility of the adverse effects for human health derive from the application of an initial risk analysis; its provisional, dynamic and exceptional nature as long as the risk assessment improves the knowledge of the uncertainties taken into consideration; that its application is due to a management measure in which the information provided by the risk assessment allows to identify accurately the source and degree of uncertainty that ensure its observance; that the decisions and actions taken should be proportional to the possible scope of the risk as regards health and should be based on the available scientific data; that the decisions and measures adopted should be in line with the ones adopted under analogous circumstances and should be based on all the relevant available information, including scientific data; that actions taken to protect consumers' health should be, to the extent practicable, the least trade-restricting ones; that the decisions and measures should be subject to a permanent and transparent revision, in which the interested parties participate; that initial decisions should be revised and other decisions should be adopted in order to maintain,	used but undefined in the context of Codex should be defined in order to improve the understanding of their scope in the text and to facilitate discussion. Therefore, we consider that its application should be regulated by developing practical principles, among which these should be taken into account: The application grounded on science-based objective facts that affect human health; that the plausibility of the adverse effects for human health derive from the application of an initial risk analysis; its provisional, dynamic and exceptional nature (...).

	amend, strengthen, or eventually annul any measure according to said information. **European Community** (CCGP 04/20/4-Add.1) 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. **European Community** (CL 2004/34-GP) **-** w*hether work proceed on the development of risk analysis principles intended for governments?* The EC considers that the issue has already been resolved by the 24th session of the CAC and was approved as a new activity by the 50th session of the Executive Committee. The EC supports the development of these principles which will contribute to helping the governments to develop a risk analysis policy to protect the consumer health and to fulfill their obligations arising from Article 5 (1) of the SPS Agreement. The SPS agreement stipulates that Members shall ensure that their measures are scientifically based on an evaluation of the risks taking into account the techniques developed by the relevant international organizations. The Codex Alimentarius is the international organization recognized by the SPS agreement for the food safety. The Codex has therefore the responsibility for providing the members of the WTO with general principles to help governments to fulfill their obligations. *- whether the format of the document as basic principle should be retained?* The EC considers that it is the responsibility for the Codex Alimentarius, as the relevant international organization recognized by the WTO, to set up principles applicable by governments, but that it rests with other organizations such as FAO, WHO or the ISO to propose directives or guidelines for the practical application of these principles. The EC is satisfied by the way in which the document is drafted in the form of principles. The necessary flexibility to adapt their risk analysis policy to the regional special conditions must be left to the Members. *- 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* *- additional guidance from FAO/WHO concerning general risk analysis principles for governments?* The EC considers that the applicable principles within Codex appearing in the Manual of Procedure are a good basis for discussion for working out principles applicable to governments. A large part of these principles is applicable by governments. On the other hand, more specific	

	principles should be established for governments in fields not covered by the Codex, in particular the implementation of the measures and the decisions taken in emergency or when scientific knowledge is incomplete. The EC opposes another approach as suggested by the Secretariat for the following reasons: The recommendations of the mixed FAO/WHO Expert Consultations were not examined, discussed and adopted by all the Members of the Codex Alimentarius Commission. They result from experts who in spite of their recognized competences do not necessarily represent the position of their governments. Their conclusions are not subject to a transparent consultation with a debate to which all the Member governments of the Codex can take part to arrive at a general consensus. The recommendations of international organizations other than the Codex Alimentarius, the OIE and the IPPC are not recognized by the SPS Agreement as being the basis on which Members have to establish their sanitary or phytosanitary measures. *- If principles intended 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.* The EC, for reasons of clarity and of reading facility, prefers a complete text appearing in the Codex Alimentarius without needing to consult the Manual of Procedure for the parts which are common to the Codex and to the Governments. As these two texts will appear in two different corpus, it is preferable to maintain them in their entirety. There is no disadvantage in repeating in this document the principles intended for the Codex appearing in the Manual of Procedure. To be complete such a document should also contain the definitions appearing in the Manual of Procedure. *As it may be difficult to reach consensus on some aspects of risk management, the Committee may consider:* *- 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 the consensus appears more likely and to advance them to further steps?* The EC strongly supports the inclusion of the section concerning the management of the risks and is opposed to the progression in the step procedure of the sections concerning the risk evaluation and communication without the section concerning the risk management. The risk analysis is a whole which cannot be divided as is indicated correctly at paragraph 5 of the proposed draft principles for risk analysis: "The risk analysis process should <u>follow a structured approach incorporating the three distinct but closely linked components of risk analysis</u> (risk assessment, risk management and risks communication), each being integral to the overall risk analysis process." *- 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? The EC welcomes and supports the indication of precaution as an inherent element in the risk analysis process which appears in paragraph 11 of Working Principles for Risk Analysis in the Manual of Procedure of the Codex Alimentarius, and identically in paragraph 9 of the proposed draft principles for Risk Analysis. However, the EC considers that there is an essential difference between the application of the principles for risk analysis by the Codex and by the governments: the Commission of the Codex Alimentarius decided at its 24th session not to carry out the development of a standard if the scientific data is incomplete. This limitation transfers implicitly to the governments the responsibility for taking provisional measures to protect the consumers pending complete scientific data. Article 5 (7), of the SPS Agreement authorizes Members to adopt temporarily sanitary or phytosanitary measures if the relevant scientific evidence is insufficient. The EC considers that the working principles for Risk Analysis for governments would be incomplete and ineffectual if these principles did not take into account the possibility of taking provisional measures when the available scientific data does not make possible to carry out complete risk assessment. Paragraph 32 of the proposed draft principle reflects correctly this possibility and the EC supports firmly its inclusion. *- 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 EC considers that this proposal is not suitable for the same reasons invoked higher: The recommendations of the FAO/WHO Expert Consultations were not examined, discussed and adopted by all the Members of the Codex Alimentarius Commission. They result from experts who in spite of their recognized competencies do not represent necessarily the position of their governments. Their conclusions are not subject to a transparent consultation with a debate to which all the Member governments of the Codex can take part to arrive at a general consensus. The recommendations of international organizations other than the Codex Alimentarius, the OIE and the IPPC are not recognized by the SPS Agreement as being the basis on which Members have to establish their sanitary or phytosanitary measures. *However, it appeared from the written comments that several countries agreed to proceed with consideration of the document in its present format and proposed specific amendments. Should the Committee decide to proceed with the consideration of the document, the text attached as Annex 2 could be used as basis for discussion? The text was redrafted in the light of the comments submitted on the earlier version in CX/GP 04/3, as follows.* The EC strongly encourages the Committee to continue the examination of the document and considers that the amended text appearing as an Annex 2 is considerably improved and constitutes a good basis for discussion. **India** (CCGP 04/20/4-Add.1) At the outset, India commends the efforts put in for preparing the document aimed at providing a	

	framework for the conduct of risk analysis as a guidance document to the governments. Last month, the CCFH has finalized a document on Principles and Guidelines for the Conduct of Microbiological Risk management and last year, the CCGP had finalized the document on Working Principles for Risk Analysis for Application in the Framework of Codex. The draft document now under consideration is within the framework of governments and will need to take into consideration certain aspects of both these documents. The following areas, however, need to be covered by this document at the appropriate places: 1) Precautionary principle should not be applied in the framework of this document. What could be used is the decision taken by the CAC at its 24th Session, which is produce below: "81. In view of the above discussion, the Chairperson proposed that the Commission should take that following position: *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."* 2) Risk management should take into account the economic and technical constraints of developing countries to comply with the options selected by importing countries. Enough flexibility needs to be provided so that the measures are proportionate to the risk identified and not more trade restrictive than required to achieve the Appropriate Level of Protection (ALOP). **Mexico** (CL 2004/34-GP) Mexico finds it important to develop a document on risk analysis for its application by the governments, so as to have a unified document that would provide risk analysis conducted on the different products with certainty regardless of the country that produces them. The document should reflect mandatory aspects that every risk analysis should meet, such as steps, assessment methodologies, databases, risk assessment studies, etc., bearing in mind the different technological capacities of member countries. It should also highlight aspects in which governments could be given further flexibility to approve according to their capacities and use and consumption patterns. Mexico believes that the Standard on Principles of Practical Application for Risk Analysis in the Context of Codex Alimentarius could be considered as the basis and that we could focus on the missing mechanisms. However, the final version of the document should entirely reflect all the aspects required to conduct a risk analysis. In order for risk analysis to be an instrument that generates or encourages fair trade practices, considerations aimed at such an end should be taken into account. **New Zealand** (CL 2004/34-GP) New Zealand strongly supports the development of the Working Principles for Risk Analysis for food safety as guidance for members. We believe that the CAC has a clear responsibility in terms of the WTO SPS Agreement to provide such guidance to enable members to base their sanitary	

	measures on sound science and the principles of risk analysis. As to the structure and format of the document, New Zealand is of the view that the principles being developed for guidance of governments should fully recognize the principles already adopted for application within the framework of Codex. We believe that the draft working principles for risk analysis for food safety would benefit from a substantial reorganization in terms of format and content to focus on those principles that are relevant to governments. To make the document simpler and more concise we see value in referring to those principles that are common to Codex and governments and then developing new material that applies only to governments. Government competent authorities essentially function as risk managers and increasingly address food safety issues in accordance with the structured approach introduced in Para 23 of the Draft Working Principles. New Zealand believes that this structure should provide the basic framework for this document. Note that Para. 1 states that the purpose of the principles is "to provide a framework for the conduct of risk analysis…". Further it should be noted that there are a number of pathways for effective risk management decision making as reflected in successive FAO/WHO Expert consultation reports. Explicit recognition of such flexibility in needed in these draft principles. New Zealand believes that the current draft does not adequately reflect a practical application of risk analysis principles by governments in the day-to-day world of risk management. In particular, the document as currently written does not clearly delineate the various principles relevant to risk management activities carried out by governments. "Who" does "what" in terms of risk management options is not clearly established e.g. government may implement a particular option by educating consumers, whereas it may implement a different option by developing a regulation. In the latter case, industry applies the risk management option and this is outside the risk management framework (as is risk assessment carried out by scientists). Any principles concerning monitoring and review also need to be clear as to their intent. The term "monitoring" is often applied to the food chain itself as well as to surveillance of human health outcomes and this confuses both the intent of this component of risk management and who is responsible for carrying it out. Finally, New Zealand considers that the principles presented in this document more represent strategic risk-based approaches to food safety than day-to-day risk management activities. These two streams of enactment of risk analysis by governments need to be better acknowledged in the document. **Thailand** (CCGP 04/20/4-Add.1) We would like to express our appreciation to the secretariat for their efforts in preparing the document CX/GP 04/20/4. Concerning the questions raised by the secretariat, we are of the opinion that Codex should proceed on the development of risk analysis principles intended for governments and the format of the document as basic principles should be retained.	**India** (CCGP 04/20/4-Add.1)**:** Precautionary principle should not be applied in the framework of this document.

