

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 3

CX/GP 02/3-Add.3

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX COMMITTEE ON GENERAL PRINCIPLES  
Seventeenth Session  
Paris, France, 15 - 19 April 2002**

**PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS  
GOVERNMENT COMMENTS AT STEP 3  
(United States, Uruguay, European Community)**

## UNITED STATES

In response to CX/GP 02/3, Proposed Draft Working Principles for Risk Analysis, the United States (U.S.) offers the following comments. The comments are based upon the revised text without the marked changes, as presented in Appendix 2.

**Paragraph 2) U.S. Comment:** The purpose of “risk analysis” in Codex is to provide a justifiable analytical and understandable scientific basis for Codex food safety decisions; i.e., decisions by which Codex sets/establishes food standards or related texts. As stated in Article 1 of the Statutes of Codex, the purpose of the standards program is protecting the health of consumers and ensuring fair practices in the food trade. The U.S. would therefore rewrite the paragraph to read:

*The purpose of risk analysis in the Codex Alimentarius Commission (Codex) is to provide a justifiable and understandable scientific basis for Codex food safety decisions by which food standards or related texts are established to protect the health of consumers and ensure fair practices in the food trade.*

**Paragraph 7) U.S. Comment (paragraph 8 in the renumbered U.S. rewrite):** For editorial clarity the U.S. recommends that the phrase “fully and systematically” be moved to in front of “documented”, so that the first sentence of the principle would read:

*The three components of risk analysis should be fully and systematically documented in a transparent manner.*

**Paragraph 9) U.S. Comment (paragraph 5 in the renumbered U.S. rewrite):** The U.S. believes that this is an important principle and should be the first principle in the “Risk Analysis – General Aspects” section. Therefore, we would designate this principle as number 5) and renumber principles 5 through 8 accordingly. Also, the U.S. believes that the wording proposed by New Zealand in the December workshop is superior to the current wording. However, as the U.S. previously commented, Codex does not carry out implementation of risk management decisions. Therefore, the U.S. would rewrite the paragraph to read:

*“The principles of risk analysis should be applied within an overarching framework of strategies and policies for management of foodborne risks to human health. A framework for Codex management of risks should include: risk evaluation, assessment of risk management options, and monitoring and review.”*

**Paragraph 11) U.S. Comment:** The U.S. notes some concern with the wording of this paragraph, and accordingly offers the following minor modifications. First, scientific data are always “incomplete”. The issue raised in the paragraph is particularly focused on situations in which the scientific data are insufficient. The U.S. recommends deleting the phrase “or incomplete” from the paragraph. Second, the phrase “such text” can be considered somewhat vague. The U.S. recommends that the wording be changed to be more explicit by referring to any text developed by Codex. Accordingly, the U.S. would rewrite the paragraph to read:

*When there is evidence that a potentially significant risk to human health exists but scientific data are insufficient to allow a standard to be established, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that any text developed by Codex is supported by the available scientific evidence.*

**Paragraph 12) U.S. Comment:** Codex should elaborate a food safety text, only when there is an identified hazard and the hazard has been characterised. However, any risk management option must take into account the uncertainties in the risk assessment. The final sentence of the paragraph, as currently written, has a potential to confuse hazard characterisation with risk characterisation. The U.S., therefore, proposes to rewrite this sentence to read:

*Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used in the risk assessment should reflect the characteristics of the hazard and the risk management options selected should reflect the degree of uncertainty and the characteristics of the risk.*

**Paragraph 13) U.S. Comment:** The U.S. is concerned that this paragraph, as written, is overly broad and somewhat unmanageable. The U.S. recommends rewriting the paragraph as follows:

*“The needs and situations of developing countries should be taken into account to the extent possible and as appropriate by the responsible bodies in the different stages of the risk analysis process”.*

**Paragraph 16) U.S. Comment:** The U.S. recommends that the word “unbiased” be inserted into the list of words describing the attributes of the risk assessment process.

**RISK ASSESSMENT U.S. Comment:** The U.S. recommends that the asterisk (and corresponding reference) be deleted from the title, as it is redundant with the reference in paragraph 22).

