

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3

CX/GP 06/23/3

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

Twenty-third Session

Paris, France, 10 – 14 April 2006

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

At its 22nd Session (Paris, France, 11 – 15 April 2005), the Codex Committee on General Principles (CCGP) agreed that a Circular Letter would invite proposals from members and observers on the objective and scope of a future Codex document on Working Principles for Risk Analysis, as well as the elements that should be included in the document, for consideration by an electronic working group chaired by the United States, with Malaysia and Morocco as co-chairs. Consideration by the working group would not be limited to the existing document. On the basis of the proposals and comments received, the Working Group would develop the structure and outline of a possible new document, which would be circulated for comments and consideration at the next session.

The report of the 22nd Session of CCGP (ALINORM 05/28/33A) included Circular Letter CL 2005/17-GP. Part B, Request for Comments and Information, invited governments and international organizations to make proposals on the objective and scope of a document, Proposed Draft Working Principles for Risk Analysis for Food Safety, as well as the elements that should be included therein. Comments were requested before 30 July 2005.

Participants in the 22nd Session of CCGP were also contacted by an e-mail of 28 April 2005 and reminded of the invitation to submit comments by 30 July 2005.

By 1 September 2005, comments had been received from seven Codex Members (Australia, Brazil, Canada, Japan, Malaysia, Zimbabwe, and the European Community) and two International Non-Government Observer Organizations (Consumer International and the Council for Responsible Nutrition).

Based on the comments received, a document containing proposed statements of objective and scope and all proposed elements was prepared and circulated to all participants in the 22nd CCGP and to all individuals who had responded to the 28 April call for comments (**Annex I**). Comments were requested on the various statements of scope and objective and on the elements that had been proposed for inclusion in such a document. Comments were requested by 15 October.

By 1 January 2006, comments had been received from eight Codex Members (Argentina, Australia, Canada, Malaysia, Morocco, New Zealand, Thailand, and the European Community) and three International Non-Government Observer Organizations (Consumer International, the International Institute of Refrigeration, and the 49th Parallel Biotechnology Consortium) (**Annex II**).

The comments show a diversity of opinion. Argentina (and Brazil) recommends that work on the document be discontinued. Canada recommends a much simplified document. New Zealand advocates a fundamental restructuring of the document. Australia, Malaysia, Morocco and Thailand generally agree with the document. The European Community and Consumers International recommend significant additions to the document. And the 49th Parallel Biotechnology Consortium questions several aspects of the document. **Annex III** is a copy of the proposed outline and elements with comments inserted at the points to which they refer.

Proposed Outline

I. Introduction

II. Objective/Scope

III. Definitions

IV. General Principles of Risk Analysis

V. Risk Analysis Framework

V(A). PRELIMINARY RISK ASSESSMENT ACTIVITIES

V(B) RISK ASSESSMENT

V(C). RISK MANAGEMENT

V(D). RISK COMMUNICATION

V(E). MONITORING AND REVIEW

APPENDIX 1: National Environment for Management of Food Safety

APPENDIX 2: International Environment for Management of Food Safety

Introduction

It is proposed this introductory section provide general information on the benefits of applying Risk Analysis for setting food safety standards at the national level, and acknowledge the challenges (e.g., expertise and data requirements) that maybe faced in implementing it, particularly by developing countries. This section should also refer to the need for adequate government support and appropriate infrastructure.

This section could also include a diagram of the risk analysis process, description of the process of iteration, and discussion of the advantages and disadvantages of various techniques and mosels.

Objective/Scope

A concise statement of the objective/scope, guided by member suggestions (below):

Member	
Australia	To provide guidance to governments on application of risk analysis principles for food safety and health-related decision making at the national level that: - complements current documentation (e.g. Codex Committees' guidance on risk analysis, FAO/WHO manual on risk analysis). -reflects the <i>Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius</i> as published in the Procedural Manual.
Canada	To provide guidance to Codex Member governments on the conduct of risk analysis in the context of food safety.
Japan	<ol style="list-style-type: none">1. These principles for risk analysis are intended for application by governments with the primary purpose of protecting the health of consumers.2. The objective of the principles is to provide a framework to member governments, so that their decision-making for food safety is based on risk analysis.3. The principles are intended to serve as common basis for risk analysis by governments and help member governments conduct their own risk analysis in a more consistent manner."
Malaysia	The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety as guidance to governments." The overall objective of risk analysis applied to food safety is to ensure public health protection."
Zimbabwe	There is need to specify situations/ instances where risk analysis could be carried out e.g. Risk analysis should be carried out where a country/government suspects a food product to pause a health threat to consumers etc. This will help to clarify the concept to those not familiar with it.
EC	These principles for risk analysis are intended for application by governments. The objective of these working principles should be to provide guidance to the relevant competent authorities that their decisions, measures and recommendations related to food safety are based on risk analysis. These principles should assist Member Governments in protecting the health of consumers and ensuring fair practices in the food trade by fostering a consistent and proportionate approach to risk analysis for food safety consistent with article 5 of the SPS agreement. They should aim at developing a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.

Definitions

Either definitions consistent with the Codex Procedural Manual or reference to the manual.

General Principles of Risk Analysis

Overarching Principles for all parts of Risk Analysis, which do not have to be repeated within each section. Members suggested statements of principle related to:

- Structured Approach: Three integral components and their interrelationships
- Scientific basis of risk analysis
- Systematic methodology
- Objective application of risk analysis
- Transparency
- Documentation
- Treatment of scientific uncertainty
- Iterative process
- Consultation / Interaction
- Information Exchange among countries
- Consideration of Codex Standards
- Consistency in application
- Measures adopted by countries based on risk analysis
- Unjustified barriers to trade avoidance
- Continuing process (on-going monitoring and review)
- Maintain confidentiality, where necessary

There may be other principles or it may be possible to consolidate some of these into a smaller set of principles.

Risk Analysis Framework

PRELIMINARY RISK ASSESSMENT ACTIVITIES

Guidance on:

- Risk Assessment Policy
- Establishing a Risk Profile (especially at the national level)
- Priority setting for Risk Assessments and for risk management
- Modes of interaction between risk assessors and managers
- Selection criteria for risk assessors
- Peer review policies

There may be other aspects for which guidance is needed. Also, some of these topics may be covered in other sections (Introduction?).

RISK ASSESSMENT

Guidance on the implementation of risk assessment, addressing areas such as:

- The question that the risk assessment is expected to answer
- Hazard identification – the problem associated with the food and the type of food
- Hazard characterization – the adverse effects
- Exposure Assessment – probability of consumption
 - Realistic exposure scenarios
 - Nationally appropriate intake date
 - Nationally appropriate food composition data
- Risk Characterization – the risk to the population
 - Appropriate population groups
- Scientific data:
 - Sources
 - Use of animal models for assessing toxicological endpoints
 - Quality
 - Treatment of scientific uncertainty throughout risk assessment

RISK MANAGEMENT

- Explanation of the purpose of Risk Management
- Discussion of Risk Management Tools available to national governments
- Guidance on selection of risk management options
- Discussion of the influence of scientific uncertainty on selection of risk management option
 - Selection of provisional measures
 - Reasonable period of time for review
- Guidance on adapting Codex recommendations and guidance at the national level

- Discussion of the need to recognize Equivalence
- Guidance on consideration of other factors at the national level
 - Economic factors
 - Cost/benefit analysis
 - Relative cost effectiveness of alternatives to limiting risk
 - Feasibility of alternative actions
 - Production methods – throughout the entire food chain
 - Existing storage, transport and handling practices
 - Regulatory controls
 - Availability of methods of analysis, sampling capabilities, inspection resources
 - Feasibility of enforcement
 - Traditional uses of the food
 - Environmental and ecological considerations
 - Societal issues
 - Ethical considerations

RISK COMMUNICATION

- Discussion of the difference between risk communication in Codex and at the national level
- Practical aspects of communication
- Involvement of stakeholders
- Exchange of information among stakeholders
- Importance of clear communication and proper perspective

MONITORING AND REVIEW

Unlike Codex, national governments implement risk management measures. The Drafting Group should consider a section on enforcement, monitoring of implementation and review of the impact of risk management decisions.

National Environment for Management of Food Safety

Consideration of:

- Consistency of approach at the national level in relation to food safety issues for both domestic and imported product
- Adequate, transparent and clearly defined legislation to support food safety processes
- National capability, i.e. infrastructure available to support, implement and monitor risk analysis processes, including timeliness of response and of review
- Mechanisms for the recognition of the food safety control systems of other countries
- Sovereignty vis-à-vis Harmonization

International Environment for Management of Food Safety

Consideration of:

- Existing Codex guidance
- Other international risk assessments that may be available (i.e. outcomes of FAO and WHO Expert Consultations)
- Recognition of member governments' obligations under other international treaties or agreements (e.g. WTO obligations).

COUNTRY COMMENTS

Argentina:**GENERAL COMMENTS:**

1. At the last session of the Codex Committee on General Principles, Argentina proposed the creation of a new working group discuss the development of a new document on Risk Analysis on a broad basis, taking into account Codex members' various concerns.

Argentina has held that this Working Group should not prejudge the outcome, given the discrepancy of ideas and the different alternatives proposed by members to address the issue, and we still hold our point of view in this respect.

2. In the past, Argentina has held that the no new Principles on Risk Analysis were needed for application by governments, as scientific principles recommended by FAO/WHO Expert Groups are still valid, and document "Codex Working Principles for Risk Analysis" was prepared based on them.

Several Codex members expressed that these principles were needed, especially to help developing countries in their work; however, a number of developing countries held a different view, and stated that risk analysis manuals being developed by FAO/WHO could be more helpful in providing them wit guidance on the development of a risk assessment policy and a methodology to follow in applying risk analyses.

At the 28th Session of the Codex Alimentarius, manuals on food safety risk analysis¹ were published.

3. Argentina appreciates the efforts made by FAO/WHO in developing the manuals, since we believe that they constitute a set of texts and case studies that will provide excellent didactic guidance for Codex members, particularly developing countries, to successfully conduct their own risk analyses.