	United States (CCGP 04/20/4-Add.1) 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. **United States** (CL 2004/34- GP) The United States believes that it is premature for Annex 2 to be discussed until the Codex Committee on General Principles (CCGP) has agreed on how to proceed with this work. In Annex 1, the Secretariat poses a number of questions that the U.S. believes the Committee should first consider. Specifically, • CCGP SHOULD CONSIDER WHETHER THE PRINCIPLES FOR RISK ANALYSIS INTENDED FOR GOVERNMENTS SHOULD BE DEVELOPED AS A CODEX DOCUMENT. IT IS IMPERATIVE THAT CCGP HAVE THIS DISCUSSION BEFORE CONSIDERING THE CURRENT DRAFT DOCUMENT. • CCGP should consider the format and type of guidance. Comments at the 21st session of CCGP questioned the current format and type of guidance. The current format does not appear suitable as the basis for advice for member countries. Many of these comments proposed that Codex provide more practical guidance to governments on how to conduct risk analysis. Although this is not the "new work" approved by the Commission, CCGP could request CAC to reconsider. The U.S. believes that it is important for CCGP to carefully consider the best approach to developing appropriate risk analysis guidance for use by countries, before proceeding further with the development of the current version of the *Proposed Draft Working Principles for Risk Analysis for Food Safety.* • FAO/WHO are developing a manual on risk analysis, intended to provide essential background information and guidance for regulators and other officials responsible for managing and/or supervising risk analysis in practice. FAO/WHO stated that this	

	document presents "principles" to structure and guide the application of risk analysis. CCGP should determine whether the guidance in this manual is sufficient. CCGP could, after reviewing the manual, consider whether a small set of over-arching principles should be developed by Codex to supplement the manual. In any case, CCGP will have to examine the guidance being developed by FAO/WHO before proceeding with the current work. • CCGP will need to discuss whether the section on precaution in risk management- (paragraph 32) should be deleted or retained, given that it could be interpreted to interfere with the establishment of interim measures, as addressed under Article 5.7 of the SPS Agreement. As an overall concern, the U.S. has concerns about Codex interpreting or paraphrasing members' obligations under the WTO agreements. These questions must be addressed before CCGP initiates a "line-by-line review of Annex 2. Recognizing that a Working Group to consider the draft working principles has been scheduled for November 6, the U.S. is providing the following specific comments for consideration by the Working Group, with the understanding that the above questions must be first considered by the 22nd (regular) session of CCGP before any "line-by-line" consideration of the Proposed Draft Working Principles for Food Safety. United States proposed a redraft that is the Annex 1 of the present document. **Consumers International** (CCGP 04/20/4-Add.1) 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	**United States** (CCGP 04/20/4-Add.1)**:** the next step cannot be determined until countries have an opportunity to study the FAO/WHO Manual. **United States** (CL 2004/34- GP) United States proposed a redraft that is the Annex 1 of the present document.

	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. **Consumers International** (CL 2004/34-GP) Consumers International (CI) considers it essential that Codex elaborate Proposed Draft Principles for Risk Analysis for Food Safety for use by governments. If the scope of such Principles were limited to principles only for use by other Codex Committees and by the Commission to develop international food standards, Codex would be failing in its responsibility to protect the health of consumers. The protection of consumer health can only be achieved through the advice that the Commission gives to governments that may adopt, implement and enforce Codex standards. Clear guidance on the principles underlying risk analysis for application at the national level is fundamental for the protection of consumer health. Comments on the possible options proposed by the Secretariat. In line with our previous comments submitted prior to the twentieth session of the Committee, we consider that the following approach is most appropriate: *(i) Whether work should proceed on the development of risk analysis principles intended for governments* As set out above, we consider it essential that this work is progressed in order to ensure that consumers are adequately protected. *(ii) Whether the format of the document as basic principles should be retained* We still consider this to be the most appropriate format and it fulfills the mandate given to the Committee by the Commission. *(iii) 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.* We consider that the principles applicable within Codex, with the amendments set out in the current draft included in Annex 2, are a sound basis for discussion and if adopted could make a significant contribution towards protecting consumer health. *(iv) Whether only a reference should be made to sections that are already included in the Working Principles, and the sections specifically intended for governments retained.* We do not think that such an approach would be very transparent, and could lead to a lot of	

	confusion. The documents should stand alone without having to be read by cross-referencing it with other documents. *(v) 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 to advance them to further steps.* As the section on risk management has tended to be most contentious, this needs to be tackled and discussed along with the rest of the principles, and at the working group session. *(vi) If the section on risk management is retained, whether it should include the section on precaution in risk management, with the general understanding that a general reference to precaution in risk analysis is retained in paragraph 9.* It is essential that precaution is addressed within the section on risk management. This is fundamental to consumer protection when decisions have to be made in the face of scientific uncertainty. The principles should therefore provide guidance on how this should be applied, as set out in paragraphs 32 and 33. *(vii) Replacing the section on risk management with a reference to the recommendations of the FAO/WHO Expert Consultation on Risk Management on Food Safety.* We do not consider that this is appropriate. As we have explained in our general guidance, we consider that this is an area where members of Codex require guidance in order to ensure that consumer health is protected. It is therefore essential that these principles are developed in order to help provide guidance as to how to apply risk analysis at the national level. **49P** (CCGP 04/20/4-Add.1) 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 co-ordinated with other relevant activities, such as the work on the FAO/WHO Manual on "Food safety Risk Analysis". **49 P** (CL 2004/34-GP) Our organization is preparing to participate in the special Working Group meeting on food risk analysis principles for governments to be held in Paris prior to the 21st session of the CCGP. That meeting, and the current Circular letter are, in our view, part of a process which is delaying any substantive work on this topic and contributing to the observation of the Chair at the last meeting that CCGP has a reputation of not acting on important matters with speed and efficiency. 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 at its 17th session and approved at the 50th meeting of the Executive Committee. CCGP finished its work expeditiously	

	on the document for Codex activities, and this was been approved by the Commission in 2003. We now should move ahead on our *obligation* to produce the companion document for governments. The concerns that have been raised are of two types: textual and contextual. We will address these in reverse order. <u>Context</u> (1) Almost all governments already perform some risk analysis operations, so the appropriateness, approaches, techniques, usefulness in the policy process, etc. are not nearly so strange and confusing as some commentators suggest. (2) Annex 1 of the CL states that "the guidance provided in the document may not be of benefit to Members in view of their rights and obligations under the WTO agreements." However, *the WTO SPS agreement calls for risk assessment,* so there is no conflict, but instead the recognition of a *need* for governments to have a risk assessment capacity. In addition, the WTO documents themselves provide no guidelines in matters of food safety assessment since the WTO is supposed to adopt the Codex principles as international norms and thus there is no WTO activity that would block the CCGP from moving ahead. Finally, it is not within Codex' mandate to follow the procedures of other international treaties (to which some of its Members are not even Parties). We should also recall that at the 20th session of the CCGP. The WTO representative raised no objection to the formulation of such principles; indeed, the WTO encouraged the Committee to do so. (3) Reference has been made to the FAO/WHO activity of producing a Manual and associated materials on risk analysis this coming winter as somehow obviating the need for CCGP to work on risk principles for governments. As the representatives of the two parent agencies said during the 20th session, this Manual is not a set of principles for risk analysis and does not have the legal standing of such principles (e.g., as fulfilling the WTO SPS expectations). The 49 P organization has reviewed the draft Manual and discussed it with colleagues. At this juncture we can say that these materials are totally inadequate to provide the sort of guidance to governments that is required of a CCGP draft, no less that might become a WTO norm. The Circular Letter implies the same. We found these materials to be ambiguous and incomplete. As the CCGP Chair stated at the meeting last May "the Manual is not the solution for Codex, but it is the other way around." (4) The principles adopted for use within Codex, and the essentials of the drafts for use by governments, adopt recommendations of FAO/WHO Expert Consultations. It is inappropriate to seek expert advice and then wholly reject it (after using it in another context!).	
SPECIFIC COMMENTS		
TITLE OF THE DOCUMENT	**Argentina** (CCGP 04/20/4-Add.2) Argentina believes that under the provisions of the Procedural Manual, the title should accurately indicate the contents of the standard concerned, because addressing risk analysis without	**Argentina** (CCGP 04/20/4 - Add. 2)**:** "Proposed Draft

	specifying the scope of application is not the same as limiting in the title the application intended for these Principles. Thus, the title should be "Proposed Draft Working Principles For Risk Analysis For Food Safety". **Canada** (CCGP 04/20/4-Add.1) 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.* **Chile** (CL 2004/34-GP) We agree on the modification of the title. In the Spanish version, it should be deleted the word "Prácticos" in order for it to be consistent with the English version.	Working Principles For Risk Analysis For Food Safety". **Canada** (CCGP 04/20/4-Add.1)**: "***Working Principles for Risk Analysis for Application to Food Safety and Nutrition".* **Chile** (CL 2004/34-GP): In the Spanish version, it should be deleted the word ~~"Prácticos"~~
SCOPE 1. The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments ~~for food safety, in order to facilitate the application of risk analysis to food safety issues~~	**Argentina** (CCGP 04/20/4-Add.2) In our opinion, it should clearly state that "The purpose of these Principles is to provide a framework for governments regarding the conduct of risk analysis applied to food safety risks that may affect human health". In additionally, taking into consideration the discussions held at other Codex Committees, it would be necessary to include the definition of Food Safety Objective and other definitions in a new heading. **Canada** (CCGP 04/20/4-Add.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.~~ *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	**Argentina** (CCGP 04/20/4-Add.2): "The purpose of these Principles is to provide a framework for governments regarding the conduct of risk analysis applied to food safety risks that may affect human health". **Canada** (CCGP 04/20/4-Add.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

	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. **Chile** (CL 2004/34-GP) We agree on the proposed changes to paragraphs 2 to 7. **New Zealand** (CL 2004/34-GP) New Zealand fully agrees with the principle stated in paragraph 2 but suggests that further text is needed to acknowledge that there are a range of applications for food safety risk analysis in addition to reducing food-borne risks to human health e.g. as a tool to validate new technologies, to ensure cost effective implementation of measures, to provide information for ranking of risks for the purposes of scientific resource allocation, to judge the equivalence of different measures applied to food in international trade.	governments ~~for food safety, in order to facilitate the application of risk analysis to food safety issues~~
RISK ANALYSIS – GENERAL ASPECTS 2. The overall objective of risk analysis applied to food safety is to ensure public health protection.	**Canada** (CCGP 04/20/4-Add.1) 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. **Iran** (CL 2004/34-GP) Recommends a section as "Definition" add before "General Aspect". **New Zealand** (CL 2004/34-GP) New Zealand considers this principle as unnecessary in the context of the document and begs the question about what 'decisions'. **49 P** (CL 2004/34-GP) In paragraph 2, shouldn't the word "assessment" be "analysis", especially since that is the subject of this section? This language was transferred from another section on assessment and doesn't quite fit here as written. Codex' use of peculiar terminology, adopted by OECD for apparently political purposes but not consistent with general literature usage, is one of the reasons for such confusions.	**Canada** (CCGP 04/20/4-Add.1)**:** To move to the Scope: "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" **Iran** (CL 2004/34-GP) recommends a section as "**Definition"** add before **"General Aspect".** **49 P** (CL 2004/34-GP): Shouldn't the word "assessment" be "analysis", especially since that is the subject of this section?

3. Health and food safety ~~aspects of~~ decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.	**Thailand** (CCGP 04/20/4-Add.1) It is important that, there should be an explicit adherence to Codex standards, guidelines or recommendations in the "Working Principles for Risk Analysis". In addition, the text should be clear and not open to misapplication in the future. Therefore, we propose that this paragraph may be modified as follows: "Health and food safety aspects of decisions and recommendations should be based ~~on a risk assessment, as appropriate to the circumstances~~ *on Codex standards, guidelines or recommendations where they exist. Should there be need for additional risk assessment, there should be scientific justification to determine whether Codex standards, guidelines or recommendations be insufficient to achieve the appropriate levels of protection, to ensure food safety".* **United States** (CCGP 04/20/4-Add.1) 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. **United States** (CL 2004/34-GP) The United States questions the placement of this principle. Because reference is made only to risk assessment, one of the three components of risk analysis, the US believes that the original position of this statement as the first principle in the Risk Assessment section is preferable to the current placement. Therefore the US would return this principle to the Risk Assessment section and renumber the document accordingly.	**Thailand** (CCGP 04/20/4-Add.1)**:** "Health and food safety aspects of decisions and recommendations should be based ~~on a risk assessment, as appropriate to the circumstances~~ *on Codex standards, guidelines or recommendations where they exist. Should there be need for additional risk assessment, there should be scientific justification to determine whether Codex standards, guidelines or recommendations be insufficient to achieve the appropriate levels of protection, to ensure food safety".* **United States** (CCGP 04/20/4-Add.1)**:** ~~Health and food safety aspects of decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.~~ **United States** (CL 2004/34-GP) believes that the original position of this statement as the first principle in the Risk Assessment section is

	Consumers International (CCGP 04/20/4-Add.1) 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.' **Consumers International** (CL 2004/34-GP) As this paragraph specifically deals with risk assessment, we consider that it is more appropriate to include it in the section on risk assessment. If it is to be retained in the general aspects section, reference should also be made to other legitimate factors which may guide health and food safety decisions and recommendations in addition to the risk assessment. CI believes that CCGP should draw attention in a footnote to the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations, approved by the 27th Session of the Commission (ALINORM 04/27/22, Appendix II, paragraph 61). These principles are to aid governments to make decisions to protect consumer health when there may not be time to base decisions on a risk assessment.	preferable to the current placement. **Consumers International** (CCGP 04/20/4-Add.1)**:** More appropriately fits in the 'risk assessment' section. 'Health and food safety decisions and recommendations should be based on a risk assessment *and other legitimate factors* as appropriate to the circumstances
4. The risk analysis process ~~and all its components~~ should be − applied consistently, − open, transparent and documented.	**Iran** (CL 2004/34-GP) Line 2: **"open"** change to **"available"** **Consumers International** (CCGP 04/20/4-Add.1) 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	**Iran** (CL 2004/34-GP) Line 2: − ~~open~~ available, transparent and documented **Consumers International** (CCGP 04/20/4-Add.1)**:** *All components of* the risk analysis process should be: - applied consistently - open, transparent and documented.