**Paragraph 23) U.S. Comment:** This paragraph indicates that “risk assessment results should be presented in a readily understandable and useful form”. Paragraph 29 indicates that “the results of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable form.” The U.S. believes that this redundancy should be resolved and recommends that the reference to presentation of results should be deleted from this paragraph and covered in Paragraph 29 (see comments below). While the U.S. agrees that risk assessments may take into account qualitative information, such information must be scientifically based. Therefore, the U.S. would rewrite this paragraph to read:

*Risk assessment should use available quantitative information to the greatest extent possible. Risk assessment may also take into account scientific qualitative information.*

**Paragraph 25) U.S. Comment:** The U.S. believes that food production throughout the world is largely through small and medium enterprises and that this introductory phrase is not particularly relevant to the rest of the paragraph. Further, paragraph 12) has already raised the issue of taking into account the needs of developing countries. Therefore, the U.S. recommends that the introductory phrase be deleted. Also, the U.S. notes that epidemiological surveillance data are not always available. Therefore the U.S. would rewrite this paragraph to read:

*Risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, if available, and exposure studies.*

**Paragraph 27) U.S. Comment:** The first sentence of the paragraph refers to “the quality of the risk estimate.” It is difficult to quantify “quality” but outcomes may be measured, therefore, the U.S. proposes that the first sentence be rewritten as follows:

*Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the outcomes of the risk estimate.*

**Paragraph 28) U.S. Comment:** The U.S. recommends that the phrase, “where relevant” be moved from the end of the final sentence to the first of that sentence, to emphasise that all types of studies are not always necessary. The first sentence would be clearer and more simple if it were rewritten to read as follows:

Risk assessments should be based on realistic exposure scenarios, with consideration of the guidelines provided in the risk assessment policy.

**Paragraph 29) U.S. Comment:** The U.S. believes that this paragraph should deal with the presentation of risk assessment results (See comments to Paragraph 23) above). For clarity, reference should be made to “results” of risk assessments rather than to the “conclusions” of risk assessments. Also, the U.S. believes that the results of each step of the risk assessment, as well as the final output, should be conveyed in a readily understandable and useful form. Further, the U.S. recommends that the reference to minority opinions be qualified to indicate that such opinions are not always available or required. In the final sentence, it may not always be possible to “resolve” the impact of uncertainty, but uncertainty must be addressed by risk managers. Therefore, the U.S. would rewrite this paragraph to read:

*The results of each step of a risk assessment, as well as the overall results of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable and useful form. Risk assessors should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and, where appropriate, minority opinions. The responsibility for addressing the impact of uncertainty on the risk management decision lies with the risk managers, not the risk assessors.*

**Paragraph 30) U.S. Comment:** The U.S. notes that the term “formal record” has legal connotations in many countries. The U.S. therefore recommends that the reference be made to a written record.

**Paragraph 31) U.S. Comment:** The U.S. recommends that the word “health” be inserted before the word “protection” in the final sentence to emphasise that Codex is concerned with protecting the health of consumers. Also, in the final sentence, the U.S. questions the phrase, “in different situations”. For example, a naturally occurring contaminant may pose a similar risk to intentionally added substance such as a pesticide residue, yet the risk management options selected may be quite different. The U.S. recommends that the phrase, “in different situations” be deleted. Therefore, the U.S. would rewrite this paragraph to read:

*Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers, while having regard to the promotion of fair practices in the food trade. Unjustified differences in the level of consumer health protection to address similar risks should be avoided.*

**Paragraph 37) U.S. Comment:** The U.S. does not understand the logic of the first sentence. “Transparency and consistency” do not, in and of themselves, necessarily result in the avoidance of unjustified trade barriers. Therefore, the U.S. would recommend that this sentence be deleted. Regarding the third sentence, the U.S. is concerned that this potentially places an unmanageable burden on the Commission. The Commission would have to evaluate the potential degree of “trade restriction” of management options, not knowing how member states will apply measures containing the risk management options. The U.S. would recommend that this sentence be deleted, with an understanding that an assessment of the potential advantages and disadvantages of risk management options would include a consideration of potential trade implications. Costs and benefits of risk management options should be considered within the assessment of potential advantages and disadvantages, and the U.S. believes that cost/benefit analysis should be included within the working principles. Therefore, the U.S. would rewrite this paragraph as follows:

Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages, including costs and benefits.