In this sense, we believe that Manuals of this kind, which – in addition to developing a theory – include practical examples, are – in conjunction with appropriate training – the actual guidance that developing and least developed countries need to successfully undertake work on risk analysis or update their policies and criteria according to new trends in these matters.

4. With regard to the text on risk analysis discussed at the Committee on General Principles, Argentina believes that it does not cover only principles, and this is one of the reasons why a number of countries reject the proposed text. In this respect, it is worth pointing out that, considering the large number of texts which address issues relating to risk assessment and risk management in various ways, a document on **general principles** on risk analysis should be shorter and clearer, and should not be misleading regarding what "principle" usually means and which are clearly "exceptions" to a "general rule or principle".

5. Discussions held in the last years show that there is no consensus to make progress on the document on risk analysis principles for application by governments with such characteristics as those of the document prepared by the CCGP Secretariat.

Argentina has belonged to the group of countries opposed to the development of a new text. However, contrary to what may be supposed, we understand that it would be extremely useful to have such a document, provided that a Codex standard is not intended to alter the healthy logic established in the WTO Agreement on Sanitary and Phytosanitary Measures (SPS) regarding principles and exceptions; a situation evident in countless discussions since the issue was first discussed in Codex.

In particular, Argentina wishes to refer to precaution, which constitutes a clear exception to the principles laid down in the SPS Agreement and the inclusion of which in this document could allow countries to adopt arbitrary, unjustified measures, only with the aim of restricting trade rather than ensuring consumer health protection, for long periods of time. Further, we believe that, given that the adoption of measures needed to ensure consumer health protection is the concern of national authorities, its inclusion in the text is unnecessary, given that this prerogative is a sovereign right of Codex members.

In view of the above, we will attempt to make a constructive contribution to this discussion.

SPECIFIC COMMENTS:

¹ Food Safety Risk Analysis. Part I: An Overview and Framework Manual. Part II Case Studies. Provisional Edition. FAO/OMS. Roma 2005

In light of the comments made, Argentina believes that the document should focus on the development of “Principles for Food Safety Risk Assessment”.

SCOPE:

The document should cover food safety related human health risks.

OBJECTIVE:

The aim would be to provide a reference framework for governments when taking decisions on food safety based on science.

The Principles should be developed considering:

- Available scientific evidence;
- Objectivity,
- Transparency;
- Independence;
- Existing Codex standards and standards being developed, the results of FAO/WHO Expert Consultations or other international risk assessments.
- Every risk assessment component;
- Consistency, non-discrimination when assessing risks associated with imported and national products;
- Although governments are responsible for the establishment of their risk assessment policy, and risk managers are the ones who should do so, we believe that in establishing principles for risk assessment, reference should be made to the fact that risk assessment shall be conducted under the terms laid down by the risk assessment policy.

Australia

General

In general Australia supports the approach being taken by the United States as the lead of the Working Group. Australia supports the content of the proposed outline and has outlined below specific comments in relation to the outline, statement of objective and the elements presented in the paper. Our comments follow in edited text.

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APPENDIX 1: National Environment for Management of Food Safety

APPENDIX 2: International Environment for Management of Food Safety

Introduction

It is proposed this introductory section provide general information on the benefits of applying risk analysis for setting food safety standards at the national level, and acknowledge the challenges (e.g., expertise and data requirements) that maybe faced in implementing it, particularly by developing countries. This section should also refer to the need for adequate government support and appropriate infrastructure.

This section could also include a diagram of the risk analysis process, description of the process of iteration, and discussion of the advantages and disadvantages of various techniques and models.

Objective/Scope

Australia suggests that, to avoid confusion the term “objective” be used here rather than “scope”. Further, we suggest moving the suggested words below previously suggested by Australia to the introduction section. The wording suggested by Japan could then sit appropriately as the objective.

Japanese proposal

- 4. These principles for risk analysis are intended for application by governments with the primary purpose of protecting the health of consumers.**
- 5. The objective of the principles is to provide a framework to member governments, so that decision-making for food safety is based on risk analysis.**
- 6. The principles are intended to serve as common basis for risk analysis by governments and help member governments conduct their own risk analysis in a more consistent manner.”**

A concise statement of the objective/scope, guided by member suggestions (below):

Member	
Australia	<p>This could be in introduction</p> <p>To provide guidance to governments on application of risk analysis principles for food safety and health-related decision making at the national level that:</p> <ul style="list-style-type: none"> - complements current documentation (e.g. Codex Committees’ guidance on risk analysis, FAO/WHO manual on risk analysis). -reflects the <i>Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius</i> as published in the Procedural Manual.
Canada	To provide guidance to Codex Member governments on the conduct of risk analysis in the context of food safety.
Japan	<ol style="list-style-type: none"> 1. These principles for risk analysis are intended for application by governments with the primary purpose of protecting the health of consumers. 2. The objective of the principles is to provide a framework to member governments, so that their decision-making for food safety is based on risk analysis. 3. The principles are intended to serve as common basis for risk analysis by governments and help member governments conduct their own risk analysis in a more consistent manner.”
Malaysia	<p>The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety as guidance to governments.”</p> <p>The overall objective of risk analysis applied to food safety is to ensure public health protection.”</p>
Zimbabwe	There is need to specify situations/ instances where risk analysis could be carried out e.g. Risk analysis should be carried out where a country/government suspects a food product to pose a health threat to consumers etc. This will help to clarify the concept to those not familiar with it.
EC	<p>These principles for risk analysis are intended for application by governments.</p> <p>The objective of these working principles should be to provide guidance to the relevant competent authorities that their decisions, measures and recommendations related to food safety are based on risk analysis.</p>

	<p>These principles should assist Member Governments in protecting the health of consumers and ensuring fair practices in the food trade by fostering a consistent and proportionate approach to risk analysis for food safety consistent with article 5 of the SPS agreement. They should aim at developing a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.</p>
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Definitions

Either definitions consistent with the Codex Procedural Manual or reference to the manual.

Scope

As mentioned above Australia would suggest a separate section on Scope be included, if the Committee sees necessary to include a scope and objective. Suggested wording for the scope could be:

These principles for risk analysis for food safety are intended to assist governments in the consistent application of risk analysis to food safety and human health aspects of domestic and imported food.

General Principles of Risk Analysis

Overarching principles for all parts of risk analysis, which do not have to be repeated within each section. Members suggested statements of principle related to:

- Structured Approach: Three integral components and their interrelationships
- Scientific basis of risk analysis
- Systematic methodology
- Objective application of risk analysis
- Transparency
- Documentation
- Treatment of scientific uncertainty
- Iterative process
- Consultation / Interaction
- Information Exchange among countries
- Consideration of Codex Standards
- Consistency in application
- Measures adopted by countries based on risk analysis
- Unjustified barriers to trade avoidance
- Continuing process (on-going monitoring and review)
- Maintain confidentiality, where necessary

There may be other principles or it may be possible to consolidate some of these into a smaller set of principles. **Australia agrees with this comment.**

Risk Analysis Framework

Australia considers that this section relates primarily to what are associated as “Risk Management Activities” and would suggest changing the title of the section accordingly

~~PRELIMINARY RISK ASSESSMENT~~ MANAGEMENT ACTIVITIES

~~Guidance on~~Reference to:

- risk assessment policy
- Establishing a risk profile (especially at the national level)
- Priority setting for risk assessments and for risk management
- Modes of interaction between risk assessors and managers
- Selection ~~criteria for~~ of risk assessors (**Australia would change this to read “selection of risk assessors” to define criteria that could impinge on the recruitment practices of member governments**).
- ~~Peer-Monitoring and~~ review policies

There may be other aspects for which guidance is needed. Also, some of these topics may be covered in other sections (Introduction?). **Australia considers that these topics should not be covered in the**

Introduction but the working group does need to consider appropriate level of detail and cross-refer to existing documents as appropriate.

RISK ASSESSMENT

Guidance on the implementation of risk assessment, addressing areas such as:

- The question that the risk assessment is expected to answer
- Hazard identification – the problem associated with the food and the type of food
- Hazard characterization – the adverse effects
- Exposure Assessment – probability of consumption
 - Realistic exposure scenarios
 - Nationally appropriate intake data
 - Nationally appropriate food composition data
- Risk Characterization – the risk to the population
 - Appropriate population groups
- Scientific data:
 - Sources, **using nationally relevant data**
 - Use of animal models for assessing toxicological endpoints
 - Quality
 - Treatment of scientific uncertainty throughout risk assessment

RISK MANAGEMENT

- **The question that is to be answered by the risk assessment**
- Explanation of the purpose of risk management
- Discussion of risk management tools available to national governments
- Guidance on selection of risk management options
- Discussion of the influence of scientific uncertainty on selection of risk management option
 - Selection of provisional measures
 - Reasonable period of time for review
- Guidance on adapting Codex recommendations and guidance at the national level
- **Guidance on food control emergency procedures (this could be by reference to existing CCFICS text CAC/GL19-1995, Rev. 1-2004 Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations)**
- ~~Discussion of the need~~ **obligation of member countries to consider** recognition of Equivalence **(reference to existing CCFICS texts CAC/GL 34-1999 and CAC/GL 53-2003)**
- Guidance on consideration of other factors at the national level
 - Economic factors
 - Cost/benefit analysis
 - Relative cost effectiveness of alternatives to limiting risk
 - Feasibility of alternative actions
 - Production methods – throughout the entire food chain
 - Existing storage, transport and handling practices
 - Regulatory controls
 - Availability of methods of analysis, sampling capabilities, inspection resources
 - Feasibility of enforcement
 - ~~Traditional uses of the food~~
 - **Traditional end-uses of the foods ie production, processing and consumer practices**
 - ~~Environmental and ecological considerations~~
 - Societal issues [**needs clarification?**]**What is meant by societal issues would require greater clarity if it is to be included.**
 - Ethical considerations

RISK COMMUNICATION

- Discussion of the ~~difference between~~ **importance of risk communication in Codex and at the national and international levels**
- Practical aspects of communication
- Involvement of stakeholders
- Exchange of information among stakeholders

- Importance of clear communication ~~and proper perspective~~ **and keeping it in perspective proportionate to the risk**

MONITORING AND REVIEW

Unlike Codex, national governments implement risk management measures. The ~~Drafting~~ **Working** Group should consider a section on enforcement, monitoring of implementation and review of the impact of risk management decisions.