	- open, transparent and documented. **Consumers International** (CL 2004/34-GP) We believe it is helpful to make it clear that all components of risk analysis should be applied consistently and be open, transparent and documented and therefore would prefer 'and all its components' to be retained.	
5. The risk analysis process should follow a structured approach incorporating the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication), each being integral to the overall risk analysis process. The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage food related risks to human health.	**49 P** (CL 2004/34-GP) We are pleased to see the statement in paragraph 5 that the 3 components of risk analysis are "closely linked," as we have several times pointed out that this conceptual schema does not reflect the way most analyses are actually done.	
6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality,		

documentation should be accessible to all interested parties[11].		
7. Effective communication and consultation with all interested parties should be ~~ensured~~ established and maintained throughout the risk analysis process.	**Argentina** (CCGP 04/20/4-Add.2) Argentina takes into consideration and agrees with the approved provisions under item 7, which states that "Effective communication and consultation with all interested parties should be ensured throughout the risk analysis", but we are also interested in ensuring that assessors' independence and objectivity is maintained throughout the risk assessment process. It should be considered that some interested parties may, due to a lack of scientific knowledge in the relevant areas, prejudge or misjudge hazards which are actually nonexistent, minimal, or not significant. It should therefore be ensured that assessors, when conducting food safety risk assessment, such concerns should not interfere in the analysis and the presentation of the outcome. In addition, it should be pointed out that "the concerns" are generally negative views of the facts and the only way to ensure a balance of these circumstances is to compare this with the lack of "concern" evident in other sectors or in similar parties. A way to ensure this is that to provide assessors with information that has been scientifically validated.	**Argentina** (CCGP 04/20/4-Add.2)**:** To ensure this is that to provide assessors with information that has been scientifically validated.
8. There should be a functional separation of risk assessment and risk management, to the extent practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of	**Argentina** (CCGP 04/20/4-Add.2) As expressed at the discussion on Principles for Risk Analysis in the framework of Codex, we believe that it should be ensured that, beyond reasonable doubt, there is a functional separation between risk assessment and risk management. This division, then, should not be considered only "to the extent possible", as this functional division is the only way to guarantee the purity of the information, criterion independence, and the integrity of the scientific analysis with which the results of the risk assessment are achieved. This way, it could be ensured that the degree of uncertainty inherent in this stage is not increased by external interference at this stage. In this respect, it is worth highlighting item 9 of the Working Principles[12], which states "There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest". **Chile** (CL 2004/34-GP)	**Argentina** (CCGP 04/20/4-Add.2)**:** There should be a functional separation of risk assessment and risk management~~, to the extent practicable,~~ in order to …. **Chile** (CL 2004/34-GP): It should be added the phrase

[11] For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication")

[12] Working Principles for Risk Analysis for Application in the framework of the CODEX Alimentarius, Procedural Manual CODEX Alimentarius Commission

interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.	Even when we agree on the spirit, in practice, in several developing countries, in the case of most risk analysis, the assessment and management responsibility correspond to the same expert. It should be added the phrase “If possible” at the beginning and the phrase "in order to" should be replaced with the expression “being it necessary to”. **Cuba** (CL 2004/34-GP) "…. in order to ensure the scientific integrity of the risk assessment, **to avoid confusion among**..." **Iran** (CL 2004/34-GP) Line 1: *“separation”* change to *“identified*” or *”characteristics”.* **Philippines** (CL 2004/34-GP) There should be a functional separation of risk assessment and risk management, to the extent practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application. The Philippines agrees with the provision of para.8 considering that the risk assessment and risk management of developing countries are lodged in one agency. **United States** (CCGP 04/20/4-Add.1) 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.* **49 P** (CL 2004/34-GP) It follows, therefore, that paragraph 8 should not proclaim that there should be “functional separation” of assessment and management; at the least, the proposed insertion of “to the extent possible” is necessary to account for the real world. Similarly, we appreciate the recognition of the iterative nature of these processes.	“If possible” at the beginning and the phrase "~~in order to~~" should be replaced with the expression “being it necessary to”. **Cuba** (CL 2004/34-GP): "…. in order to ensure the scientific integrity of the risk assessment, to avoid ~~the risk of~~ confusion among..." **Iran** (CL 2004/34-GP): “There should be a functional ~~separation~~ *“identified*” or *”characteristics”.* of risk assessment and **United States** (CCGP 04/20/4-Add.1)**:** …and *Interaction between risk assessors and risk managers, which is needed to develop meaningful risk assessment, should be transparent.*

9. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. The risk management options selected should reflect the assumptions used for the risk assessment, the degree of uncertainty and the characteristics of the hazard.	**Argentina** (CCGP 04/20/4-Add.2) As regards Paragraph 9 on precaution, Argentina believes that a number of interesting discussions have been held in this regard within Codex, which reflected the position of their members on this matter. We also believe that, to the extent possible, they should not be repeated, as nothing indicates that Members have changed their opinion on this issue. The approach to this matter has shown that the inclusion of subtle changes regarding the provisions under Article 5.7 of the SPS Agreement might seriously affect WTO Members' rights and obligations, thus providing "legal" grounds for sanitary measures which, in the light of the current legal basis, would not constitute an exception under the provisions of Article 5.7 of the SPS. In particular, we do not agree with the overall idea expressed in this paragraph regarding the existence of a number of sources of uncertainty in the risk assessment process and the risk management process. However, the uncertainty and the characteristics of the risks must be reflected in the above-mentioned process in a reliable manner. In addition, we believe that the supposed cases hereby mentioned result in an ambiguous term which, depending on the interpretation, might be included within uncertainties. In the light of this reality, Argentina believes that it is preferable not to include this issue in a document. We believe that the legal basis and the criteria for the application of measures by governments should be those established in the SPS Agreement. **Chile** (CL 2004/34-GP) We suggest deleting the phrase "and variability in the available scientific information should be explicitly considered" and replacing it with the phrase "should be explicitly identified and considered" because the variability is, *inter alia*, a source of uncertainty. The Spanish version of this very paragraph refers to "*incertidumbre científica*", while the English version only to "uncertainty". **New Zealand** (CL 2004/34-GP) Referring to the 'characteristics of the hazard' is redundant as it is implicit in the risk assessment. **United States** (CCGP 04/20/4-Add.1) 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.* **United States** (CL 2004/34-GP)	**Argentina** (CCGP 04/20/4-Add.2)**:** it is preferable not to include this issue in a document. We believe that the legal basis and the criteria for the application of measures by governments should be those established in the SPS Agreement. **Chile** (CL 2004/34-GP): To delete the phrase "~~and variability in the available scientific information should be explicitly considered~~" and replacing it with the phrase "should be explicitly identified and considered." **United States** (CCGP 04/20/4-Add.1)**:** … risk analysis process. *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.*

	The final sentence of this principle refers to risk management, rather than to the general aspects of risk analysis. The United States would move this statement to the Risk Management section as a separate principle. As this is a primary consideration in selecting risk management options, the "principle" could be placed just after current 25bis). Also the US questions whether the reference to hazard characterization should be a reference to risk characterization. The US would rewrite this new principle to read: "*The risk management options selected should reflect the assumptions used for the risk assessment and the degree of uncertainty in the risk characterization."* **Consumers International** (CL 2004/34-GP) CI proposes that this paragraph be amended so that the last sentence makes reference to "data gaps, uncertainties and their documented affects on risk management decisions" instead of "degree of uncertainty". **49 P** (CL 2004/34-GP) In paragraph 9, we are not certain (although English is our mother tongue) what is meant by the verb "reflect" in the proposed insertion; since this "reflection" should be transparent, as we hope the Secretariat intended, we propose that the word be replaced by a less ambiguous verb such as "specify" or "detail" or "discuss."	**United States** (CL 2004/34-GP): The final sentence of this principle The U.S. would rewrite this new principle to read: "*The risk management options selected should reflect the assumptions used for the risk assessment and the degree of uncertainty in the risk characterization."* **Consumers International** The risk management options the assumptions used for th ~~degree of uncertainty~~ data g their documented affects decisions and the characteris

RISK ASSESSMENT POLICY	**Argentina** (CCGP 04/20/4-Add.2) Regarding Risk Assessment Policy, Argentina believes that the drafting of this item is unclear. Therefore, it provides governments with little input. This inclusion should take into consideration other elements that serve as effective guidance, for example, how risk assessment priorities shall be established, i.e. on the basis of what parameters or information, clearer rules that establish the independence of the stages of the risk assessment process and the risk management process regarding the outcome and the procedures for interaction between risk assessors and risk managers, as well as the procedures and time for measure review. Also, as we are addressing risk analysis policy for food safety, it should be clear that some interested parties' perceptions may be considered in the risk management stage, but if these perceptions do not have scientific grounds they should not affect the outcome of the stage of risk assessment for food safety or interfere with them. **United States** (CCGP 04/20/4-Add.1) This section (10 to 13), 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.	**Argentina** (CCGP 04/20/4-Add.2)**:** This inclusion should take into consideration other elements that serve as effective guidance, for example, how risk assessment priorities shall be established, i.e. on the basis of what parameters or information, clearer rules that establish the independence of the stages of the risk assessment process and the risk management process regarding the outcome and the procedures for interaction between risk assessors and risk managers, as well as the procedures and time for measure review. **United States** (CCGP 04/20/4-Add.1)**:** 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.

	United States (CL 2004/34-GP) 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. Perhaps a footnote to the title, explaining risk assessment policy would be useful. Such footnote could read: "Elements of risk assessment policy include, among others: 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".	**United States** (CL 2004/34-GP): Footnote to the title, Such footnote could read: "Elements of risk assessment policy include, among others: 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".
10. Determination of risk assessment policy should be included as a specific component of risk management.	**New Zealand** (CL 2004/34-GP) New Zealand suggests that establishment of risk assessment policy alone will not ensure that risk assessments are 'systematic, complete, unbiased and transparent'. The text of this paragraph should realistically describe what risk assessment policy provides.	
11. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.	**Cuba** (CL 2004/34-GP) To redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*" (those in charge of the risk assessment and those in charge of the risk management).	**Cuba** (CL 2004/34-GP): To redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "~~*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*~~" (those in charge of the risk assessment and those in charge of the risk management).
12. The mandate given by	**Cuba** (CL 2004/34-GP)	**Cuba** (CL 2004/34-GP): To

risk managers to risk assessors should be as clear as possible	To redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*" (those in charge of the risk assessment and those in charge of the risk management).	redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "~~*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*~~" (those in charge of the risk assessment and those in charge of the risk management).
13. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.	**Chile** (CL 2004/34-GP) We suggest replacing the phrase at the beginning "Where necessary" with the phrase "When appropriate" and replacing the word "should" with the word "may". **Cuba** (CL 2004/34-GP) To redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*" (those in charge of the risk assessment and those in charge of the risk management). **New Zealand** (CL 2004/34-GP)	**Chile** (CL 2004/34-GP): To replace the phrase at the beginning "~~Where necessary~~" with the phrase "When appropriate" and replacing the word "~~should~~" with the word "may". **Cuba** (CL 2004/34-GP): To redraft it in such a way that its interpretation is consistent and that it refers to risk assessors and managers instead of "~~*los encargados de la evaluación de riesgos y los encargados de la gestión de riesgos*~~" (those in charge of the risk assessment and those in charge of the risk management).