**Paragraph 38) U.S. Comment:** *The U.S. recommends that the sentences in this paragraph should be reordered to emphasise first flexibility and consumer health protection. In the current second sentence, the U.S. notes that economic consequences cannot outweigh unacceptable risks. Therefore, the U.S. recommends that the sentence be introduced with “as appropriate”. The U.S. considers that the words “in particular” in this sentence put too great an emphasis on developing countries. The principle is applicable to all countries. The U.S. recommends that the sentence be reworded with the phrase “including the impact on developing countries.” Accordingly, the U.S. would rewrite the paragraph as follows:*

Risk management should recognise the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers’ health. As appropriate, risk management should take into account the economic consequences and the feasibility of risk management options, including the impact on developing countries.

**RISK COMMUNICATION U.S. Comment:** This is essentially the first opportunity for member countries to review the working principles regarding “risk communication”. The U.S. finds in our review of this section, that there appears not to be a logical sequence in which the principles are listed and there is redundancy among the principles. For example, Paragraphs 41 and 42 both specify a “major function” of risk communication and the wording needs to be reconciled. Paragraphs 42 and 45 appear to the U.S. to be, for the most part, redundant. Paragraph 43 speaks of “determining” standards and related texts; whereas, the U.S. believes that “establishing” is a better term. The reference to “non-specialists” in Paragraph 44 is, without further explanation, puzzling, and the U.S. believes that “those not directly engaged in the process ...” includes “non-specialists”. Therefore, the U.S. recommends that the term “non-specialist” be deleted. The second part of Paragraph 44 contains goals, which are not technically principles. The U.S. considers these goals to be important and suggests that, even though not “principles” the goals should be included as the first paragraph under “Risk Communication”. Paragraph 45 implies that there is a single risk communication strategy for all of Codex, but there is no indication of who will develop this strategy for Codex. With these specific comments in mind, the U.S. offers the following re-draft of the Risk Communication section for the Committee’s consideration:

40. *The goals of risk communication are to:*

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis process;*
- ii) promote consistency and transparency in formulating risk management options/recommendations;*
- iii) provide a sound basis for understanding the risk management decisions proposed;*
- iv) improve the overall effectiveness and efficiency of the risk analysis process;*
- v) strengthen the working relationships among participants;*
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;*
- vii) promote the appropriate involvement of all interested parties; and*
- viii) exchange information in relation to the concerns of interested parties about the risks associated with food.*

41. *In Codex, risk analysis should include clear, interactive and documented communication, amongst risk assessors (expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and communication with member countries and all interested parties in all aspects of the process.*

42. *A major requirement for risk communication by Codex is establishing a proactive process whereby information and opinion essential to effective risk assessment and risk management is exchanged amongst all interested parties and appropriately considered in the risk analysis process*
43. *Risk communication is more than the dissemination of information. Its major function is to ensure that all information and opinion essential for effective risk management is incorporated into the decision making process. Ongoing reciprocal communication amongst all interested parties is an integral part of the risk analysis process.*
44. *Risk communication should include a transparent explanation of the risk assessment policy and of the impact of uncertainties and assumptions on the risk analysis process. Risk communication should include relevant minority opinions.*
45. *Risk communication with interested parties should include the need for specific standards or related texts, the procedures followed to establish them, and the reasons for selection of specific risk management options.*
46. *The guidance on risk communication in these working principles is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process, including consumers, those involved in the production, manufacture and distribution of food and their representative organisations, and other interested parties.*

## **PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX<sup>1</sup>**

**(As rewritten and renumbered by the United States)**

(suggested changes are underlined)

### **SCOPE**

- 1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
- 2) The purpose of risk analysis in the Codex Alimentarius Commission (Codex) is to provide a justifiable and understandable scientific basis for Codex food safety decisions by which food standards or related texts are established to protect the health of consumers and ensure fair practices in the food trade.
- 3) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
- 4) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies, while the responsibility for risk assessment normally lies with the joint FAO/WHO expert bodies and consultations.