Appendix 1. National Environment for Management of Food Safety

Consideration of:

- Consistency of approach at the national level in relation to food safety issues for both domestic and imported product
- Adequate, transparent and clearly defined legislation to support food safety processes
- National capability, i.e. infrastructure available to support, implement and monitor risk analysis processes, including timeliness of response and of review
- Mechanisms for the recognition of the food safety control systems of other countries
- Sovereignty vis-à-vis Harmonization [~~not needed? already addressed by WTO Agreement~~]**Australia considers that this is an issue that lies more within the context of the World Trade Organization than with Codex.**

Appendix 2. International Environment for Management of Food Safety

Consideration of:

- Existing Codex guidance
- Other international risk assessments that may be available (i.e. outcomes of FAO and WHO Expert Consultations)
- Recognition of member governments' obligations under other international treaties or agreements (e.g. WTO obligations).

Malaysia

General comments

Malaysia is generally agreeable to the format and content of the proposed outline.

Specific comments

Introduction

Malaysia is agreeable to the proposed contents. We propose an editorial correction to the last word of the second paragraph to read "models".

Definitions

Malaysia would like to seek clarification on whether the document once adopted would appear in the Procedural Manual or as a separate document. If the latter is the case, we propose that the definitions appear in the document so that the document is stand-alone.

General Principles of Risk Analysis

Malaysia is agreeable that the overarching principles for all parts of risk analysis should not have to be repeated within each section.

In line with our earlier comments, Malaysia proposes to add another bullet point to the elements for this section as follows:

- "Maintain scientific integrity and reduce conflict of interest through functional separation between risk assessors and risk managers"

Risk Analysis Framework

Risk Management

Malaysia proposes that the principles on preliminary risk management activities should be included i.e. 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, and consideration of the result of risk assessment.

These activities need to be undertaken before any decision is made to undertake risk assessment.

RISK ASSESSMENT

In terms of scientific data, Malaysia proposes to provide an alternative to the use of animal models for assessing toxicological end i.e. computer modeling in view that the use of animal models for assessing toxicological endpoints is not feasible in terms of its implementation by developing countries. Hence, the bullet on scientific data will now read as follows:

- “Scientific data:
 - Sources
 - Use of animal models for assessing toxicological endpoints or computer modelling
 - Quality
 - Treatment of scientific uncertainty through risk assessment

Malaysia notes that there is an editorial correction at the second indented bullet of the fourth main bullet on Exposure Assessment. The word “date” should be amended to read “data”.

RISK MANAGEMENT

Malaysia proposes the following comments:

- i. Regarding the bullet on “Guidance on consideration of other factors at the national level, Malaysia has concerns on the inclusion of the points “Environmental and ecological considerations”, “societal issues” and “ethical considerations” as these are not relevant to food safety and proposes deletion of these points;
- ii. To insert the words “, including traditional practices” after the words “Existing storage, transport and handling practices” to take into account the practices of small and medium scale enterprises at the national level;
- iii. To insert another bullet point after the bullet point “Feasibility of alternative actions” in view that this is one of the factors that would contribute to the decision making process as follows:
 - Prevalence of specific adverse health effects”
- iv. That the indent “Traditional usage of the food” appears as a separate bullet point under “Guidance on consideration of other factors at the national level”. This factor is not as part of regulatory control. Examples of traditional uses of food is in cases where the food has been traditionally and culturally accepted, and has not been associated with any health hazard.

Morocco

GENERAL COMMENTS

The Codex Alimentarius being the food safety international organization recognized by the SPS Agreement, Morocco deems paramount that the Codex develop risk analysis guidelines to help governments implement a risk analysis policy to protect consumer health and to fulfil their obligations arising from the WTO Agreement, particularly Article 5.1 of the SPS Agreement. The objective is to develop an internationally accepted system for assessing food safety, able to protect consumer health and to promote fair trade practices.

To that effect, Morocco believes that said project should be further developed for the following reasons:

- The international significance of the document and its related guidelines, based on Article 5.1 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
- The development of guidelines covering all risk analysis components would help governments implement measures in an objective and appropriate manner.
- The need for government-oriented principles for coherent risk analysis implementation, in both developing and developed countries.

- The objective and scope of the FAO/WHO Manual are intended as educational and basic training tools, not as guidelines.
- Obstacles encountered by countries in regards to the implementation of risk analysis.

SCOPE:

Morocco proposes the following wording for added clarity and accuracy:

1. Taking into account the purpose of the Codex Alimentarius Commission, this document seeks to provide working principles to conduct risk analysis in regards to food safety issues, as guidelines intended for government use.

2. The overall objective of these principles is to.....so that the various aspects of their measures and their recommendations.....[and for health].

And taking into account that:

- Recommendations could be considered as optionally applicable.
- Protecting consumer health is an objective already covered in Paragraph 1.

OTHER ITEMS TO BE INCLUDED IN THE DOCUMENT:

- Risk Analysis – General Aspects:

3bis. Risk Analysis is an integral part of all activities undertaken by the Codex Alimentarius Commission. The Commission agreed that Risk Analysis included three components: assessment, management, and communication.

7.bis. Conclusions of the risk analysis process should be presented to the general population as well as to target groups and the private sector in order to prevent or reduce food-related risks through voluntary or mandatory measures.

- Risk Assessment Policy:

Move paragraph 13 to the “Risk Management” Section and add the following paragraph:

13bis. Decisions pertaining to risk management lie with legislative and political authorities.

- Risk Assessment:

To cover each and every step of the food chain, the following boldface words should be added to paragraph 18.

18. Risk assessment....., including production, **treatment**, processing, transport, storage, **marketing** and handling processes,....

New Zealand

New Zealand regrets the delay in submitting comments on the draft outline and would appreciate if the following comments could be taken into account in any further revision of the document.

NZ agrees with the proposed outline.

NZ would like to see clarity around Section V. At the moment, it is an amalgam of the components of risk analysis (risk assessment, risk management and risk communication) and the components of the risk management framework (RMF).

At the national level, a clear presentation of the process by which risk analysis is applied i.e. the RMF, is essential. The four steps are as agreed by FAO/WHO and Codex: preliminary risk management activities, identification and selection of risk management options, implementation, and monitoring and review. Stepping through this process allows the short-term application (e.g. qualitative risk assessment and more rapid action) and longer-term application (e.g. quantitative risk assessment and risk-based controls) of risk analysis at the national level to be clearly shown. It also clearly illustrates the differences between Codex and national governments – the former not doing the last two steps in the RMF.

Another fundamental issue is - what constitutes a risk management option? It is NZ’s view that basic food hygiene activities are prerequisites and constitute the platform for more targeted, risk-based measures. They

are fundamental to any food control programme – risk-based or otherwise – and should not clutter an understanding of risk analysis.

A clear description of “who does what” should emerge from the guidelines.

We strongly support the section on National Environment for Risk Management and would like to see a subsection on establishment of public health (and other) goals that drive application of the RMF process. These can obviously take a number of forms. We would also like to see this section after Principles rather than later in the paper.

New Zealand looks forward to the further development of this important item of work.

Thailand

We do appreciate your efforts in preparing the outline of the Working Principle which forms an excellent working basis and welcome your Proposed Outline. However, we would like to propose some specific comments as follows:

1. Objective / Scope

We would like to propose the following objectives:

“The purpose of these Principles is to provide guidance to governments on application of risk analysis principles for food safety.

The overall objective of risk analysis applied to food safety is to protecting the health of consumers and ensuring fair practices in food trade”

2. General Principles of Risk Analysis

The general principles should include the issue on “evaluated and reviewed in the light of newly generated scientific data”

3. Risk Assessment

The issue on the report of the risk assessment should be added to indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions as addressed in paragraph 20 of the Proposed Draft Principles of Risk Analysis for Food Safety

4. Risk Management

This section should also include the recommendation on who should involve in the risk management process.

5. Risk Communication

The issue on confidentiality of commercial and industrial information should be added if this issue is not yet intended to be included in one of the subsection under this topic.

European Community

The European Community and its 25 Member States (ECMS) are grateful to the delegation of the United States of America for their synthesis of the comments submitted in response to CL 2005/17-GP. The ECMS appreciate the opportunity to comment on the outline, a statement of objective and the elements in the outline.

The ECMS suggest that a consistent Codex terminology be used throughout the document, taking into account the latest amendments to the Rules of Procedure, which have widened the previous definition of Codex Members by recognizing the full membership of Regional Economic Intregation Organisation (REIO) [Rule II – Procedural Manual (14th Edition) p. 6], alongside Member Nations [Rule I]. They suggest a more uniform terminology, using the phrase “[Codex] Member(s)”, instead of the various terms “country/ies”, “government(s)”, “national”, “national & regional”.

The ECMS note a good degree of agreement on the objective and scope of the proposed document. Based on the comments submitted the ECMS propose that these comment could be consolidated into the following:

Objective/scope

These principles are intended:

- to provide guidance to Codex Members on the conduct of risk analysis in the context of food safety and to assist decision making to protect the health of consumers and ensure fair practices in the food trade;
- to foster a consistent and proportionate approach to risk analysis for food safety consistent with Article 5 of the SPS agreement; and
- to develop a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.

These principles:

- complement current documentation (e.g. Codex Committees’ guidance on risk analysis, FAO/WHO manual on risk analysis); and
- reflect the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius as published in the Procedural Manual.

The ECMS broadly agree with the headings in the proposed outline but offer the following suggestions to further clarify the document.