	The activity described under this paragraph is not part of risk assessment policy. It can be described more appropriately as an output of risk assessment. **United States** (CL 2004/34-GP) This "principle" is not a component of risk assessment policy. Rather it reflects the iterative approach that must sometimes be followed in selecting a risk management option. As such, the United States would move this statement to the "risk management" section. It can perhaps be combined with current Principle 27, where the possible need for alternative options is recognized.	**United States** (CL 2004/34-GP): As such, the United States would move this statement to the "risk management" section. It can perhaps be combined with current Principle 27, where the possible need for alternative options is recognized.
RISK ASSESSMENT ~~Health and food safety aspects of decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances~~. (transferred to **RISK ANALYSIS** – para. 3) 14. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization, and should be documented	**Cuba** (CL 2004/34-GP) It should be redrafted in a clearer way, to read: "Food safety risk assessment should be soundly based on science, should be documented in a transparent manner, and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization." **Mexico** (CL 2004/34- GP) Risk analyses cannot be imported because the cultural, economic and social conditions of the countries are very different and this makes risk analysis have different characteristics. However, some basic aspects should be considered and the fundamental analysis criteria should be unified in such a way that most countries, regardless of their degree of development, are able to adopt them, i.e. taking into account the different technological capacities of each country as, if not so, that could lead to significant distortions that may turn into non-tariff barriers. **New Zealand** (CL 2004/34-GP) This statement is too rigid in terms of the four steps. While appropriate in some contexts, we need to recognize that some risk assessments may use alternative components and still be robust, e.g. use of human health epidemiological data as an estimate of risk.	**Cuba** (CL 2004/34-GP): "Food safety risk assessment should be soundly based on science should be documented in a transparent manner and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization~~, and should be documented in a transparent manner~~."

in a transparent manner.	**49 P** (CL 2004/34-GP) The introductory words of paragraph 14 (“soundly based on science”) are not consistent with the rest of the document (e.g., paragraph 9 on uncertainty; see also new paragraph 20). We suggest insertion of the qualifying phrase “insofar as possible” to reflect the inevitable admixture of assumptions, uncertainties, ignorance, etc. in the assessment procedure.	
15. The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined.	**Cuba** (CL 2004/34-GP) As follows: “The scope and purpose of the particular risk assessment, as well as the output form, should be clearly stated".	**Cuba** (CL 2004/34-GP): “The scope and purpose of the particular risk assessment, as well as the output form, should be clearly stated. ~~The output form and possible alternative outputs of the risk assessment should be defined.~~"
16. Government officials involved in risk assessments should have no personal interests or biases with regard to the subjects of their risk assessments. Information on the identities of these government experts, their individual expertise and their professional experience should be publicly available. Experts from outside government responsible for risk	**Chile** (CL 2004/34-GP) We propose some changes so that, to its effects, no distinction among government officials and others as to conflicts of interest is possible. It is suggested replacing the sentence “Government officials (...) risk assessments" with the phrase “Risk assessors should have no personal interests or biases with regard to the subjects of their risk assessments." After the stop, it is suggested replacing "Experts from outside government responsible for risk assessment should be selected" with “Experts responsible for risk assessment should be selected."	**Chile** (CL 2004/34-GP): It is suggested replacing the sentence “~~Government officials (...) risk assessments~~" with the phrase “Risk assessors should have no personal interests or biases with regard to the subjects of their risk assessments." After the stop, it is suggested replacing "~~Experts from outside government responsible for risk assessment should be selected~~" with “Experts responsible for risk assessment should be selected."

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.	**European Community** (CCGP 04/20/4-Add.1) Add at the end of second sentence "*taking into account the need to protect them from external influence during the risk assessment process*". **New Zealand** (CL 2004/34-GP) This is, in part, unrealistic. Many government officials are passionate about their areas of work and may have had an involvement in other than government risk assessment activities (e.g. involvement in FAO/WHO expert groups). We believe that the paragraph could more appropriately state that '*Government officials involved in risk assessment should be objective in their scientific work and not be subject to any conflict of interest.'* **Thailand** (CCGP 04/20/4-Add.1) We propose to replace the term "personal interests" with "conflict of interest" **United States** (CCGP 04/20/4-Add.1) 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,	**European Community** (CCGP 04/20/4-Add.1)**:** …. Information on the identities of these government experts, their individual expertise and their professional experience should be publicly available, *taking into account the need to protect them from external influence during the risk assessment process*. **New Zealand** (CL 2004/34-GP): Government officials involved in risk assessments should ~~have no personal interests or biases with regard to the subjects of their risk assessments.~~ *be objective in their scientific work and not be subject to any conflict of interest.'* Information …" **Thailand** (CCGP 04/20/4-Add.1)**:** have no ~~personal interests~~ conflict of interest or biases **United States** (CCGP 04/20/4-Add.1)**:** rewrite the principle, to read: *"Experts responsible for risk*

	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.* **United States** (CL 2004/34-GP) 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 unlikely. The correct emphasis should be on transparency. Therefore, the U.S. would delete the first sentence of this principle. **Consumers International** (CCGP 04/20/4-Add.1) 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.	*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."* **United States** (CL 2004/34-GP): The U.S. would delete the first sentence of this principle. **Consumers International** (CCGP 04/20/4-Add.1): 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'. **Consumers International** (CL 2004/34-GP): A footnote should be added to

	Consumers International (CL 2004/34-GP) We support the wording proposed by the Secretariat which makes this paragraph much clearer and more comprehensive. A footnote should be added to the word 'personal' in the first sentence to indicate that "personal should be understood to include financial interests and corporate interests". **49P** (CCGP 04/20/4-Add.1) 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.	the word 'personal' in the first sentence to indicate that "personal should be understood to include financial interests and corporate interests".
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 qualitative information.	**Argentina**(CCGP 04/20/4-Add.2) The qualitative data are mentioned. In our opinion, said mention is very wide and gives rise to the possibility to use any qualitative datum. Therefore, it should be specified that said qualitative information will be considered if appropriate and only when it needs to be included. **Chile** (CL 2004/34-GP) It is suggested replacing "It should use (...) possible" with the sentence "It should use quantitative data to the greatest extent possible." However, in some cases, in the absence of quantitative data, it should be considered the available scientific information that is semi-quantitative or qualitative. **United States** (CCGP 04/20/4-Add.1) 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: *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.*	**Argentina** (CCGP 04/20/4-Add.2)**:** Therefore, it should be specified that said qualitative information will be considered if appropriate and only when it needs to be included. **Chile** (CL 2004/34-GP): It is suggested replacing ~~"It should use (...) possible"~~ with the sentence "It should use quantitative data to the greatest extent possible." **United States** (CCGP 04/20/4-Add.1)**:** *Risk assessment should be based on all available scientific data. It should use available quantitative*

	United States (CL 2004/34-GP) The same comment to CCGP 04/20/4-Add.1**.**	*information to the greatest extent possible. Risk assessment may also take into account relevant qualitative information, when appropriate.* **United States** (CL 2004/34-GP): The same comment to CCGP 04/20/4-Add.1**.**
18. Risk assessment should take into account 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 and the prevalence of specific adverse health effects.	**Argentina** (CCGP 04/20/4-Add.2) Bearing in mind that risks related to ecological and environmental issues are part of the relevant factors that, in some cases, must be taken into account in conducting a risk assessment, we believe that the reference to "ecological and environmental conditions" should be deleted since it is not possible to establish a thorough list of these. **Brazil** (CCGP 04/20/4-Add.1) 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. **Brazil** (CL 2004/34-GP) Repeats comments CCGP 04/20/4-Add.1. **Canada** (CCGP 04/20/4-Add.1) 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.	**Argentina** (CCGP 04/20/4-Add.2)**:** **"**Risk assessment should take into account ~~relevant ecological and environmental conditions~~, production, transport, storage and handling…" **Canada** (CCGP 04/20/4-Add.1)**:** Addition of the text "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 ….”
	Chile (CL 2004/34-GP) It is suggested deleting the phrase “ecological (...) effects" and replacing it with “the impact of all specific health effects throughout the entire food chain.” We do not find it appropriate to highlight some factors as we believe that "all" aspects related to food safety should be considered.	**Chile** (CL 2004/34-GP): To delete the phrase ~~“ecological (...) effects"~~ and replacing it with “the impact of all specific health effects throughout the entire food chain.”
	Iran (CL 2004/34-GP) Line 1: after *”production”* add *”processing”*	**Iran** (CL 2004/34-GP): “Risk assessment should take into account relevant ecological and environmental conditions, production, *processing*, transport,
	Mexico (CL 2004/34-GP) We suggest that Codex should abide by its mandate and not include ecological and environmental aspects in its documents.	
	New Zealand (CL 2004/34-GP) Risk assessment is a scientific discipline and risk estimates will be generated within a specific hazard/food chain context. We believe that it is unnecessary to refer to ‘relevant ecological and environmental conditions’. These words should be deleted from this as well as Para 25.	**New Zealand** (CL 2004/34-GP): “Risk assessment should take into account ~~relevant ecological and environmental conditions,~~ production …”
	United States (CCGP 04/20/4-Add.1) 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:	**United States** (CCGP 04/20/4-Add.1)**:** *Risk assessment should take into account relevant ecological and environmental conditions as they effect the hazard,*

	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.	*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.*
	United States (CL 2004/34-GP) The same comment to CCGP 04/20/4-Add.1**.**	**United States** (CL 2004/34-GP): The same comment to CCGP 04/20/4-Add.1**.**
	Thailand (CCGP 04/20/4-Add.1) The phrase "ecological and environmental conditions" and "transportation" need to be clarified to ensure it is not open to misapplication in the future.	
	India (CCGP 04/20/4-Add.1) Paragraph 18 & 25 refer to ecological and environmental conditions as part of the risk assessment process. We feel that ecological and environment conditions if made part of the risk assessment process there may be possibility of creating trade barriers for developing countries. Further more, the ecological and environmental conditions do not directly relate to food safety issues. We, therefore, propose to delete the inclusion of ecological and environment conditions from para 18 & 25. It is important to mention that the risk assessment process should lead to an option to manage the identified risk. However, these options should facilitate decision making in transparent manner, which does not lead to unjustified trade barriers. We, therefore, propose to add a paragraph to address this issue as follows: **Para 22 bis** the outcome of the risk assessment process should be evaluated with a view to select an option to manage the identified risk. In such a manner that the decision is transparent, consistent and fully documented and do not lead to any unjustified trade barriers.	**India** (CCGP 04/20/4-Add.1)**:** We, therefore, propose to delete the inclusion of ecological and environment conditions from para 18 & 25. **Para 22 bis** the outcome of the risk assessment process should be evaluated with a view to select an option to manage the identified risk. In such a manner that the decision is transparent, consistent and fully documented and do not lead to any unjustified trade barriers.