### **RISK ANALYSIS - GENERAL ASPECTS**

5. The principles of risk analysis should be applied within an overarching framework of strategies and policies for management of foodborne risks to human health. A framework for Codex management of risks should include: risk evaluation, assessment of risk management options, and monitoring and review.
6. The risk analysis process used in Codex should be:
  - applied consistently
  - open, transparent and documented
  - conducted in accordance with both the *Statements of Principle Concerning the Role of Science and the Extent to Which Other Factors are Taken into Account* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*

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<sup>1</sup> These principles will be incorporated into the Codex Procedural Manual. These principles should not prejudice the principles of risk analysis for application by governments, which will be addressed in separate Codex guidelines.

7. The risk analysis process should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission<sup>2</sup>, each component being integral to the overall risk analysis process.
8. The three components of risk analysis should be fully and systematically documented in a transparent manner. While respecting legitimate concerns to preserve confidentiality<sup>3</sup>, documentation should be accessible to all interested parties<sup>4</sup>.
9. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis process.
10. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.
11. When there is evidence that a potentially significant risk to human health exists but scientific data are insufficient to allow a standard to be established, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that any text developed by Codex is supported by the available scientific evidence.

Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used in the risk assessment should reflect the characteristics of the hazard and the risk management options selected should reflect the degree of uncertainty and the characteristics of the risk.

12. The needs and situations of developing countries should be taken into account to the extent possible and as appropriate by the responsible bodies in the different stages of the risk analysis process.

### **Risk Assessment Policy**

13. Determination of risk assessment policy should be included as a specific component of risk management.
14. Risk assessment policy consists of documented guidelines for policy choices and related judgements and their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.<sup>5</sup>
15. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.
16. The mandate given by risk managers to risk assessors should be as clear as possible.
17. Where necessary, risk managers should ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

### **RISK ASSESSMENT**

18. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
19. The scope and purpose of the particular risk assessment being carried out should be clearly stated. The output form and possible alternative outputs of the risk assessment should be defined

<sup>2</sup> Definitions of Risk Analysis Terms Related to Food Safety page 48 11<sup>th</sup> Edition Codex Alimentarius Commission Procedural Manual.

<sup>3</sup> A definition should be added at a later stage into the glossary in annex

<sup>4</sup> For the purpose of the present document, “interested parties” are defined as “risk assessors, risk managers, consumers, industry, the academic community and other interested parties and their representative organizations” (see definition of “risk communication” in the Glossary)

<sup>5</sup> This paragraph is also included in the Definitions (Annex 1) and might be deleted later if the Definitions are retained in the final text

20. Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise and experience. Where possible, expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.
21. Risk assessment should be conducted in accordance with the Statements of Principle Relating to the Role of Food Safety Risk Assessment and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterisation, exposure assessment and risk characterisation.
22. Risk assessment should use available quantitative information to the greatest extent possible. Risk assessment may also take into account scientific qualitative information.
23. Risk assessment should take into account all available scientific data and relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.
24. Risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, if available, and exposure studies.
25. Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.
26. Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the outcomes of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
27. Risk assessments should be based on realistic exposure scenarios, with consideration of the guidelines provided in the risk assessment policy. They should include consideration of susceptible and high-risk population groups. Where relevant acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment.
28. The results of each step of a risk assessment, as well as the overall results of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable and useful form. Risk assessors should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and, where appropriate, minority opinions. The responsibility for addressing the impact of uncertainty on the risk management decision lies with the risk managers, not the risk assessors.
29. To ensure a transparent risk assessment, a written record, including a summary, should be prepared and made available to other risk assessors and interested parties so that they can review the assessment.

## **RISK MANAGEMENT**

30. Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers, while having regard to the promotion of fair practices in the food trade. Unjustified differences in the level of consumer health protection to address similar risks should be avoided.
31. Risk management should follow a structured approach including risk evaluation, assessment of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment as appropriate to the circumstances, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*<sup>6</sup>.
32. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

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<sup>6</sup> These criteria have been adopted by the 24<sup>th</sup> Session of the Commission (see Annex 2)

33. The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.
34. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer protection they achieve. The option of not taking any action should also be considered.
35. The outcome of the risk evaluation process should be combined with the assessment of available risk management options in order to reach a decision on management of the risk. In arriving at a decision on risk management, protection of consumers' health should be the primary consideration, with other legitimate factors being considered as appropriate.<sup>7</sup>
36. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages, including costs and benefits.
37. Risk management should recognise the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. As appropriate, risk management should take into account the economic consequences and the feasibility of risk management options, including the impact on developing countries.
38. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