Proposed Outline

I. Introduction

II. Objective/Scope

III. Definitions

IV. General Principles of Risk Analysis

V. Risk Analysis Framework

V(A). PRELIMINARY RISK ASSESSMENT ACTIVITIES

V(B) RISK ASSESSMENT

V(C). RISK MANAGEMENT

V(D). RISK COMMUNICATION

V(E). MONITORING AND REVIEW

APPENDIX 1: Environment for Management of Food Safety at Codex Members’ Level

APPENDIX 2: International Environment for Management of Food Safety

Introduction

It is proposed that this introductory section provide general information on the benefits of applying risk analysis for setting food safety standards at Codex Members’ level and on the obligations related to the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

~~–and acknowledge the challenges (e.g., expertise and data requirements) that maybe faced in implementing it, particularly by developing countries.~~

This section should also refer to the need for adequate support to Codex Members and appropriate infrastructure.

The challenges in implementing risk analysis (e.g., expertise and data requirements) that maybe faced, particularly by developing countries, should also be highlighted.

This section could also include a diagram of the risk analysis process, description of the process of iteration, and discussion of the advantages and disadvantages of various techniques and ~~models~~-models. [A diagram could be useful but we think it would be better placed in an Annex rather than in the introduction]

Objective/Scope

A concise statement of the objective/scope, guided by member suggestions (below):

Member	
Australia	To provide guidance to governments on application of risk analysis principles for food safety and health-related decision making at the national level that:

	<p>- complements current documentation (e.g. Codex Committees' guidance on risk analysis, FAO/WHO manual on risk analysis).</p> <p>-reflects the <i>Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius</i> as published in the Procedural Manual.</p>
Canada	To provide guidance to Codex Member governments on the conduct of risk analysis in the context of food safety.
Japan	<p>7. These principles for risk analysis are intended for application by governments with the primary purpose of protecting the health of consumers.</p> <p>8. The objective of the principles is to provide a framework to member governments, so that their decision-making for food safety is based on risk analysis.</p> <p>9. The principles are intended to serve as common basis for risk analysis by governments and help member governments conduct their own risk analysis in a more consistent manner.”</p>
Malaysia	<p>The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety as guidance to governments.”</p> <p>The overall objective of risk analysis applied to food safety is to ensure public health protection.”</p>
Zimbabwe	There is need to specify situations/ instances where risk analysis could be carried out e.g. Risk analysis should be carried out where a country/government suspects a food product to pause a health threat to consumers etc. This will help to clarify the concept to those not familiar with it.
EC	<p>These principles for risk analysis are intended for application by Codex Members.</p> <p>The objective of these working principles should be to provide guidance to the relevant competent authorities that their decisions, measures and recommendations related to food safety are based on risk analysis.</p> <p>These principles should assist Codex Members in protecting the health of consumers and ensuring fair practices in the food trade by fostering a consistent and proportionate approach to risk analysis for food safety consistent with article 5 of the SPS agreement. They should aim at developing a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.</p>

The main objective of risk analysis is to enhance the scientific basis of regulatory decisions.

Definitions

Either definitions consistent with the Codex Procedural Manual or reference to the manual. [For ease of reference, we think the relevant definitions should be repeated in this section]

General Principles of Risk Analysis

Overarching principles for all parts of risk analysis, which do not have to be repeated within each section. Members suggested statements of principle related to:

- Structured approach: three integral components and their interrelationships
- Scientific basis of risk analysis
- Systematic methodology
- Objective application of risk analysis
- Transparency, objectivity, excellency and independence
- Documentation, including documenting the basis for decisions
- Provisional measures taken in case ~~Treatment~~ of scientific uncertainty
- Other relevant legitimate factors
- Iterative process [The difference with the “*Continuing process*” mentioned below (next but last bullet) would need to be clarified]
- Consultation / interaction

- Information exchange among countries
- Consideration of Codex Standards and related texts
- Consistency in application
- Measures adopted by countries based on risk analysis
- Avoidance of unjustified barriers to trade
- Continuing process (on-going monitoring and review)
- Protection of confidentiality, where necessary

There may be other principles or it may be possible to consolidate some of these into a smaller set of principles.

Risk Analysis Framework

PRELIMINARY RISK ASSESSMENT ACTIVITIES

Guidance on:

- Risk assessment Policy
- Establishing a risk profile (especially at the national, or regional, level)
- Priority setting for risk assessments ~~and for risk management~~
- Modes of interaction between risk assessors and managers
- Selection criteria for risk assessors
- Peer review policies

There may be other aspects for which guidance is needed. Also, some of these topics may be covered in other sections (Introduction?).

RISK ASSESSMENT

Guidance on the implementation of risk assessment, addressing areas such as:

- The question that the risk assessment is expected to answer
- The importance of asking risk assessors the right questions
- Hazard identification – the problem associated with the food and the type of food
 - Compound/product/pathogen characterisation
 - Safety data – species, route
 - Assumptions made, data/knowledge gaps and the action that might be taken to address them
 - Factors affecting safety – processing, sources of contamination in supply chain, storage
- Hazard characterization – the adverse effects (including long term effects)
 - Dose-response relationships: NOAEL/BMDL
 - Acceptable level of exposure
 - TDI/ADI
 - Genotoxic carcinogens ALARP
- Exposure assessment – probability of consumption
 - Identification of all the sources of contamination
 - Realistic exposure scenarios
 - Range and levels found in food
 - Frequency of consumption
 - Nationally appropriate intake data
 - Intake data by age, sex, susceptible/high risk groups
 - Nationally appropriate food composition data
 - Exposure mitigation/reduction (possible measures)
- Risk characterization – the risk to the population
 - Appropriate population groups
 - Identification of key risk(s)
 - Margin of exposure
 - Uncertainties
- Scientific data:
 - Sources
 - Use of animal models for assessing toxicological endpoints
 - Quality
 - Ensuring data are sufficiently representative
 - Treatment of variability and scientific uncertainty, including limitations on the quality of the available data and lack of knowledge throughout risk assessment

- Identifying data needed to refine risk assessment

RISK MANAGEMENT

- Explanation of the purpose of risk management
- Discussion of risk management Tools available to Codex Members
- Guidance on the selection of risk management options
- Discussion of the influence of scientific uncertainty on selection of risk management option
 - Selection of provisional measures
 - Reasonable period of time for review
- Guidance on adapting Codex recommendations ~~and guidance~~ at Codex Members' level
- Discussion of the need to recognize equivalence
- Guidance on the consideration of other factors at Codex Members' level
 - Economic factors
 - Cost-benefit analysis
 - Relative cost effectiveness of alternatives to limiting risk
 - Feasibility of alternative actions
 - Production methods – throughout the entire food chain
 - Existing storage, transport and handling practices
 - Regulatory controls
 - Availability of methods of analysis, sampling capabilities, inspection resources
 - Feasibility of enforcement
 - Traditional uses of the food
 - Environmental and ecological considerations
 - Societal issues
 - Ethical considerations

RISK COMMUNICATION

- Discussion of the difference between risk communication in Codex and at Codex Members' level
- Communication - an iterative process
- Practical aspects of communication
 - Why?
 - What? – findings, what do they mean, what needs to be done
 - Who?
 - When?
 - Where?
- Involvement of stakeholders
- Exchange of information among stakeholders
- Importance of clear communication and proper perspective
- Provide practical advice
- Provide timely updates and advice if the evidence changes

MONITORING AND REVIEW

Unlike Codex, Members not only formulate but also implement risk management measures. The Drafting Group should consider a section on enforcement, monitoring of implementation and review of the impact of risk management decisions.

Environment for Management of Food Safety at Codex Members' level

Consideration of:

- Consistency of approaches at Codex Members' level in relation to food safety issues for both domestic and imported product
- Adequate, transparent and clearly defined legislation to support food safety processes
- Comprehensive and effective implementation of Good Practices.
- Codex Members' capability, i.e. infrastructure available to support, implement and monitor risk analysis processes, including timeliness of response and of review
- Mechanisms for the recognition of the food safety control systems of other Codex Members ~~countries~~

- Sovereignty versus harmonization

International Environment for Management of Food Safety

Consideration of:

- Existing Codex guidance
- Other international risk assessments that may be available (i.e. outcomes of FAO and WHO Expert Consultations)
- Recognition of Codex Members' obligations under other international treaties or agreements (e.g. WTO obligations).

Consumer International

Introduction

Consumers International (CI) represents 234 consumer organisation members in 113 countries around the world. We welcome this opportunity to comment on the draft outline to take forward work on Working Principles for Risk Analysis for Food Safety, as they relate to national governments.

These Principles are essential for consumer protection and it is unfortunate that work on them is taking so long. We welcome the efforts to come forward with a new draft and hope that governments can now agree to make some progress based on public health considerations over trade protection issues.

I Introduction

We agree that this should provide general information on the benefits and challenges that may be faced when applying risk analysis at the national level. Reference to scientific uncertainty should also be included here.

II Objective/ Scope

As stated in the government comments, this section should state clearly that the Principles are for application at the national level and that the overriding objective of risk analysis is the protection of the health of consumers. We believe that reference should be made to food safety and other health-related risks. The Principles should reflect the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

III Definitions

No comments.

IV General Principles of Risk Analysis

This section must also include reference to the application of precaution and to the role of 'other factors'. We suggest that 'Consultation/ Interaction' is changed to 'Involvement of all interested parties'.

V Risk analysis framework

V(a) Preliminary Risk Assessment Activities

As well as modes of interaction between risk assessors and risk managers, this section should include modes of interaction between all interested parties. It should also consider how the issue to be addressed is framed and what the question is that needs to be answered (within risk assessment policy).

It should also set out the modes of operation for risk assessors as well as their selection, for example: how to ensure the credibility and independence of the process; procedures to ensure openness of the process; ensuring a multi-disciplinary approach; public declaration of any potential conflict of interests; and how to take account of minority scientific opinion (which may not turn out to be minority in the longer term).