	Consumers International (CL 2004/34-GP) We strongly support the reference to “ecological and environmental conditions” and to “transport, storage and handling practices”.	
19. (former para. 20) Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups, as appropriate. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.	**Chile** (CL 2004/34-GP) We propose that the paragraph ends with the phrase "as appropriate", deleting the rest of it. It is redundant to give details. **Iran** (CL 2004/34-GP) Line3: “as appropriate” delete. **United States** (CCGP 04/20/4-Add.1) 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.* **United States** (CL 2004/34-GP) The United States believes that the final sentence of this principle creates unrealistic expectations and is, in practice, often unachievable. The appropriate consideration of acute, chronic, cumulative or combined health effects should be spelled out by risk managers (engaged in iterative discussions with risk assessors) in the risk assessment policy. Therefore, the U.S. would rewrite the final sentence to read: “*If relevant to the risk assessment and if available, acute, chronic (including long-term), cumulative, and/or combined adverse health effects should be taken*	**Chile** (CL 2004/34-GP): We propose that the paragraph ends with the phrase "as appropriate", ~~deleting the rest of it~~. **Iran** (CL 2004/34-GP): “…They should include consideration of susceptible and high-risk population groups, ~~as appropriate~~. Acute, … “ **United States** (CCGP 04/20/4-Add.1)**:** **“***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~~, where relevant..~~”* **United States** (CL 2004/34-GP): Therefore, the U.S. would rewrite the final sentence to read: *“If relevant to the risk assessment and if*

	into account in carrying out the risk assessment". **49 P** (CL 2004/34-GP) The text should recognize that the best assessments also look at "unrealistic" –ie, low probability—scenarios as well, for at least three reasons: low probability events *do* occur (and governments need to be able to anticipate such events); low probability events may have large and unacceptable consequences so that public policies *must* be adopted to deal with them (eg, nuclear meltdowns, food bioterrorism, etc); and the best way to test the models used is to apply them to events a bit beyond the usual and to observe if they hold.	*available, acute, chronic (including long-term), cumulative, and/or combined adverse health effects should be taken into account in carrying out the risk assessment".*
20. (former para. 19) Constraints, uncertainties and assumptions ~~having an~~ and their impact on the risk assessment should be explicitly considered at each step in the risk assessment process and documented in a transparent manner. Expression of uncertainty or of variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically	**New Zealand** (CL 2004/34-GP) We believe that the intent of this paragraph is to encourage quantification to the extent possible and as suggest a rewording of the last sentence of this paragraph along the following lines: '*expression of uncertainty and/or variability should be quantified to the extent possible.'*	**New Zealand** (CL 2004/34-G rewording of the last sente along the following lines: '*ex and/or variability should be possible.'*

achievable.		
21. The report of the risk assessment should include the scope and purpose of the risk assessment carried out, the background of the request, the information considered, the scientific reasoning and the conclusions of the risk assessors. The report should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.	**49 P** (CL 2004/34-GP) Should also include language about revealing the interests of the assessors, as a means of preventing (or at least disclosing) conflicts of interest (see paras16 and 36).	
22. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk	**United States** (CCGP 04/20/4-Add.1) 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, …* **United States** (CL 2004/34-GP)	**United States** (CCGP 04/20/4-Add.1)**:** *The results ~~conclusion~~ of the risk assessment including a risk estimate, if available, …* **United States** (CL

managers and made available to other risk assessors and interested parties so that they can review the assessment	The same comment to CCGP 04/20/4-Add.1**.**	2004/34-GP): The same comment to CCGP 04/20/4-Add.1**.**
RISK MANAGEMENT	**Australia** (CL 2004/34-GP) AS IT MAY BE DIFFICULT TO REACH CONSENSUS ON SOME ASPECTS OF RISK MANAGEMENT, THE COMMITTEE MAY CONSIDER *c.Replacing the section on risk management with a reference to recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety* While replacing the section on risk management with direct reference to the recommendations from the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety may be useful in principle, is not entirely appropriate as the recommendations were primarily directed at what Codex should do, and were written in 1997. As such, Australia considers that the principles in the recommendations could be used but need to be amended to reflect current regulatory practices for member countries. **Chile** (CL 2004/34-GP) For the sake of clarity, we suggest dividing into three sections: the first one related to Preliminary Aspects, the second one to Management, and the third one to Monitoring and Inspection. **United States** (CL 2004/34-GP) The United States notes that the Codex Committee on Food Hygiene (CCFH), in the document, *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* (at Step 3) had introduced a principle (and accompanying explanatory material) relating to risk management policy. Specifically, the principle read: “Risk managers should establish and follow a Microbiological Risk Management policy”. The explanatory text to this principle provided examples of risk management policy elements including: priority setting; risk management option selection; economic and technical feasibility; and, the use of precaution. The reference to risk management policy has since been deleted. However, this raises the question of whether CCGP may wish to consider if discussion of risk management policy should be included. Alternatively, CCGP, in its role of reviewing risk analysis principles developed by Codex Committees, could consider whether	**Chile** (CL 2004/34-GP): For the sake of clarity, we suggest dividing into three sections: the first one related to Preliminary Aspects, the second one to Management, and the third one to Monitoring and Inspection.

	it is appropriate for CCFH to introduce "risk management policy". If CCGP endorses the concept of "risk management policy" as being appropriate, the Committee should consider whether the "elements" introduced by CCFH are appropriate. Also, CCGP might consider whether the committee needs to reopen the Working Principles for Risk Analysis.	
RISK MANAGEMENT 23. Risk management should follow a structured approach including ~~risk evaluation~~ preliminary risk management activities[13], ~~assessment~~ evaluation of risk management options, implementation of management decisions, monitoring and review of the decision taken.[14]	**Argentina**(CCGP 04/20/4-Add.2) In paragraph 23, it should be included the cost-efficiency analysis of the measure so as to be possible to assess the different risk management options analysed, the proportionality of the measure, and the consideration that the proposed measure is the least trade restrictive one. **Canada** (CCGP 04/20/4-Add.1) 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.	**Argentina** (CCGP 04/20/4-Add.2)**:** It should be included the cost-efficiency analysis of the measure. **Canada** (CCGP 04/20/4-Add.1)**:** 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

[13] For the purpose of these Principles, preliminary risk management activities are taken to include: 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 the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[14] *FAO/WHO Expert Consultation on Risk Management and Food Safety* and *Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards*

		review to ensure that public health objectives are being achieved
	Chile (CL 2004/34-GP) After paragraph 13, a new subtitle "Preliminary Aspects" should be added**.** After this subtitle, a paragraph 23bis with the text of footnote 4 related to preliminary aspects should be added. We believe it is more appropriate to insert it in the text as, unlike risk assessment components, these are neither included nor defined in the Rules of Procedure. Paragraph 23bis should read as follows: "Preliminary risk management activities include: a) identification of a food safety problem; b) establishment of a risk profile; c) ranking of the hazard for risk assessment and risk management priority; d) establishment of risk assessment policy for the conduct of the risk assessment; e) commissioning of the risk assessment; and f) consideration of the result of the risk assessment.	**Chile** (CL 2004/34-GP): After paragraph 13, a new subtitle "Preliminary Aspects" should be added**.** Paragraph 23bis should read as follows: "Preliminary risk management activities include: g) identification of a food safety problem; h) establishment of a risk profile; i) ranking of the hazard for risk assessment and risk management priority; j) establishment of risk assessment policy for the conduct of the risk assessment; k) commissioning of the risk assessment; and l) consideration of the result of the risk assessment.
	European Community (CCGP 04/20/4-Add.1) 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*".	**European Community** (CCGP 04/20/4-Add.1)**:** To add "*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".
	Mexico (CL 2004/34-GP) Risk management, unlike risk assessment, addresses economic, social, political and regulatory aspects. We find it appropriate to include some issues regulated in the SPS Agreement in this paragraph, certainly on the basis of health protection but considering cost-effectiveness aspects.	
	United States (CCGP 04/20/4-Add.1) The United States would insert the word "identification" before "evaluation", to read: *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.*	**United States** (CCGP 04/20/4-Add.1)**:** **"***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."*
	United States (CL 2004/34-GP) The United States would insert the word "identification" before "evaluation", because risk management options first have to be identified before being evaluated. After evaluation, appropriate options would then be selected. The U.S. would rewrite this principle to read: "*Risk management should follow a structured approach including preliminary risk management activities, identification and evaluation of risk management options, selection of appropriate option(s), implementation of management decisions, monitoring and review of the decision taken".*	**United States** (CL 2004/34-GP): The U.S. would rewrite this principle to read: "*Risk management should follow a structured approach including preliminary risk management activities, identification and evaluation of risk management options, selection of appropriate option(s), implementation of management decisions, monitoring and review of the decision taken".*

	Consumers International (CCGP 04/20/4-Add.1) 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 **49 P** (CL 2004/34-GP) Again, Codex terminology is unnecessarily confusing. In para 23, aren't "preliminary risk assessment activities" what the adopted Codex Principles on Biofoods calls a "safety assessment"? Why is the organization using so many different terms?	**Consumers International** (CCGP 04/20/4-Add.1)**:** Risk management should follow a structured approach including ~~risk evaluation~~ 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
24. Risk management decisions should be determined primarily	**Argentina** (CCGP 04/20/4-Add.2) Paragraph 24 includes the consideration of other legitimate factors. From our standpoint, while other variables that do not relate to food safety should be considered as management measures,	**Argentina** (CCGP 04/20/4-Add.2)**:** 0ther legitimate factors should be

by human health considerations, 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 reasons for the justification of a measure should not lead to confusion. Therefore, other legitimate factors should be considered only if grounded on the identification of a food safety risk and not on other legitimate objectives, as the management measures that are adopted to ensure the protection of other legitimate objectives will neither have a scientific ground based on food safety nor relate to risk analysis. **Canada** (CCGP 04/20/4-Add.1) 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. New Footnote: Some Members refer to this concept as the "precautionary principle" while others refer to it as "the application of precaution". **Chile** (CL 2004/34-GP) Before paragraph 24, it should be added the subtitle "Management in the Strict Sense". In paragraph 24, legitimate factors should be directly related to safety and the word "other" should not be used in order to avoid the reference to unrelated issues. It could be quoted in a footnote the provision of the Rules of Procedure regarding "other legitimate factors." **New Zealand** (CL 2004/34-GP) The principles relating to risk management do not provide a clear understanding of what a "risk management option" actually is and who is responsible for its implementation. New Zealand considers that a principle should be elaborated to limit the term "risk manager" to a	considered only if grounded on the identification of a food safety risk. **Canada** (CCGP 04/20/4-Add.1)**:** New Footnote: 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". **Chile** (CL 2004/34-GP): Before paragraph 24, it should be added the subtitle "Management in the Strict Sense". It could be quoted in a footnote the provision of the Rules of Procedure regarding "other legitimate factors." **New Zealand** (CL 2004/34-GP): New Zealand considers that a principle should be elaborated to limit the term "risk manager"

	governmental body or officially recognised body. The language of this paragraph is not very clear and New Zealand suggests consideration should be given to amalgamating the ideas contained in paras 24, 25 and 25 bis. **United States** (CCGP 04/20/4-Add.1) 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.* **United States** (CL 2004/34-GP) The primary consideration of risk management is human health. The reference to unjustified differences in consumer health is a paraphrase of obligations under the WTO agreements and as such should be deleted. The United States finds the final two sentences of this principle to be misplaced. That should be a stand alone principle. Other legitimate factors, if considered, should not be considered in an arbitrary manner and such consideration should be made explicit. Therefore, the U.S. would delete the final two sentences of principle 24 and insert a new principle after current Principle 27 to read: *28. Other legitimate factors relevant to the risk management may be considered in selecting risk management options. However, such consideration should not be carried*	to a governmental body or officially recognised body. The language of this paragraph is not very clear and New Zealand suggests consideration should be given to amalgamating the ideas contained in paras 24, 25 and 25 bis. **United States** (CCGP 04/20/4-Add.1)**:** To delete the final two sentences of principle 24 and insert a new principle, Principle 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"* **United States** (CL 2004/34-GP): *28. Other legitimate factors relevant to the risk management may be considered in selecting risk management options. However, such consideration should not be carried out in an arbitrary manner and any such consideration should be made transparent.*

	out in an arbitrary manner and any such consideration should be made transparent. **Thailand** (CCGP 04/20/4-Add.1) We are of the opinion that the scope of "other legitimate factors" should be consistent with the "Statements of Principle Concerning the Role of Science in the Codex Decision - Making Process and the Extent to which Other Factors are Taken into account". We, therefore, propose to add the footnote to reference the "Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle". **Consumers International** (CL 2004/34-GP): We suggest that reference to "unjustified differences in the level of consumer health protection" is replaced with "unjustified measures to protect consumer health" in the first sentence of this paragraph. We also propose that the second sentence is simplified by re-wording it to read: 'Consideration of other legitimate factors may be appropriate in the determination of the measures to be taken.'	**Thailand** (CCGP 04/20/4-Add.1)**:** We propose to add the footnote to reference the "Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle". **Consumers International** (CL 2004/34-GP): Risk management decisions should be determined primarily by human health considerations, and ~~unjustified differences in the level of consumer health protection~~ unjustified measures to protect consumer health 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.~~ Consideration of other legitimate factors may be appropriate in the determination of the measures to be taken.