## **RISK COMMUNICATION**

41. The goals of risk communication are to:
  - i) promote awareness and understanding of the specific issues under consideration during the risk analysis process;
  - ii) promote consistency and transparency in formulating risk management options/recommendations;
  - iii) provide a sound basis for understanding the risk management decisions proposed;
  - iv) improve the overall effectiveness and efficiency of the risk analysis process;
  - v) strengthen the working relationships among participants;
  - vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
  - vii) promote the appropriate involvement of all interested parties; and
  - viii) exchange information in relation to the concerns of interested parties about the risks associated with food.
47. In Codex, risk analysis should include clear, interactive and documented communication, amongst risk assessors (expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and communication with member countries and all interested parties in all aspects of the process.
48. A major requirement for risk communication by Codex is establishing a proactive process whereby information and opinion essential to effective risk assessment and risk management is exchanged amongst all interested parties and appropriately considered in the risk analysis process
49. Risk communication is more than the dissemination of information. Its major function is to ensure that all information and opinion essential for effective risk management is incorporated into the decision making process. Ongoing reciprocal communication amongst all interested parties is an integral part of the risk analysis process.

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<sup>7</sup> Joint FAO/WHO Expert Consultation on Risk Management and Food Safety



50. Risk communication should include a transparent explanation of the risk assessment policy and of the impact of uncertainties and assumptions on the risk analysis process. Risk communication should include relevant minority opinions.
51. Risk communication with interested parties should include the need for specific standards or related texts, the procedures followed to establish them, and the reasons for selection of specific risk management options.
52. The guidance on risk communication in these working principles is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process, including consumers, those involved in the production, manufacture and distribution of food and their representative organisations, and other interested parties.

## ANNEX 1

**DEFINITIONS:** No changes

### URUGUAY (English version)

Uruguay considers that the Proposed Draft Working Principles for Risk Analysis is a fundamental document and hopes that it will be finalized rapidly and provide more solid basis for Codex work and discussions and contribute to expedite its international standardization work.

Uruguay wishes to convey to other members its comments concerning the following aspects of the Proposed Draft:

- a) promotion of fair trade practices
- b) Future Proposed Draft Working Principles for Risk Analysis in the framework of Codex with respect to the WTO
- c) the distinction between the concepts of health and safety in paras. 3 and 18
- d) translation into Spanish (Spanish version only)

#### **a) Promotion of Fair Trade Practices**

The Procedural Manual in Article 1 of the Statutes provides that the main purpose of the Joint FAO/WHO Food Standards Programme is "protecting the health of the consumers and ensuring fair practices in the food trade". Although the concepts contained in this double objective have guided the work of Codex since its creation, Uruguay believes that the expression "ensuring fair practices in the food trade" is very ambiguous and vague and should be clarified, especially in the framework of the present Proposed Draft Working Principles for Risk Analysis and taking into account the role of Codex with respect to the WTO since 1995.

The recent adoption by the Commission of the Criteria to take into account "other factors" referred to in the *Second Statement of Principle* represented a fundamental step to facilitate Codex discussions and work, but at this stage it is necessary to move towards a clear definition of what is meant by "fair practices in the food trade". Firstly in order to avoid erroneous interpretations and deviations in the application of standards and related texts and to prevent Codex work to be blocked and delayed in some cases. Secondly because it will not be possible to progress further with the *Principles* without an adequate definition of this expression, in order to distinguish clearly what is the prerogative of governments and what is relevant within Codex, especially when considering risk management. Uruguay recalls that the CCGP will consider the elaboration of "Proposed Draft Working Principles for Risk Analysis applicable to governments" in the future.

In our opinion the concept of "ensuring fair practices in the food trade" in the context of Codex includes two substantial components:

**i) To promote a predictable and fair international trade system.**<sup>8</sup> The existence of Codex standards based on science facilitate the process of international harmonization of national food regulations. This harmonization process ensures the predictability of international trade and reduces trade protectionism. This component has a close relationship with the obligations of Codex Members who also are WTO Members.