V(b) Risk assessment

In addition to the areas set out, it is important to look at how 'on the ground' practicalities are taken into account. Risk assessors need, for example, to be aware of any issues around implementation and enforcement that may impact on the risk assessment.

We suggest that the bullet point under 'Risk characterisation – the risk to the population' is amended to read:

'Appropriate *and vulnerable* population groups'

V(c) Risk management

The section discussing the influence of scientific uncertainty on selection of the risk management options, must address the issue of the application of precaution. The section on ‘selection of provisional measures’ does not adequately cover this. ‘Precaution’ reflects the need to take action in order to prevent a risk when there may not be a full understanding of its nature or magnitude.

This section should also set out how and when to involve interested parties/ stakeholders in the risk management process. It should also provide guidance on the role of risk managers after a product has come onto the market – for example, the need for traceability to be in place or for measures to enable post-market monitoring.

We agree that it is important that this section includes guidance on the consideration of ‘other factors’, such as environmental, societal and ethical aspects, at the national level.

V(d) Risk communication

It is important that this section explains the importance of two-way risk communication throughout the risk analysis process. It is also important that when looking at the ‘Importance of clear communication and proper perspective’ that it gives guidance on how individual risks can be put into a broader context. It should also provide guidance on the communication of scientific uncertainty to the public.

V (e) Monitoring and review

We agree that it is important that this is included.

Appendix I: National environment for management of food safety

As well as the areas identified, this section should include guidance on the importance of ensuring the independence of the risk analysis process and of food controls and inspection more generally. It should also emphasise the importance of putting public health and consumer interests first and should stress the value of multi-disciplinary working.

Appendix II: International environment for management of food safety

If reference is to be made to the policies and agreements adopted by other international organisations, it is important that this is a comprehensive list of all relevant agreements or treaties that are relevant to food safety considerations.

International Institute of Refrigeration

Generally speaking, the IIR supports the proposed draft outline on Working Principles for Risk Analysis, as it relates to “cold chain” training and operation.

This being said, Risk Analysis must be twofold:

- Consumer-oriented item/food safety hazards
- Mean-related hazards – material/energy – operating safety and environmental constraints – climate and logistics.

The timeframe must be taken into account in regards to cold chain breakdown and overall risks.

As for the item pertaining to risk communication (V[d]), determining “risk perception” of both producers and consumers would be valuable.

In regards to “legitimate” factors, the IIR is well aware of the issue and has been studying it with the help of member countries.

Finally, we support the position of the European Commission:

- particularly in regards to the “Precautionary Principle” and the definition of key words (translation issues).

49th Parallel Biotechnology Consortium

The 49th Parallel Biotechnology Consortium is pleased to respond to the Co-Chair’s Draft Proposed Outline, as circulated by email on 8 September. While we appreciate that much work has gone into the process so far, we find a number of places where changes or improvements can be made; we offer the comments below as a contribution to this process.

At the outset, we should re-iterate our strong view that **the existing Risk Analysis Principles for use within Codex should be the template we follow**. There seems to be no plausible policy reason to claim that a

distinctive policy is needed for governmental risk assessments. Any accommodations necessary should be accomplished by appropriately amending the text of the document already adopted.

General Principles of Risk Analysis

- Risk Analysis, as the term is used in Codex, has three components: risk assessment, risk management, and risk communication. The last two are *clearly not “scientific”*; therefore, **the draft’s second bullet is inaccurate.**

In addition, it is our view that even the risk assessment module itself is *not wholly scientific* for reasons we have previously stated—there are subjective elements in: the definition of what is a “hazard” (ie, undesirable); how to actually measure a hazard, especially if it combines different aspects not subject to a single metric; how to account for incomplete knowledge, uncertainty, etc. in the nature/consequences of the hazard as well as its probability; who has the burden of proof of developing the necessary data; how to account for the social distribution of risk, since hazards impact different sectors/classes in society differently; how to discount future events in light of present actions; how to monitor a risk, and how much surveillance is “worth” in both monetary and non-monetary terms; and how to balance risks against “benefits“, since benefits involve all the above factors as well.

- Is there only one “systematic methodology” (third bullet)?
- What is the meaning of “objective application” of risk assessment (4th bullet)? Isn’t this duplicative of “consistency in application” (bullet 12)?
- Bullet 14 is inappropriate and should be eliminated. “Unjustified barriers to trade avoidance” is *subjective* and is **no more a part of risk analysis than is any other socio-economic effect**, desirable or negative, that go unmentioned. As written, it is also unclear grammatically.
- Bullet 16 is also not a general principle as written. Who decides when confidentiality is “necessary”? This is certainly **subjective**, since there are different policy views regarding the desirability of the increased claims that business information is proprietary and must be held in confidence, especially when such claims affect the regulation of public health and safety.

Preliminary Risk Assessment Activities

Is this the same as what the literature calls “defining a hazard”? Shouldn’t we advocate these steps be conducted also for the purported benefits, which are similarly probabilistic?

Risk Assessment

- The second bullet, on hazard identification, should be moved to the section above.
- The Exposure Assessment (4th bullet) needs to be **disaggregated** more finely than just using national statistics. Certain populations are more vulnerable to certain risks. Variables such as age, gender, immune-compromised state, etc. should be examined to see if they are relevant.
- Missing: all assumptions should be flagged, in a transparent manner, so they may be discussed in public participation procedures.

Risk Management

- “Equivalence,” bullet 6, is merely the logical principle of analogy; why should this one mode of reasoning be singled out?
- Bullet 7, “other factors”. Since the literature has well-established that people’s reaction to a given risk depends not only on its probability and severity but also on whether it has been **voluntarily** assumed or involuntarily thrust upon the population, this factor should be noted. Also, covered in the literature is that certain types of risks are “**dread**,” even though their probability or severity may be low. There should also be a sub-bullet on the societal posture re: protection; even the SPS agreement is explicit that a country may decide on a greater or lesser degree of public health protection. Finally, “ethical considerations” (unfortunately listed last) need to be understood as running throughout the other entries.

Risk Communication

- We do not understand what is “the difference” between communication in Codex and at the national level (bullet one). Both need to be comprehensible to non-expert audiences. Is this referring to things such as number of languages, modes of dissemination, etc.?
- “exchange of information” (bullet 4). This should be clearly noted as a two-way street, since members of the public often first alert officials to hazards, know of the actual effects, and play an

important democratic role in determining **what level of risk is acceptable** (the literature's definition of "safe")

Monitoring and Review

We believe that this function also needs to be performed within Codex as well—how else to tell if assumptions and estimates in the face of uncertainties are accurate, if changes need to be made in the analysis, etc. There are important factors omitted from the list in the draft text: monitoring of risk reduction (effectiveness and costs of amelioration), actual damages and claims for compensation, etc.

International Environment for Management of Food Safety

We do not believe that trying to account for member governments' obligations under other treaties is a proper Codex function; it is the prerogative of the national governments themselves, when—and if—they accept Codex guidelines. In particular, the privileging of WTO in the 3rd bullet is inappropriate for several reasons, not the least of which is that **WTO contains no obligations regarding human health**, since it only covers *trade* obligations after a country decides on the level of health protection needed and how to achieve it.

Comments Inserted into Proposed Outline

GENERAL COMMENTS

ARGENTINA

In the past, Argentina has held that the no new Principles on Risk Analysis were needed for application by governments, as scientific principles recommended by FAO/WHO Expert Groups are still valid, and document “Codex Working Principles for Risk Analysis” was prepared based on them. At the 28th Session of the Codex Alimentarius, manuals on food safety risk analysis² were published. We believe that Manuals of this kind, which – in addition to developing a theory – include practical examples, are – in conjunction with appropriate training – the actual guidance that developing and least developed countries need to successfully undertake work on risk analysis or update their policies and criteria according to new trends in these matters.

Discussions held in the last years show that there is no consensus to make progress on the document on risk analysis principles for application by governments with such characteristics as those of the document prepared by the CCGP Secretariat. Argentina has belonged to the group of countries opposed to the development of a new text. However, contrary to what may be supposed, we understand that it would be extremely useful to have such a document, provided that a Codex standard is not intended to alter the healthy logic established in the WTO Agreement on Sanitary and Phytosanitary Measures (SPS) regarding principles and exceptions; a situation evident in countless discussions since the issue was first discussed in Codex. In particular, Argentina wishes to refer to precaution, which constitutes a clear exception to the principles laid down in the SPS Agreement and the inclusion of which in this document could allow countries to adopt arbitrary, unjustified measures, only with the aim of restricting trade rather than ensuring consumer health protection, for long periods of time. Further, we believe that, given that the adoption of measures needed to ensure consumer health protection is the concern of national authorities, its inclusion in the text is unnecessary, given that this prerogative is a sovereign right of Codex members.

In light of the comments made, Argentina believes that the document should focus on the development of “Principles for Food Safety Risk Assessment”.

AUSTRALIA

In general Australia supports the approach being taken by the United States as the lead of the Working Group. Australia supports the content of the proposed outline.

BRAZIL

Brazil has been presenting its opposition to the elaboration of this document and agrees with the Committee’s conclusion (para 52 – Alinorm 05/28/33A) that there is no consensus on whether to proceed with the Principles in their present form.

Brazil also considers that this work should be interrupted due to the fact that the document already approved by the Commission on Risk Analysis to the Codex system applies also to governments.

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.

CANADA

It is Canada’s view that the outline, as proposed, will result in the development of a document that is more detailed than required, particularly in light of the guidance provided by the FAO/WHO publication on food safety risk analysis. We question whether such detailed guidance can be developed by CCGP in a reasonable timeframe. As we have noted in earlier comments, guidance for governments on the application of risk analysis should be in the form of principles that would provide a framework to assist governments in developing a consistent, systematic approach to risk analysis. Accordingly, we are of the view that Sections

² Food Safety Risk Analysis. Part I: An Overview and Framework Manual. Part II Case Studies. Provisional Edition. FAO/OMS. Roma 2005

IV and V should be combined into one section that addresses principles of risk analysis applicable at the national level.