	49P (CCGP 04/20/4-Add.1) 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.	
25. In achieving agreed outcomes, risk management should take into account 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.	**Argentina** (CCGP 04/20/4-Add.2) As to paragraph 25, the comments on the ecological and environmental considerations referred to in paragraph 18 herein are applicable to this. **Brazil** (CCGP 04/20/4-Add.1) 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. **Brazil** (CL 2004/34-GP) Repeats the comments CCGP 04/20/4-Add.1. **Canada** (CCGP 04/20/4-Add.1) 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. **Chile** (CL 2004/34-GP) To make it consistent with paragraph 18 referred to risk assessment, it should be read as follows: "In achieving agreed outcomes, risk management should take into account the repercussions of all specific adverse health effects throughout the food chain."	**Canada** (CCGP 04/20/4-Add.1)**:** Addition of the text In achieving agreed outcomes, the risk management should taken into account the impact on food safety and nutritional quality of relevant **Chile** (CL 2004/34-GP): "In achieving agreed outcomes, risk management should take into account the repercussions of all specific adverse health effects throughout the food chain."

	India (CCGP 04/20/4-Add.1) Paragraph 18 & 25 refer to ecological and environmental conditions as part of the risk assessment process. We feel that ecological and environment conditions if made part of the risk assessment process there may be possibility of creating trade barriers for developing countries. Further more, the ecological and environmental conditions do not directly relate to food safety issues. We, therefore, propose to delete the inclusion of ecological and environment conditions from para 18 & 25. **Iran** (CL 2004/34-GP) Line 2: *'' processing"* add after *"production"* **New Zealand** (CL 2004/34-GP) Risk assessment is a scientific discipline and risk estimates will be generated within a specific hazard/food chain context. We believe that it is unnecessary to refer to 'relevant ecological and environmental conditions'. These words should be deleted from this as well as Para 25. **Philippines** (CL 2004/34-GP) In achieving agreed outcomes, risk management should take into account 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. We believe that there should be a statement on the extent of scope of ecological and environmental conditions. **United States** (CCGP 04/20/4-Add.1) 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. *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.* **United States** (CL 2004/34-GP) The phrase "ecological and environmental conditions" should be deleted. In some cases	**India** (CCGP 04/20/4-Add.1)**:** We propose to delete the inclusion of ecological and environment conditions from para 18 & 25. **Iran** (CL 2004/34-GP): "…relevant ecological and environmental conditions, production, *processing*, transport, storage …" **United States** (CCGP 04/20/4-Add.1)**:** *In achieving …. should take into account relevant ~~ecological and environmental conditions~~ production, transport, storage…."* **United States** (CL 2004/34-GP): The phrase

		environment and ecology could be other relevant factors and thus, they are subsumed with the new Principle above. **49P** (CCGP 04/20/4-Add.1) 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.	"ecological and environmental conditions" should be deleted.
25	bis) The risk management process should be transparent, consistent and fully documented. Decisions and recommendations on risk management should be documented, and, where appropriate, clearly identified in national standards and regulations so as to facilitate a wider understanding of the risk management by all interested parties.	**European Community** (CCGP 04/20/4-Add.1) - 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. **United States** (CCGP 04/20/4-Add.1) Principle 25bis: The meaning of the term "consistent" is unclear (consistent with what?). The United States would delete the word "consistent". **United States** (CL 2004/34-GP) The meaning of the term "consistent" is unclear (consistent with what?). The United States would delete the word "consistent". Also, the U.S. would eliminate "bis" paragraphs in the working document and renumber all paragraphs consecutively.	**European Community** (CCGP 04/20/4-Add.1)**:** Delete "~~*and, where appropriate, clearly identified in national standards and regulations*~~". **United States** (CCGP 04/20/4-Add.1)**:** The risk management process should be transparent, ~~consistent~~ and fully documented ….. **United States** (CL 2004/34-GP): The risk management process should be transparent, ~~consistent~~ and fully documented ….. Also, the U.S. would eliminate "bis" paragraphs in the working document and renumber all paragraphs consecutively.

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 option of not taking any action should also be considered. The outcome of the ~~risk evaluation process~~ preliminary risk management activities should be combined with the ~~assessment~~ evaluation of all available risk management options in order to reach a decision on management of the risk.	**Chile** (CL 2004/34-GP) In paragraph 26, as regards the "option of not taking any action", a clarification is needed as to what it is meant; it is important to clarify its meaning and its actual scope. The concrete question is whether this sentence would encourage the regulatory inactivity of a State to justify the entry denial to imported food although the risk assessment is satisfactory. **Cuba** (CL 2004/34-GP) It should be drafted in a clearer way to achieve the approach sought. **United States**(CCGP 04/20/4-Add.1) 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: *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.* **United States** (CL 2004/34-GP) Repeats comments to CCGP 04/20/4-Add.1**.**	**United States** (CCGP 04/20/4-Add.1)**:** *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 option of not taking any action should also be considered~~ 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*. **United States** (CL 2004/34-GP): The same comment to CCGP 04/20/4-Add.1**.** **Consumers International**

	Consumers International (CL 2004/34-GP) Instead of "the option of not taking any action", CI proposes that the second sentence of this paragraph should read: "The documented justification for not taking any action should also be considered".	(CL 2004/34-GP): " … ~~The option of not taking any action should also be considered.~~ The documented justification for not taking any action should also be considered. …."
27. Risk management should take into account the economic consequences and the feasibility of risk management options and recognize the need for alternative options. When different risk management options are equally effective in protecting the health of the consumer, the measure chosen should be the one that is the least restrictive to trade.	**Argentina** (CCGP 04/20/4-Add.2) Argentina believes that, for specification purposes, a footnote with a reference to SPS Article 5.4 should be added to the last sentence stating that "the chosen measure shall be the least trade-restrictive one." New Footnote New Footnote: SPS Agreement 5.4. In determining the adequate level of sanitary or phytosanitary protection, Members shall consider the objective to reduce the negative effects on trade as much as possible **Cuba** (CL 2004/34-GP) It should be drafted in a clearer way to achieve the approach sought. **Chile** (CL 2004/34-GP) After paragraph 27 and before paragraph 28, insert the subtitle "Monitoring and Inspection"**.** **United States** (CCGP 04/20/4-Add.1) 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: *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.*	**Argentina** (CCGP 04/20/4-Add.2)**:** To add a New Footnote: SPS Agreement 5.4. In determining the adequate level of sanitary or phytosanitary protection, Members shall consider the objective to reduce the negative effects on trade as much as possible **Chile** (CL 2004/34-GP): After paragraph 27 and before paragraph 28, insert the subtitle "Monitoring and Inspection"**.** **United States** (CCGP 04/20/4-Add.1)**:** 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~~. When different risk management~~

	United States (CL 2004/34-GP) For member countries, the primary consideration should be whether the risk management option achieves the appropriate level of protection. If there is more than one option that achieves the appropriate level of protection, then economic consequences should be considered in assessing the various options. Also, 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 the trade agreements. Codex should not attempt to paraphrase or elaborate upon the language of the SPS or 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. Either this section of the SPS Agreement should be quoted in its entirety (including all footnotes) or this requirement of the principle should be deleted. The U.S. much prefers that the final sentence of this principle be deleted, to read: "*Risk management should take into account economic consequences of options that achieve the same level of protection. Risk management should consider the feasibility of risk management options and recognize the need for alternative options".* **Consumers International**(CCGP 04/20/4-Add.1) 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. **49 P** (CL 2004/34-GP) para 27 is not in accord with the Codex mandate, which has no references to minimizing restrictions to trade. It would be more realistic to state that the one chosen should be the cheapest (i.e., highest benefit/cost ratio).	~~options are equally effective in protecting the health of the consumer, the measure chosen should be the one that is the least restrictive to trade.~~ **United States** (CL 2004/34-GP): The U.S. much prefers that the final sentence of this principle be deleted, to read: "*Risk management should take into account economic consequences of options that achieve the same level of protection. Risk management should consider the feasibility of risk management options and recognize the need for alternative options".*
28. Where appropriate, implementation of the risk management decision should be	**Argentina** (CCGP 04/20/4-Add.2) In our opinion, we consider that there should be no reference to relevant factors to be taken into account in the risk assessment as certainly it could not constitute a thorough list; neither should some management measures be mentioned because some would benefit to the detriment of	

followed by monitoring both the effectiveness of the control measures and their impact on risk to the exposed consumer population, to ensure that the purpose of the measure is met.	others, if it were not possible to make a thorough list of them (we consider that this option is totally non-viable and inappropriate). **United States** (CL 2004/34-GP) The use of the word "monitoring" in this principle is confusing when read in conjunction with the next principle, which also uses the term "monitoring". The two concepts are quite different. The United States would suggest that perhaps the word "evaluation" should be used in this principle.	**United States** (CL 2004/34-GP): The use of the word "monitoring" in this principle is confusing when read in conjunction with the next principle, which also uses the term "monitoring". The two concepts are quite different. The United States would suggest that perhaps the word "evaluation" should be used in this principle.
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.	**Cuba** (CL 2004/34-GP) It should be drafted in a clearer way to achieve the approach sought. **New Zealand** (CL 2004/34-GP) The intent of this paragraph is not very clear as a principle. All food control systems require functional elements such as traceability capacity. This capacity is not a risk management option. **United States** (CCGP 04/20/4-Add.1) 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: *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,*	**New Zealand** (CL 2004/34-GP): All food control systems require functional elements such as traceability capacity. This capacity is not a risk management option. **United States** (CCGP 04/20/4-Add.1)**:** **"***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*

	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.	*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."*
	United States (CL 2004/34-GP) 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 was agreed upon by the Codex *ad hoc* Intergovernmental 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. Such circumstances include:* *a. Verifying conclusions about the absence or the possible occurrence, impact or significance of potential consumer health effects; or,* *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* *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.*	**United States** (CL 2004/34-GP): *29. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Such circumstances include:* *a. Verifying conclusions about the absence or the possible occurrence, impact or significance of potential consumer health effects; or,* *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 *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.*
	Consumers International (CCGP 04/20/4-Add.1) 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].'	**Consumers International** (CCGP 04/20/4-Add.1)**:** 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].'
	Consumers International (CL 2004/34-GP) 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]."	**Consumers International** (CL 2004/34-GP): 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~~

	49P (CCGP 04/20/4-Add.1) 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.	**49P** (CCGP 04/20/4-Add.1)**:** Post-marketing monitoring (Principle 29) might have to include keeping track of some environmental indicators.
30. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference 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.	**Argentina** (CCGP 04/20/4-Add.2) We believe that paragraph 30 should be considered on a wider basis, without the examples of the different tools. In that sense, it should include the phrase "under certain circumstances, specific tools to facilitate the implementation and enforcement of risk management measures may be necessary when a risk to human health related to food safety has been identified."	**Argentina** (CCGP 04/20/4-Add.2)**:** ~~Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference 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 circumstancesit should include the phrase~~ "Under certain circumstances, specific tools to facilitate the implementation and enforcement of risk management measures may be necessary when a risk to human health related to food safety has been identified."