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<sup>8</sup> It is understood that fair trade exists when the restrictive measures applied are not discriminatory, are duly justified and are strictly necessary to comply with the legitimate objective proposed or the appropriate level of protection to be achieved.

**ii) To protect consumers from misleading practices.** This objective is achieved when general concerns<sup>9</sup> are incorporated into Codex standards (in the framework of its mandate) and standards ensuring adequate consumer information<sup>10</sup> are elaborated.

Perhaps this last aspect (ii) should be discussed and clarified more carefully. What type of information should be provided to consumers? To what extent should their concerns be incorporated into each standard? Should the decisions on these questions be taken on the basis of risk analysis, or on the basis of the values shared by those for whom the standard is intended?

Uruguay is of the view that the international character of Codex limits the consideration of individual concerns expressed by countries or social groups. This limitation should be clearly integrated into the text on risk management in the Proposed Draft Working Principles for Risk Analysis within Codex, in relation to the consideration of other legitimate factors relevant for fair practices in food trade (paras. 30 to 39 of the current version), possibly through the inclusion of a new paragraph after the current para. 30 to reflect this aspect.

It is clear that governments have the sovereign right to resolve these problems, as they judge necessary to address national specificities and to the extent and with the level of specificity required in view of the values and convictions of each society. Notwithstanding, Codex should establish standards with a certain flexibility and according to a "common denominator" based on universally shared concerns, which would not violate the cultural, social and economic diversity (and thereby the diversity of priorities) of its members.

**b) Future "Proposed Draft Working Principles for Risk Analysis in the framework of Codex" with respect to the WTO**

Uruguay understands that as a document intended to orient the work of Codex and not directed to governments, they would not be taken as a reference by the WTO. Consequently we propose that the version adopted by the CAC should include the following preliminary statement: "This text is not intended to be applied by the governments of the Members of the Codex Alimentarius Commission"

**c) Distinction between the concepts of health and safety in paras. 3 and 18**

Uruguay is of the view that the distinction between "health" and "safety" in paras. 3 and 18 of the English version is not correct. Safety and nutrition are the fundamental aspects of health relevant where food is concerned. Uruguay would be opposed to the inclusion of certain aspects such as health claims under the concept of "health". In addition, Uruguay recalls that the mandate of Codex is limited to human health aspects associated with food. The expression "health" in itself includes other aspects that are not exclusively related to food.

The following wording is therefore proposed for these paragraphs:

Para. 3:

The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and nutrition aspects of Codex standards and related texts are based on risk analysis.

Para. 18

Safety and nutrition aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances

**d) Translation into Spanish (Spanish version only)**

**URUGUAY (Versión en español)**

Uruguay entiende que el "Anteproyecto de Principios Prácticos sobre el Análisis de Riesgos aplicables en el Marco del Codex" es un documento fundamental y espera que su pronta culminación provea de bases más firmes para las discusiones y los trabajos del Codex y contribuya a acelerar su tarea de normalización internacional.

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<sup>9</sup> Uruguay believes that specific socio-cultural aspects, such as consumer perception or philosophical or religious convictions should be considered at the national level and not in an international organization such as Codex Alimentarius.

<sup>10</sup> This is for example the work of the CCFL and the work of Commodity Committees as regards the identity and essential quality of foods.

Uruguay desea transmitir a los demás miembros sus observaciones respecto de los siguientes aspectos del Anteproyecto:

- a) La promoción de prácticas equitativas en el comercio (párrafos 2 y 30)
- b) Los futuros “Principios Prácticos sobre el Análisis de Riesgos aplicables en el Marco de Codex” frente a la Organización Mundial del Comercio (OMC)
- c) La distinción entre los conceptos de salud e inocuidad en los párrafos 3 y 18
- d) La traducción al español

**a) La promoción de prácticas equitativas en el comercio (párrafos 2 y 30)**

El Manual de Procedimiento de la CCA, en el artículo 1 de sus Estatutos, establece que el primer doble objetivo de las normas del Programa Conjunto FAO/OMS sobre Normas Alimentarias será “*proteger la salud de los consumidores y asegurar práctica equitativas en el comercio de los alimentos*”<sup>11</sup>. Si bien los conceptos contenidos en ese primer doble objetivo han guiado el trabajo del Codex desde su creación, Uruguay cree que la expresión “*asegurar práctica equitativas en el comercio de los alimentos*” es sumamente ambigua e imprecisa y debe ser aclarada, especialmente en el marco del presente “Anteproyecto de Principios Prácticos sobre el Análisis de Riesgos aplicables en el Marco del Codex” y teniendo en cuenta el rol que le cabe al Codex a partir del año 1995 con respecto a la OMC.