MALAYSIA

Malaysia is generally agreeable to the format and content of the proposed outline.

MOROCCO

The Codex Alimentarius being the food safety international organization recognized by the SPS Agreement, Morocco deems paramount that the Codex develop risk analysis guidelines to help governments implement a risk analysis policy to protect consumer health and to fulfill their obligations arising from the WTO Agreement, particularly Article 5.1 of the SPS Agreement. The objective is to develop an internationally accepted system for assessing food safety, able to protect consumer health and to promote fair trade practices.

To that effect, Morocco believes that said project should be further developed for the following reasons:

- The international significance of the document and its related guidelines, based on Article 5.1 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).
- The development of guidelines covering all risk analysis components would help governments implement measures in an objective and appropriate manner.
- The need for government-oriented principles for coherent risk analysis implementation, in both developing and developed countries.
- The objective and scope of the FAO/WHO Manual are intended as educational and basic training tools, not as guidelines.
- Obstacles encountered by countries in regards to the implementation of risk analysis.

NEW ZEALAND: A clear description of “who does what” should emerge from the guidelines.

EUROPEAN COMMUNITY

The ECMS suggest that a consistent Codex terminology be used throughout the document, taking into account the latest amendments to the Rules of Procedure, which have widened the previous definition of Codex Members by recognizing the full membership of Regional Economic Integration Organization (REIO) [Rule II – Procedural Manual (14th Edition) p. 6], alongside Member Nations [Rule I]. They suggest a more uniform terminology, using the phrase “[Codex] Member(s)”, instead of the various terms “country/ies”, “government(s)”, “national”, “national & regional”.

CONSUMERS INTERNATIONAL

These principles are essential for consumer protection and it is unfortunate that work on them is taking so long. We welcome the efforts to come forward with a new draft and hope that governments can now agree to make some progress based on public health considerations over trade protection.

International Institute of Refrigeration (IIR)

Risk Analysis must be twofold:

- Consumer-oriented item/food safety hazards
- Mean-related hazards – material/energy – operating safety and environmental constraints – climate and logistics.

The timeframe must take into account cold chain breakdown and overall risks.

49th Parallel Biotechnology Consortium (49P)

At the outset, we should re-iterate our strong view that **the existing Risk Analysis Principles for use within Codex should be the template we follow**. There seems to be no plausible policy reason to claim that a distinctive policy is needed for governmental risk assessments. Any accommodations necessary should be accomplished by appropriately amending the text of the document already adopted.

Introduction

It is proposed this introductory section provide general information on the benefits of applying Risk Analysis for setting food safety standards at the national level, and acknowledge the challenges (e.g., expertise and data requirements) that maybe faced in implementing it, particularly by developing countries. This section should also refer to the need for adequate government support and appropriate infrastructure.

The EUROPEAN COMMUNITY would strike the phrase:

~~–and acknowledge the challenges (e.g., expertise and data requirements) that maybe faced in implementing it, particularly by developing countries.~~

This section could also include a diagram of the risk analysis process, description of the process of iteration, and discussion of the advantages and disadvantages of various techniques and models.

EUROPEAN COMMUNITY

A diagram could be useful but we think it would be better placed in an Annex rather than in the introduction

AUSTRALIA

In view of the advantages and disadvantages of various techniques and models.

CANADA suggests that the introduction should also reference current FAO/WHO publications and Codex Alimentarius texts that are relevant to risk analysis.

CONSUMERS INTERNATIONAL

We agree that this should provide general information on the benefits and challenges that may be faced when applying risk analysis at the national level. Reference to scientific uncertainty should also be included here.

Objective/Scope

A concise statement of the objective/scope, guided by member suggestions (below):

Member	
Australia	To provide guidance to governments on application of risk analysis principles for food safety and health-related decision making at the national level that: <ul style="list-style-type: none"> - complements current documentation (e.g. Codex Committees’ guidance on risk analysis, FAO/WHO manual on risk analysis). -reflects the <i>Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius</i> as published in the Procedural Manual.
Canada	To provide guidance to Codex Member governments on the conduct of risk analysis in the context of food safety.
Japan	10. These principles for risk analysis are intended for application by governments with the primary purpose of protecting the health of consumers. 11. The objective of the principles is to provide a framework to member governments, so that their decision-making for food safety is based on risk analysis. 12. The principles are intended to serve as common basis for risk analysis by governments and help member governments conduct their own risk analysis in a more consistent manner.”
Malaysia	The purpose of these Principles is to provide a framework for the conduct of risk analysis applied to food safety as guidance to governments.” The overall objective of risk analysis applied to food safety is to ensure public health protection.”
Zimbabwe	There is need to specify situations/ instances where risk analysis could be carried out e.g. Risk analysis should be carried out where a country/government suspects a food product to pose a health threat to consumers etc. This will help to clarify the concept to those not familiar with it.
EC	These principles for risk analysis are intended for application by governments. The objective of these working principles should be to provide guidance to the relevant competent authorities that their decisions, measures and recommendations related to food safety are based on risk analysis. These principles should assist Member Governments in protecting the health of consumers and ensuring fair practices in the food trade by fostering a consistent and proportionate approach to risk analysis for food safety consistent with article 5 of the SPS agreement. They should aim at developing a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.

ARGENTINA

Scope:

The document should cover food safety related human health risks.

Objective:

The aim would be to provide a reference framework for governments when taking decisions on food safety based on science.

AUSTRALIA

Australia suggests that, to avoid confusion the term “objective” be used here rather than “scope”. Further, we suggest moving the suggested words below previously suggested by Australia to the introduction section. The wording suggested by Japan could then sit appropriately as the objective.

Scope

As mentioned above Australia would suggest a separate section on Scope be included, if the Committee sees necessary to include a scope and objective. Suggested wording for the scope could be:

These principles for risk analysis for food safety are intended to assist governments in the consistent application of risk analysis to food safety and human health aspects of domestic and imported food.

CANADA agrees that the objective/scope should be in the form of a concise statement. We concur with the common idea in many of the member suggestions regarding the application of risk analysis for food safety and health-related decision-making. While food safety and health decisions based on risk analysis principles can contribute to fair practices in food trade, Canada does not believe that risk analysis is applicable to decisions on fair practices in food trade *per se*. Finally, as interpretation of international agreements is not within the mandate of Codex, references to consistency with Articles of the SPS Agreement should be avoided.

MOROCCO proposes the following wording for added clarity and accuracy:

1. Taking into account the purpose of the Codex Alimentarius Commission, this document seeks to provide working principles to conduct risk analysis in regards to food safety issues, as guidelines intended for government use.

2. The overall objective of these principles is to.....so that the various aspects of their measures ~~and their recommendations.....[and for health].~~

And taking into account that:

Recommendations could be considered as optionally applicable.

Protecting consumer health is an objective already covered in Paragraph 1.

THAILAND

We would like to propose the following objectives:

- The purpose of these Principles is to provide guidance to governments on application of risk analysis principles for food safety.
- The overall objective of risk analysis applied to food safety is to protecting the health of consumers and ensuring fair practices in food trade”

EUROPEAN COMMUNITY

The ECMS note a good degree of agreement on the objective and scope of the proposed document. Based on the comments submitted the ECMS propose that these comment could be consolidated into the following:

Objective/scope

These principles are intended:

- to provide guidance to Codex Members on the conduct of risk analysis in the context of food safety and to assist decision making to protect the health of consumers and ensure fair practices in the food trade;
- to foster a consistent and proportionate approach to risk analysis for food safety consistent with Article 5 of the SPS agreement; and
- to develop a more transparent and predictable environment for international food trade by becoming a reference tool for developing and developed countries.

These principles:

- complement current documentation (e.g. Codex Committees’ guidance on risk analysis, FAO/WHO manual on risk analysis); and
- reflect the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius as published in the Procedural Manual.

CONSUMERS INTERNATIONAL

As stated in the government comments, this section should state clearly that the Principles are for application at the national level and that the overriding objective of risk analysis is the protection of the health of consumers. We believe that reference should be made to food safety and other health-related risks. The Principles should reflect the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Definitions

Either definitions consistent with the Codex Procedural Manual or reference to the manual.

CANADA supports the inclusion of definitions consistent with the Codex Procedural Manual in the document for ease of reference, with the understanding that any amendments to the definitions in the Procedural Manual will require consequent amendments to this document.

MALAYSIA would like to seek clarification on whether the document once adopted would appear in the Procedural Manual or as a separate document. If the latter is the case, we propose that the definitions appear in the document so that the document is stand-alone.

EUROPEAN COMMUNITY

[For ease of reference, we think the relevant definitions should be repeated in this section]

General Principles of Risk Analysis

Overarching principles for all parts of Risk Analysis, which do not have to be repeated within each section. Members suggested statements of principle related to:

- Structured Approach: Three integral components of Risk Analysis and their interrelationships
- Scientific basis of risk analysis

49P

Risk Analysis, as the term is used in Codex, has three components: risk assessment, risk management, and risk communication. The last two are *clearly not “scientific”*; therefore, **the draft’s second bullet is inaccurate**. In addition, it is our view that even the risk assessment module itself is *not wholly scientific* for reasons we have previously stated—there are subjective elements in: the definition of what is a “hazard” (i.e., undesirable); how to actually measure a hazard, especially if it combines different aspects not subject to a single metric; how to account for incomplete knowledge, uncertainty, etc. in the nature/consequences of the hazard as well as its probability; who has the burden of proof of developing the necessary data; how to account for the social distribution of risk, since hazards impact different sectors/classes in society differently; how to discount future events in light of present actions; how to monitor a risk, and how much surveillance is “worth” in both monetary and non-monetary terms; and how to balance risks against “benefits“, since benefits involve all the above factors as well.

- Systematic methodology

MOROCCO adds: Risk Analysis is an integral part of all activities undertaken by the Codex Alimentarius Commission. The Commission agreed that Risk Analysis included three components: assessment, management, and communication.

49P

Is there only one “systematic methodology”?