	Iran (CL 2004/34-GP) Line 4: IRAN recommends *"visible management"* replace instead of *"Post-Market monitoring"*	**Iran** (CL 2004/34- GP): "… been identified or to support visible management ~~post-market monitoring~~ as required according to the circumstances. …"
	New Zealand (CL 2004/34-GP) Same comments as above. These tools are normal components of a food control system and do not need to be included in a risk analysis paper.	**New Zealand** (CL 2004/34-GP) Same comments as above. These tools are normal components of a food control system and do not need to be included in a risk analysis paper.
	United States (CCGP 04/20/4-Add.1) 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: *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.*	**United States** (CCGP 04/20/4-Add.1)**:** *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.*
	United States (CL 2004/34-GP)	**United States** (CL 2004/34-GP): *30. Specific*

	The concept of "tracing" is introduced at this point without context or discussion. The United States believes that it would be more appropriate to refer to documentation as a tool, rather than to a concept ("tracing"). Therefore, the U.S. would rewrite this principle 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 materials; and documentation to permit the trace back to the source of the problem whenever a risk to human health has been identified or to support post-market monitoring as required according to the circumstances.* **Thailand** (CCGP 04/20/4-Add.1) As the term "**appropriate** analytical methods" is too subjective and difficult to justify, we propose to replace the word "appropriate" with "validated".	*tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and documentation to permit the trace back to the source of the problem whenever a risk to human health has been identified or to support post-market monitoring as required according to the circumstances.* **Thailand** (CCGP 04/20/4-Add.1)**: " …** *These may include ~~appropriate~~ validated analytical methods; reference…"*
31. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Decisions should be evaluated regularly and updated as necessary to reflect new scientific knowledge and other information relevant to		

risk analysis.		
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 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 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 the measures taken reviewed, all in a reasonable time frame.]*	**Argentina** (CCGP 04/20/4-Add.2) Paragraph 32 repeats the adoption of measures when the scientific evidence is insufficient, i.e. the application of the precaution. Comments to paragraph 9 are also applicable in this case in the sense that they suggest the deletion of any reference to this issue. **Australia** (CL 2004/34-GP) AS IT MAY BE DIFFICULT TO REACH CONSENSUS ON SOME ASPECTS OF RISK MANAGEMENT, THE COMMITTEE MAY CONSIDER *b. 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.* Australia considers the section on precaution (paragraph 32, Annex 2) should be deleted. In taking this view, Australia considers that precaution is adequately covered in paragraph 9 and therefore does not need to be included under the section on risk management. This is also considered to be an issue that should be dealt with at the national level. Many countries, including Australia, already have in place a range of food safety measures, which are sufficiently flexible to adequately address these concerns. **Brazil** (CCGP 04/20/4-Add.1) 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.	**Argentina** (CCGP 04/20/4-Add.2)**:** it is preferable not to include this issue in a document. We believe that the legal basis and the criteria for the application of measures by governments should be those established in the SPS Agreement. **Australia** (CL 2004/34-GP): ~~**:** *[When relevant scientific evidence is insufficient to …. reviewed, all in a reasonable time frame.]*~~ **Brazil** (CCGP 04/20/4-Add.1)**:** 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. **Brazil** (CL 2004/34-GP): Repeats comments CCGP 04/20/4-Add.1

	Brazil (CL 2004/34-GP) Repeats comments CCGP 04/20/4-Add.1. **Canada** (CCGP 04/20/4-Add.1) *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.* ***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". **Chile** (CL 2004/34-GP)	**Canada** (CCGP 04/20/4-Add.1)**:** *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.* **Chile** (CL 2004/34-GP): In paragraph 32, it is necessary: • to limit its eventual

	In paragraph 32, it is necessary: • to limit its eventual application further; • to grant the responsibility to justify to those that apply it; • to clearly establish its exceptional use in order to prevent it from turning into an usual practice; • that there are scientific grounds for its decision; • that its scope for these purposes is limited to food safety; • in addition to supporting the temporal condition of the measure as specified in Article 5.7 of the WTO SPS Agreement. **European Community** (CCGP 04/20/4-Add.1) 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.	application further; • to grant the responsibility to justify to those that apply it; • to clearly establish its exceptional use in order to prevent it from turning into an usual practice; • that there are scientific grounds for its decision; • that its scope for these purposes is limited to food safety; • in addition to supporting the temporal condition of the measure as specified in Article 5.7 of the WTO SPS Agreement. **European Community** (CCGP 04/20/4-Add.1)**: "**~~[~~*When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, ……. information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame*~~]~~*"*

	India (CCGP 04/20/4-Add.1) **Paragraphs 32 and also 33** suggest interim measures in case relevant scientific evidence is insufficient. In such cases the interim measures could be only code of practice and/or guidelines, which the Commission has also endorsed in its 24th Session (Alinorm 01/41, para 81). Therefore to have consistency in the approach we suggest removal of square brackets from both para. In Paragraph 33 the words "**as far as practicable"** may be added after the word "measures". We therefore propose the following in para 33: ~~*In such situation*~~ *The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures as far as practicable:* **Mexico** (CL 2004/34-GP) It is believed that the inclusion of long-term aspects in the risk analyses should not turn into an international trade barrier. This is a very significant issue and it should be specified under which circumstances this argument can be accepted, mainly if current data show, on the basis of science and not on vague assumptions, potential long-term adverse effects. Risk analyses cannot be stopped just because it is speculated, with no justification at all, that adverse effects might arise. **Philippines** (CL 2004/34-GP) The connotation of time frame has to be clearly defined. The options may include stating time frame in terms of number of years or an exact definition of what is a reasonable time frame. We propose that another sentence be inserted between the word "assessment" and "However". The text to read as: *[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 adverse effects on human health may occur, but it is difficult their nature extent, it may be appropriate for risk managers to apply precaution though interim measures, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment.* ***Such interim measures must be periodically reviewed taking into account the adverse comments from affected countries challenging the measures.*** *However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]*	**India** (CCGP 04/20/4-Add.1)**: "**~~[~~*When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, ……. information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame*~~]~~*"* **Philippines** (CL 2004/34-GP): *[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 adverse effects on human health may occur, but it is difficult their nature extent, it may be appropriate for risk managers to apply precaution though interim measures, in order to protect the health of consumers without awaiting*

	United States (CCGP 04/20/4-Add.1) 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.	*additional scientific data and full risk assessment.* ***Such interim measures must be periodically reviewed taking into account the adverse comments from affected countries challenging the measures.*** *However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]* **United States** (CCGP 04/20/4-Add.1)**:** ***"~~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 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 measures, in order to protect the health of consumers without awaiting additional scientific data~~***

	United States (CL 2004/34- GP) This principle, as written, is vague and confusing. The United States prefers that this principle be deleted. If not deleted, it should be rewritten to more explicitly address the rights and obligations of member countries to take interim measures. The U.S. suggests the following rewrite: 32 " *When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete it may be appropriate for member countries to establish interim measures to protect the health of consumers until additional relevant scientific information is available and a more complete risk assessment performed. Member countries that establish an interim measure must seek the additional relevant scientific evidence and review the interim measures accordingly, within a reasonable period of time."* **Consumers International** (CCGP 04/20/4-Add.1) The inclusion of this paragraph under this section on risk management is essential for consumer	~~*and full risk assessment. However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame"*~~ **United States** (CL 2004/34-GP): 32 " *When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete it may be appropriate for member countries to establish interim measures to protect the health of consumers until additional relevant scientific information is available and a more complete risk assessment performed. Member countries that establish an interim measure must seek the additional relevant scientific evidence and review the interim measures accordingly, within a reasonable period of time."* **Consumers International** (CCGP 04/20/4-Add.1)**: "**~~I~~ *When relevant scientific evidence is insufficient to*

	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. **Consumers International** (CL 2004/34-GP) Paragraphs 32-33. CI strongly supports retention of these two paragraphs which are currently in italics. Reference is made to the amendments that we proposed to improve these paragraphs in our comments submitted prior to the twentieth session. **49 P** (CCGP 04/20/4-Add.1) 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. **49 P** (CL 2004/34-GP) The 49 P organization strongly supports inclusion of the italicized para 32, currently in brackets. This precautionary language reflects the WTO SPS provision on precautionary measures and is needed since not all Codex members are parties to the WTO. Furthermore, it is consistent with recent international practice (eg, the Cartagena Biosafety Protocol, the new US food import rules to combat bioterrorism, EU rulings, etc.) as well as actual laws in many member countries (it has been estimated that 40 US statutes include precautionary regulation).	*objectively and fully assess risk from a hazard in food, ……. information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame ~~]~~"* **49 P** (CCGP 04/20/4-Add.1)**: "**~~[~~*When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, ……. information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame ~~]~~"*
33. [~~In such situation~~ The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures:	**Brazil** (CCGP 04/20/4-Add.1) 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. "	**Brazil** (CCGP 04/20/4-Add.1)**:** 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.

(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*	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. **Canada** (CCGP 04/20/4-Add.1) *[~~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. **Chile** (CL 2004/34-GP)	**Canada** (CCGP 04/20/4-Add.1)**:** *[~~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:* *(a) Examination* *(b) There should…..* *(c) The decisions….* *(d) The decisions / measure…* *(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 …..* *(g) Information should….* **Chile** (CL 2004/34- GP): To expressly point out consistency and non discrimination issues. countries should not apply

circumstances, based on all the available pertinent information, including available scientific information. *(e) The measures taken are the least trade restrictive to achieve 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]*	In paragraph 33, to expressly point out consistency and non discrimination issues. There is some vague reference but an express mention would be preferred. Another related aspect that should be indicated is that countries should not apply precautionary measures to imported food if they have not done so to their national products under similar circumstances. In the WTO context, this is called "National Treatment." *Alternative 2 for Precaution* Another approach could be to develop the precaution issue in a more incipient way, in this part of Risk Management, in any case, making it consistent with Article 5.7 of the SPS Agreement and expressing in the text the relationship between uncertainty and precaution. Then, in the section Risk Assessment, to elaborate on precaution, especially as regards the lack of background information. With this approach, precaution will represent, in a way, a form of uncertainty. With this second alternative, in elaborating more on uncertainty than precaution, further objectivity is likely to be achieved when it is incorporated as a part of the assessment and it is possible to quantify it. **European Community** (CCGP 04/20/4-Add.1) 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. **India** (CCGP 04/20/4-Add.1) Paragraphs 32 and also 33 suggest interim measures in case relevant scientific evidence is insufficient. In such cases the interim measures could be only code of practice and/or guidelines, which the Commission has also endorsed in its 24th Session (Alinorm 01/41, para 81). Therefore	precautionary measures to imported food if they have not done so to their national products under similar circumstances. **European Community** (CCGP 04/20/4-Add.1): ~~*[In such situation*~~ *The following considerations should be taken into account when deciding on the measures to be applied,* ~~*especially as regards*~~ *"including". interim measures:* (a)*"Wherever possible* 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*. It is recognised that this may not always be possible in emergency situations.* . **India** (CCGP 04/20/4-Add.1)**:** ~~*[In such situations*~~

	to have consistency in the approach we suggest removal of square brackets from both para. In Paragraph 33 the words "as far as practicable" may be added after the word "measures". We therefore propose the following in para 33: ~~*In such situation*~~ *The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures as far as practicable:* **Mexico** (CL 2004/34-GP) It is believed that the inclusion of long-term aspects in the risk analyses should not turn into an international trade barrier. This is a very significant issue and it should be specified under which circumstances this argument can be accepted, mainly if current data show, on the basis of science and not on vague assumptions, potential long-term adverse effects. Risk analyses cannot be stopped just because it is speculated, with no justification at all, that adverse effects might arise. **New Zealand** (CL 2004/34-GP) Paragraph 33(a) is unrealistic as a general principle. **United States** (CCGP 04/20/4-Add.1) 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.	*The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures as far as practicable:* *(a) Examination* *(b) There should…..* *(c) The decisions….* *(d) The decisions / measure…* *(e) The measures taken …* *(f) The decisions / measures …..* *(g) Information should….* **United States** (CCGP 04/20/4-Add.1)**:** ~~*[In such situation The following considerations should be taken … interim measures:*~~ ~~*(a) Examination of the full … effectiveness considerations.*~~ ~~*(b) There should be a … followed to establish them.*~~ ~~*(c) The decisions / measures …scientific data.*~~ ~~*(d) The decisions / measures taken … available scientific information.*~~ ~~*(e) The measures taken*