- Objective application of risk analysis

49P

What is the meaning of “objective application” of risk assessment? Isn’t this duplicative of “consistency in application” (bullet 12)?

- Transparency
- Documentation

MOROCCO adds: Conclusions of the risk analysis process should be presented to the general population as well as to target groups and the private sector in order to prevent or reduce food-related risks through voluntary or mandatory measures.

- Treatment of scientific uncertainty

The **EUROPEAN COMMUNITY** would rewrite this bullet to read:

- Provisional measures taken in case of scientific uncertainty
- Iterative process

EUROPEAN COMMUNITY: [The difference with the “*Continuing process*” mentioned below (next but last bullet) would need to be clarified]

- Consultation / Interaction

CONSUMERS INTERNATIONAL would change this bullet to read:

- Involvement of all interested parties
- Information Exchange among countries
- Consideration of Codex Standards

ARGENTINA: add standards being developed, the results of FAO/WHO Expert Consultations or other international risk assessments.

- Consistency in application
- Measures adopted by countries based on risk analysis
- Unjustified barriers to trade avoidance

49P

This bullet is inappropriate and should be eliminated. “Unjustified barriers to trade avoidance” is *subjective* and is **no more a part of risk analysis than is any other socio-economic effect**, desirable or negative, that goes unmentioned. As written, it is also unclear grammatically.

- Continuing process (on-going monitoring and review)
- Maintain confidentiality, where necessary

49P

This is not a general principle as written. Who decides when confidentiality is “necessary”? This is certainly **subjective**, since there are different policy views regarding the desirability of the increased claims that business information is proprietary and must be held in confidence, especially when such claims affect the regulation of public health and safety.

ARGENTINA: would add Principles considering:

- Use of available scientific evidence;
- Independence;
- Non-discrimination when assessing risks associated with imported and national products;
- Risk assessment shall be conducted under the terms laid down by the risk assessment policy.

CANADA is of the opinion that the above section should be combined with the section below. We suggest that the heading for the new section be **FOOD SAFETY RISK ANALYSIS FRAMEWORK - PRINCIPLES FOR APPLICATION BY NATIONAL GOVERNMENTS**. The combined section should start by identifying general principles of risk analysis. It should then set out the elements of the risk analysis process (sub-sections V (a) through V (e) in the current outline) and identify relevant principles for each. Taking into consideration the “step by step” guidance on risk analysis provided in the FAO/WHO Manual, Canada does not see the need to reproduce that level of detail in this document.

The level of detail proposed in the current outline is the underlying reason for many of Canada’s concerns regarding the sub-sections under Risk Analysis Framework. A more “principle-based” approach to this document would address many of these concerns.

CANADA believes that “general” principles of risk analysis should reflect the broadest sense of the word; i.e., applicable to all the risk analysis components but also concerned with universal rather than particular aspects. As such, we agree that it may be possible to consolidate some of the suggested statements of principles. As well, some of the principles may be best treated within a specific component of risk analysis; e.g., the 11th, 13th and 14th bullets, if retained, may be more appropriately considered under Risk Management.

MALAYSIA proposes to add another bullet point to the elements for this section as follows:

- “Maintain scientific integrity and reduce conflict of interest through functional separation between risk assessors and risk managers”

THAILAND

The general principles should include the following bullet:

- “evaluated and reviewed in the light of newly generated scientific data”

CONSUMERS INTERNATIONAL

This section must also include reference to the application of precaution and to the role of ‘other factors’.

IIR

We support the position of the European Commission: particularly in regards to the “Precautionary Principle” and the definition of key words (translation issues).

Risk Analysis Framework

AUSTRALIA considers that this section relates primarily to what are associated as “Risk Management Activities” and would suggest changing the title of the section accordingly

NEW ZEALAND would like to see clarity around this section. At the moment, it is an amalgam of the components of risk analysis (risk assessment, risk management and risk communication) and the components of the risk management framework (RMF). At the national level, a clear presentation of the process by which risk analysis is applied i.e. the RMF, is essential. The four steps are as agreed by FAO/WHO and Codex: preliminary risk management activities, identification and selection of risk management options, implementation, and monitoring and review. Stepping through this process allows the short-term application (e.g. qualitative risk assessment and more rapid action) and longer-term application (e.g. quantitative risk assessment and risk-based controls) of risk analysis at the national level to be clearly shown. It also clearly illustrates the differences between Codex and national governments – the former not doing the last two steps in the RMF.

PRELIMINARY RISK ASSESSMENT ACTIVITIES

Guidance on:

- Risk Assessment Policy
- Establishing a Risk Profile (especially at the national level)
- Priority setting for Risk Assessments and for risk management

EUROPEAN COMMUNITY: delete the phrase “~~and for risk management~~”

- Modes of interaction between risk assessors and managers

CONSUMERS INTERNATIONAL

As well as modes of interaction between risk assessors and risk managers, his section should include modes of interaction between all interested parties. It should also consider how the issue to be addressed is framed and what the question is that needs to be answered (within risk assessment policy).

- Selection criteria for risk assessors

AUSTRALIA would change this to read “selection of risk assessors” to define criteria that could impinge on the recruitment practices of member governments).

CONSUMERS INTERNATIONAL

It should also set out modes of operation for risk assessors as well as their selection, for example: how to ensure the credibility and independence of the process; procedures to ensure openness of the process; ensuring a multi-disciplinary approach; public declaration of any potential conflict of interests; and how to take account of minority scientific opinion (which may not turn out to be minority in the longer term).

- Peer review policies

AUSTRALIA would change this to read “Monitoring and review policies”

There may be other aspects for which guidance is needed. Also, some of these topics may be covered in other sections (Introduction?).

AUSTRALIA considers that these topics should not be covered in the Introduction but the working group does need to consider appropriate level of detail and cross-refer to existing documents as appropriate.

CANADA agrees with the areas identified in this sub-section but notes that the brief description of each area should fully reflect Codex definitions, where they exist. For example, hazard characterization includes dose-response assessment in addition to an evaluation of the adverse health effects, and exposure assessment addresses the level of hazard that is consumed as well as the probability of consumption. Risk characterization is not only the risk to the population, but could be based on risk to individuals, risk to sub populations, etc.

MOROCCO to the “Risk Management” Section and add the following paragraph:

- Decisions pertaining to risk management lie with legislative and political authorities.

49P

Is this section what the literature calls “defining a hazard”? Shouldn’t we advocate these steps be conducted also for the purported benefits, which are similarly probabilistic?

RISK ASSESSMENT

Guidance on the implementation of risk assessment, addressing areas such as:

- The question that the risk assessment is expected to answer

The **EUROPEAN COMMUNITY** would add the following bullet

- The importance of asking risk assessors the right questions
- Hazard identification – the problem associated with the food and the type of food

The **EUROPEAN COMMUNITY** would add the following sub-bullets

- Compound/product/pathogen characterization
- Safety data – species, route
- Assumptions made, data/knowledge gaps and the action that might be taken to address them
- Factors affecting safety – processing, sources of contamination in supply chain, storage

49P

The bullet on hazard identification should be moved to the section above.

- Hazard characterization – the adverse effects

The **EUROPEAN COMMUNITY** would rewrite this bullet, with added sub-bullets to read:

- Hazard characterization – the adverse effects (including long term effects)
 - Dose-response relationships: NOAEL/BMDL
 - Acceptable level of exposure
 - TDI/ADI
 - Genotoxic carcinogens ALARP

- Exposure Assessment – probability of consumption

The **EUROPEAN COMMUNITY** would add a sub-bullet:

- Identification of all the sources of contamination

49P

Exposure Assessment needs to be **disaggregated** more finely than just using national statistics. Certain populations are more vulnerable to certain risks. Variables such as age, gender, immune-compromised state, etc. should be examined to see if they are relevant.

- Realistic exposure scenarios

The **EUROPEAN COMMUNITY** would add sub-sub-bullets:

- Range and levels found in food
- Frequency of consumption

- Nationally appropriate intake data

The **EUROPEAN COMMUNITY** would add a sub-sub-bullet:

- Intake data by age, sex, susceptible/high risk groups

- Nationally appropriate food composition data

The **EUROPEAN COMMUNITY** would add a sub-bullet:

- Exposure mitigation/reduction (possible measures)

- Risk Characterization – the risk to the population

- Appropriate population groups

The **EUROPEAN COMMUNITY** would add sub-sub-bullets:

- Identification of key risk(s)
- Margin of exposure
- Uncertainties

CONSUMERS INTERNATIONAL would re-write this sub-bullet to read:

- Appropriate and vulnerable population groups
- Scientific data:
 - Sources

AUSTRALIA would add “, using nationally relevant data”

- Use of animal models for assessing toxicological endpoints

MALAYSIA proposes to provide an alternative to the use of animal models for assessing toxicological end i.e. computer modeling in view that the use of animal models for assessing toxicological endpoints is not feasible in terms of its implementation by developing countries. Hence, the bullet would read as follows:

- Use of animal models for assessing toxicological endpoints or computer modeling
 - Quality

The **EUROPEAN COMMUNITY** would add a sub-bullet:

- Ensuring data are sufficiently representative
- Treatment of scientific uncertainty throughout risk assessment

The **EUROPEAN COMMUNITY** would re-write this bullet to read:

- Treatment of variability and scientific uncertainty, including limitations on the quality of the available data and lack of knowledge throughout risk assessment

THAILAND

The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions (as addressed in paragraph 20 of the Proposed Draft Principles of Risk Analysis for Food Safety).

CONSUMERS INTERNATIONAL

In addition to the areas set out, it is important to look at how ‘on the ground’ practicalities are taken into account. Risk assessors need, for example, to be aware of any issues around implementation and enforcement that may impact on the risk assessment.

49P

Add that all assumptions should be flagged, in a transparent manner, so they may be discussed in public participation procedures.

RISK MANAGEMENT

- Explanation of the purpose of Risk Management

AUSTRALIA would add as the first bullet: “The question that is to be answered by the risk assessment”

- Discussion of Risk Management Tools available to national governments

The **EUROPEAN COMMUNITY** would replace all references to “national governments” with the phrase “Codex Members”

- Guidance on selection of risk management options

NEW ZEALAND: Another fundamental issue is - what constitutes a risk management option? It is NZ’s view that basic food hygiene activities are prerequisites and constitute the platform for more targeted, risk-based measures. They are fundamental to any food control programme – risk-based or otherwise – and should not clutter an understanding of risk analysis.

- Discussion of the influence of scientific uncertainty on selection of risk management option
 - Selection of provisional measures
 - Reasonable period of time for review

CONSUMERS INTERNATIONAL

This section must address the application of precaution. The section on ‘selection of provisional measures’ does not adequately cover this. ‘Precaution’ reflects the need to take action in order to prevent a risk when there may not be a full understanding of its nature or magnitude.

- Guidance on adapting Codex recommendations and guidance at the national level

AUSTRALIA would add as the following bullet

- Guidance on food control emergency procedures (this could be by reference to existing CCFICS text CAC/GL19-1995, Rev. 1-2004 *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations*)

The **EUROPEAN COMMUNITY** would re-write this bullet to read:

- Guidance on adapting Codex recommendations at the Codex Members' level
- Discussion of the need to recognize Equivalence

AUSTRALIA would rewrite the above bullet to read: "The obligation of member countries to consider recognition of Equivalence (reference to existing CCFICS texts CAC/GL 34-1999 and CAC/GL 53-2003)"

49P

"Equivalence," is merely the logical principle of analogy; why should this one mode of reasoning be singled out?

- Guidance on consideration of other factors at the national level
 - Economic factors
 - Cost/benefit analysis
 - Relative cost effectiveness of alternatives to limiting risk
 - Feasibility of alternative actions

MALAYSIA proposes to insert another bullet point here in view that this is one of the factors that would contribute to the decision making process as follows:

- "Prevalence of specific adverse health effects"
- Production methods – throughout the entire food chain
 - Existing storage, transport and handling practices

MALAYSIA Proposes to insert the words ", including traditional practices" after the words "Existing storage, transport and handling practices" to take into account the practices of small and medium scale enterprises at the national level;

- Regulatory controls
 - Availability of methods of analysis, sampling capabilities, inspection resources
 - Feasibility of enforcement
 - Traditional uses of the food

AUSTRALIA would rewrite the above sub-bullet to read: "Traditional end-uses of the foods i.e. production, processing and consumer practices"

MALAYSIA: This factor is not as part of regulatory control. Examples of traditional uses of food are in cases where the food has been traditionally and culturally accepted, and has not been associated with any health hazard.

- Environmental and ecological considerations

AUSTRALIA would delete the above bullet

- Societal issues

AUSTRALIA: What is meant by societal issues would require greater clarity if it is to be included.

- Ethical considerations

CANADA is of the opinion that the 3rd and 6th bullets should be combined. Guidance on selection of risk management options must include the concept that different options can provide the same outcome (i.e., the concept of equivalence). However, the process for judgement and recognition of equivalence should not form part of this document.

Regarding the last bullet (guidance on consideration of other factors at the national level), **CANADA** believes that such guidance should be consistent with the mandate of Codex and should reflect, to the degree possible, 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. **CANADA** is of the view that, while Codex may recognize that national governments may choose to address environmental, ecological, societal and ethical considerations in their regulatory frameworks and decisions, it is not within the mandate of Codex to provide specific guidance on these factors.

MALAYSIA has concerns on the inclusion of the points “Environmental and ecological considerations”, “societal issues” and “ethical considerations” as these are not relevant to food safety and proposes deletion of these points.

THAILAND

This section should also include the recommendation on who should be involved in the risk management process.

CONSUMERS INTERNATIONAL

This section should also set out how and when to involve interested parties/stakeholders in the risk management process. It should also provide guidance on the role of risk managers after a product has come into the market – for example, the need for traceability to be in place or for measures to enable post-market monitoring.

IIR

In regards to “legitimate” factors, the IIR is well aware of the issue and has been studying it with the help of member countries.

49P

Since the literature has well-established that people’s reaction to a given risk depends not only on its probability and severity but also on whether it has been **voluntarily** assumed or involuntarily thrust upon the population, this factor should be noted. Also, covered in the literature is that certain types of risks are “**dread,**” even though their probability or severity may be low. There should also be a sub-bullet on the societal posture re: protection; even the SPS agreement is explicit that a country may decide on a greater or lesser degree of public health protection. Finally, “ethical considerations” (unfortunately listed last) need to be understood as running throughout the other entries.

RISK COMMUNICATION

- Discussion of the difference between risk communication in Codex and at the national level

AUSTRALIA would rewrite the bullet to read: “Discussion of importance of risk communication at the national and international levels”

CANADA does not believe that a discussion of the difference between risk communication in Codex and at the national level is necessary for this document. A similar discussion has not been suggested for the other components of risk analysis.

The **EUROPEAN COMMUNITY** changes “national level” to “Codex Members’ level”

The **EUROPEAN COMMUNITY** would add another bullet as follows:

- Communication – an iterative process

49P

We do not understand what is “the difference” between communication in Codex and at the national level. Both need to be comprehensible to non-expert audiences. Is this referring to things such as number of languages, modes of dissemination, etc.?

- Practical aspects of communication

The **EUROPEAN COMMUNITY** would add the following sub-bullets:

- Why?
- What? – findings, what do they mean, what needs to be done
- Who?
- When?
- Where?
- Involvement of stakeholders
- Exchange of information among stakeholders

49P

This should be clearly noted as a two-way street, since members of the public often first alert officials to hazards, know of the actual effects, and play an important democratic role in determining **what level of risk is acceptable** (the literature’s definition of “safe”)

- Importance of clear communication and proper perspective

AUSTRALIA would rewrite the bullet to read: “Importance of clear communication and keeping it in perspective proportionate to the risk”

THAILAND

The issue on confidentiality of commercial and industrial information should be added if this issue is not yet intended to be included in one of the subsection under this topic.

The **EUROPEAN COMMUNITY** would add the following bullets

- Provide practical advice
- Provide timely updates and advice if the evidence changes

CONSUMERS INTERNATIONAL

It is important that this section explains the importance of two-way risk communication throughout the risk analysis process. It is also important that when looking at the ‘importance of clear communication and proper perspective’ that it gives guidance on how individual risks can be put into a broader context. It should also provide guidance on the communication of scientific uncertainty to the public.

IIR

Determining “risk perception” of both producers and consumers would be valuable.

MONITORING AND REVIEW

Unlike Codex, national governments implement risk management measures. The Working Group should consider a section on enforcement, monitoring of implementation and review of the impact of risk management decisions.

MALAYSIA would like to seek clarification on the need to include “enforcement” in this section as we believe this is the sovereign right of member governments. **MALAYSIA** is also of the view that “Monitoring and Review” should be part of risk management and hence it is not necessary to have a separate section on this point.

The **EUROPEAN COMMUNITY** would re-write the first sentence above to read:

Unlike Codex, Members not only formulate but also implement risk management measures.

49P

We believe that this function also needs to be performed within Codex as well—how else to tell if assumptions and estimates in the face of uncertainties are accurate, if changes need to be made in the analysis, etc. There are important factors omitted from the list in the draft text: monitoring of risk reduction (effectiveness and costs of amelioration), actual damages and claims for compensation, etc.

Appendix 1: National Environment for Management of Food Safety

Consideration of:

- Consistency of approach at the national level in relation to food safety issues for both domestic and imported product

The **EUROPEAN COMMUNITY** would change “national” to “Codex Members”

- Adequate, transparent and clearly defined legislation to support food safety processes

The **EUROPEAN COMMUNITY** would add the following bullet:

- Comprehensive and effective implementation of Good Practices
 - National capability, i.e. infrastructure available to support, implement and monitor risk analysis processes, including timeliness of response and of review

The **EUROPEAN COMMUNITY** would change “National” to “Codex Members”

- Mechanisms for the recognition of the food safety control systems of other countries

CANADA suggests deleting this bullet. Mechanisms for the recognition of the food safety control systems of other countries, while valid in the Guidelines for Food Import Control Systems, does not appear to have relevance with respect to risk analysis.

The **EUROPEAN COMMUNITY** would change “national” to “Codex Members”

- Sovereignty vis-à-vis Harmonization

AUSTRALIA considers that this is an issue that lies more within the context of the World Trade Organization than with Codex.

MALAYSIA would like to seek clarification as to the rationale of including these elements in the guidelines including the reference to “Sovereignty vis-à-vis Harmonization”.

NEW ZEALAND: We strongly support the section on National Environment for Risk Management and would like to see a sub-section on establishment of public health (and other) goals that drive application of the RMF process. These can obviously take a number of forms. We would also like to see this section after Principles rather than later in the paper.

CONSUMERS INTERNATIONAL

As well as the areas identified, this section should include guidance on the importance of ensuring the independence of the risk analysis process and of food controls and inspection more generally. It should also emphasize the importance of putting public health and consumer interests first and should stress the value of multi-disciplinary working.

Appendix 2: International Environment for Management of Food Safety

Consideration of:

- Existing Codex guidance
- Other international risk assessments that may be available (i.e. outcomes of FAO and WHO Expert Consultations)
- Recognition of member governments’ obligations under other international treaties or agreements (e.g. WTO obligations).

CONSUMERS INTERNATIONAL

If reference is to be made to the policies and agreements adopted by other international organizations, it is important that this is a comprehensive list of all relevant agreements or treaties that are relevant to food safety considerations.

49P

We do not believe that trying to account for member governments’ obligations under other treaties is a proper Codex function; it is the prerogative of the national governments themselves, when—and if—they accept Codex guidelines. In particular, the privileging of WTO in the 3rd bullet is inappropriate for several reasons, not the least of which is that **WTO contains no obligations regarding human health**, since it only covers *trade* obligations after a country decides on the level of health protection needed and how to achieve it.