	United States (CL 2004/34-GP) 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. If paragraph 33 is not to be deleted, the U.S. believes that element a) could be combined with principle 27, as this consideration applies to all measures, not just to interim measures. The U.S. believes that element b) can be improved by including language to refer to refer to interim measures. The U.S. would rewrite element b) to read: 33 "*There should be a transparent explanation of the consumer health need for an interim measure, the procedures followed to establish the measure and the reason for not waiting for more complete scientific information.* In element c), the U.S. believes that the word "potential" should be deleted and the phrase "as determined by a risk assessment" should be added. The U.S. would rewrite the element to read: *The interim decisions/measures taken are proportional to the extent of the health risk as determined by a risk assessment, based on the available scientific data.* Element e) is redundant and should be deleted	~~*... of consumers.*~~ ~~*(f) The decisions / ... stakeholders.*~~ ~~*(g) Information should ... such information]*~~ **United States** (CL 2004/34-GP): *[The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures:* *a.) There should be a transparent explanation of the consumer health need for an interim measure, the procedures followed to establish the measure and the reason for not waiting for more complete scientific information.* *b.) The interim decisions/measures taken are determined by a risk assessment, based on the available scientific data.* *c.) The interim decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.* *d.) The*

	Consumers International (CCGP 04/20/4-Add.1) (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*	*decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.* *e.) 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]* **Consumers International** (CCGP 04/20/4-Add.1)**:** (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 *'taking into account potential costs of failing to act.'* (c) 'The decisions / measures taken are proportional to the potential extent of the health risk, based on the available

	account other legitimate factors.' **Consumers International** (CL 2004/34-GP) Paragraphs 32-33. CI strongly supports retention of these two paragraphs which are currently in italics. Reference is made to the amendments that we proposed to improve these paragraphs in our comments submitted prior to the twentieth session. Sub-paragraph 33(a). We suggest the addition of the following wording at the end of the sentence: "as well as the potential costs if no action is taken". Sub-paragraph 33 (c). We suggest that the following wording is included at the end of the paragraph to reflect the need for care that there is not over-reliance on limited data when faced with scientific uncertainty which could prove to be misleading or wrong – for example, initial assumptions that Bovine Spongiform Encephalopathy (BSE) would behave like scrapie: *"while acknowledging any potential limitations".* **49P** (CCGP 04/20/4-Add.1) In regard to Principle 33, we see that some provisions appear to duplicate language in other parts of the Proposed Draft. **49 P** (CL 2004/34-GP) We also support the bracketed para 33, except for subsection (e); it is not within the mandate of Codex to favor certain trade policies over others. In subsections (a) and (f) the term "stakeholders" should be replaced by the term *already used in this text*, "interested parties" (see definition in footnote 3; see usage para 36). Again, this would simplify the confusing multiplicity of terms used in Codex materials on this subject.	scientific data *while acknowledging any potential limitations, and taking into account other legitimate factors.'*
RISK COMMUNICATION 34. Risk communication should: (i) promote awareness and understanding of the specific issues under consideration during the risk analysis process; (ii) promote	**Iran** (CL 2004/34-GP) IRAN recommends **(/)** after *"option"* delete &change to "and". As you know "public" covers all common people including**"** interested parties". IRAN recommends **"**awareness**"** add after "understanding". **United States** (CL 2004/34-GP)	**Iran** (CL 2004/34-GP): "… promote awareness and understanding of the specific issues under consideration during the risk analysis process; &" "public" covers all common people including interested parties". Iran recommends "awareness" add after "understanding".

consistency and transparency in formulating risk management options/recommendations; (iii) provide a sound basis of information for understanding the risk management decisions proposed; (iv) improve the overall effectiveness and efficiency of the risk analysis process; (v) strengthen the working relationships among participants; (vi) foster public understanding of the risk analysis process, so as to enhance trust and confidence in the safety of the food supply; (vii) promote the appropriate involvement of all interested parties; and (viii) foster the exchange of information in relation to the concerns of interested parties about the risks associated with food. 35. Risk analysis should include clear, interactive and documented	This section does not fully convey the importance of accurately communicating the nature of the risk, the management measures and their anticipated effect. Consequently, the U.S. suggests adding a header paragraph, to read:34 "*Risk communication involving all stakeholders should include an accurate description of the nature of the risk and a transparent explanation of the risk management actions, including the options available, the rationale for selecting the option(s) and the anticipated effect(s). This will include:…"*	**United States** (CL2004/34-GP): Risk communication involving all stakeholders should include an accurate description of the nature of the risk and a transparent explanation of the risk management actions, including the options available, the rationale for selecting the option(s) and the anticipated effect(s). This will include: (i) promoting awareness and understanding of the specific issues under consideration during the risk analysis process; (ii) promoting consistency and transparency in formulating risk management options/recommendations; (iii) providing a sound basis of information for understanding the risk management decisions proposed; (iv) improving the overall effectiveness and efficiency of the risk analysis process; strengthening the working relationships among participants; (iv) fostering public understanding of the risk analysis process, so as to enhance trust and

communication, amongst risk assessors and risk managers, and reciprocal communication with all interested parties in all aspects of the process.	**Consumers International** (CCGP 04/20/4-Add.1) 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. **Consumers International** (CL 2004/34-GP) Paragraph 35. We propose that this is changed to "Risk analysis should include clear, interactive, *timely* and documented communication……." **49P** (CCGP 04/20/4-Add.1) 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.	confidence in the safety of the food supply; (v) promoting the appropriate involvement of all interested parties; and (vi) fostering the exchange of information in relation to the concerns of interested parties about the risks associated with food.
36. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion essential for effective risk assessment and risk management is exchanged among interested parties and incorporated into the decision making		

process. ~~Ongoing reciprocal communication amongst all interested parties should be an integral part of the risk analysis process.~~		
37. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis process, and minority opinions.	**Iran** (CL 2004/34-GP) Line 5: If "minority opinion" effects in risk analysis, IRAN recommends either it- minority opinion- adds after "assumption" on- line 4-or mentions clearly & or as separate sentence. **Consumers International** (CL 2004/34-GP) We suggest that the first sentence is amended as follows: "Risk communication involving interested parties should include a transparent explanation of the risk assessment policy, and of the assessment of risk, including *methodological uncertainty, data gaps, and risk assessment and risk management assumptions resulting from such uncertainty and data gaps. In the event that precautionary interim measures are taken, risk communication should indicate the rationale for such measures and the time frame in which full risk assessment and risk management decisions will be taken, pending the availability of pertinent scientific data".*	**Iran** (CL 2004/34-GP): "…It should indicate any constraints, uncertainties, assumptions minority opinion and their …" **Consumers International** (CL 2004/34-GP): "Risk communication involving interested parties should include a transparent explanation of the risk assessment policy, and of the assessment of risk, including *methodological uncertainty, data gaps, and risk assessment and risk management assumptions resulting from such uncertainty and data gaps. In the event that precautionary interim measures are taken, risk communication should indicate the rationale for such measures and the time frame in which full risk assessment and risk management decisions will be taken, pending the*

		availability of pertinent scientific data". The …"

ANNEX 1

U.S. REDRAFT
PROPOSED DRAFT PRINCIPLES FOR RISK ANALYSIS[15] (At Step 3 of the Procedure)

SCOPE

1. The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments.

RISK ANALYSIS - GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure public health protection.

3. The risk analysis process should be
- applied consistently,
- open, transparent and documented

4. The risk analysis process should follow a structured approach incorporating the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication), each being integral to the overall risk analysis process. The three components of risk analysis should be applied within an overarching framework of strategies and policies to manage food related risks to human

5. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.[16]

6. Effective communication and consultation with all interested parties should be ensured established and maintained throughout the risk analysis process.

7. There should be a functional separation of risk assessment and risk management, to the extent practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

8. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related 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[17]

[15] These principles are intended for governments and will be incorporated into the Codex Alimentarius.
[16] For the purpose of the present document, the term "interested parties" refers to "risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations" (see definition of "Risk Communication")
[17] Elements of risk assessment policy include, among others: 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

9. Determination of risk assessment policy should be included as a specific component of risk management.

10. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.

11. The mandate given by risk managers to risk assessors should be as clear as possible.

RISK ASSESSMENT

12. Health and food safety decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

13. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization, and should be documented in a transparent manner.

14. The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined

15. Information on the identities of government experts, their individual expertise and their professional experience should be publicly available. Experts from outside government 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.

16. 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.

17. Risk assessment should take into account relevant ecological and environmental conditions as they affect 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.

18. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups, as appropriate. If relevant to the risk assessment and if available, acute, chronic (including long-term), cumulative, and/or combined adverse health effects should be taken into account in carrying out the risk assessment.

19. Constraints, uncertainties and assumptions and their impact on the risk assessment should be explicitly considered at each step in the risk assessment process and documented in a transparent manner. Expression of uncertainty or of variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

20. The report of the risk assessment should include the scope and purpose of the risk assessment carried out, the background of the request, the information considered, the scientific reasoning and the conclusions of the risk assessors. The report should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

21. The results of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

22. Risk management should follow a structured approach including preliminary risk management activities[18], identification and evaluation of risk management options, selection of appropriate option(s), implementation of management decisions, monitoring and review of the decision taken.[19]

23. Risk management decisions should be determined primarily by human health considerations.

24. In achieving agreed outcomes, risk management should take into account 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.

25 The risk management process should be transparent and fully documented. Decisions and recommendations on risk management should be documented, and, where appropriate, clearly identified in national standards and regulations so as to facilitate a wider understanding of the risk management by all interested parties.

26. The risk management options selected should reflect the assumptions used for the risk assessment and the degree of uncertainty in the risk characterization.

27. 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.

28. Risk management should take into account economic consequences of options that achieve the same level of protection. Risk management should consider the feasibility of risk management options and recognize the need for alternative options. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options. 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.

29. Other legitimate factors relevant to the risk management may be considered in selecting risk management options. However, such consideration should not be carried out in an arbitrary manner and any such consideration should be made transparent.

30. Where appropriate, implementation of the risk management decision should be followed by evaluation of both the effectiveness of the control measure(s) and its impact on risk to the exposed consumer population, to ensure that the purpose of the measure(s) is met.

31. Post-market monitoring may be an appropriate risk management measure in specific circumstances. Such circumstances include:

a.) Verifying conclusions about the absence or the possible occurrence, impact or significance of potential consumer health effects; or,

[18] For the purpose of these Principles, preliminary risk management activities are taken to include: 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 the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

[19] *FAO/WHO Expert Consultation on Risk Management and Food Safety* and *Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards*

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

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.

32. Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and documentation to permit the trace back to the source of the problem whenever a risk to human health has been identified or to support post-market monitoring as required according to the circumstances.

33. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Decisions should be evaluated regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

34. *[When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete it may be appropriate for member countries to establish interim measures to protect the health of consumers until additional relevant scientific information is available and a more complete risk assessment performed. Member countries that establish an interim measure must seek the additional relevant scientific evidence and review the interim measures accordingly, within a reasonable period of time."*

35. *[The following considerations should be taken into account when deciding on the measures to be applied, especially as regards interim measures:*

f.) There should be a transparent explanation of the consumer health need for an interim measure, the procedures followed to establish the measure and the reason for not waiting for more complete scientific information.

g.) The interim decisions/measures taken are determined by a risk assessment, based on the available scientific data.

h.) The interim decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.

i.) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.

j.) 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]

RISK COMMUNICATION

36. Risk communication involving all stakeholders should include an accurate description of the nature of the risk and a transparent explanation of the risk management actions, including the options available, the rationale for selecting the option(s) and the anticipated effect(s). This will include:

(i) promoting awareness and understanding of the specific issues under consideration during the risk analysis process;

(ii) promoting consistency and transparency in formulating risk management options/recommendations;

(iii) providing a sound basis of information for understanding the risk management decisions proposed;

(iv) improving the overall effectiveness and efficiency of the risk analysis process;

strengthening the working relationships among participants;

(iv) fostering public understanding of the risk analysis process, so as to enhance trust and confidence in the safety of the food supply;

(v) promoting the appropriate involvement of all interested parties; and
(vi) fostering the exchange of information in relation to the concerns of interested parties about the risks associated with food.

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

38. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion essential for effective risk assessment and risk management is exchanged among interested parties and incorporated into the decision making process.

39. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis process, and minority opinions.