La reciente aprobación por parte de la Comisión de los criterios para tomar en cuenta los “otros factores” mencionados en la 2ª Declaración de Principios constituyó un paso fundamental para facilitar las discusiones y los trabajos en el Codex, pero ahora es necesario avanzar hacia una pronta y clara definición de lo que se entiende por “*prácticas equitativas en el comercio de los alimentos*”. En primer lugar, para evitar interpretaciones erróneas y desviaciones de aplicación de las normas y textos afines del Codex y para prevenir el bloqueo y la dilación de ciertos trabajos del Codex. Y, en segundo lugar, porque mientras no se cuente con una definición adecuada de dicha expresión no se podrá avanzar en estos Principios, deslindando adecuadamente lo que es prerrogativa de los gobiernos de lo que es pertinente en el marco del Codex, especialmente cuando se lleva a cabo la etapa de gestión de riesgos. Uruguay recuerda que el CCPG deberá abordar en el futuro la elaboración de “Principios Prácticos para el Análisis de Riesgos aplicables en el marco de los Gobiernos”.

En nuestra opinión el concepto “*asegurar prácticas equitativas en el comercio de los alimentos*” en el contexto del Codex incluye dos componentes sustanciales:

**i) Propender a un sistema internacional de comercio previsible y justo**<sup>12</sup>. La existencia de normas del Codex basadas en la ciencia favorecen el proceso de armonización internacional de las prescripciones nacionales sobre alimentos. Dicho proceso de armonización dota de previsibilidad al comercio internacional y desalienta el proteccionismo comercial. Este componente tiene estrecha relación con las obligaciones de los miembros del Codex que también son miembros de la OMC.

**ii) Proteger a los consumidores de prácticas que puedan inducir a error.** Este objetivo es logrado cuando se incorporan adecuadamente en las normas del Codex las preocupaciones generales<sup>13</sup> (dentro

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<sup>11</sup> La expresión originaria del inglés “*fair practices in the food trade*” fue traducida al español como “*prácticas equitativas en el comercio de los alimentos*”. Hacemos notar que, según el diccionario de la Real Academia Española, la palabra “equitativo” significa “*Que tiene equidad*” y que “*equidad*” significa “*Igualdad de ánimo. // 2. Bondadosa templanza habitual; propensión a dejarse guiar, o a fallar, por el sentimiento del deber o de la conciencia, más bien que por las prescripciones rigurosas de la justicia o por el texto terminante de la ley. // 3. Justicia natural por oposición a la letra de la ley positiva // 4. Moderación en el precio de las cosas que se compran, o en las condiciones que se estipulan para los contratos.*”.

<sup>12</sup> Se entiende que existe comercio justo cuando las medidas restrictivas aplicadas son no discriminatorias, están debidamente justificadas y son las estrictamente necesarias para lograr el objetivo legítimo propuesto o el nivel adecuado de protección que se desea alcanzar

<sup>13</sup> Uruguay entiende que los aspectos socioculturales particulares, tales como la percepción de los consumidores o sus convicciones filosóficas o religiosas, deben ser objeto de consideración a nivel nacional y no a nivel de una organización internacional como el Codex Alimentarius.

del ámbito de su mandato) y se elaboran normas que aseguran una información apropiada al consumidor<sup>14</sup>.

Quizás este último punto (ii) sea el aspecto que con más cuidado deba aún debatirse y aclararse. Qué tipo de información debe suministrarse al consumidor? En qué grado deben incorporarse sus preocupaciones en cada norma? Las decisiones sobre las interrogantes anteriores deberían tomarse sobre la base de un análisis de riesgos, o más bien sobre la base de los valores compartidos por aquellos a quienes va dirigida la norma?

Uruguay opina que la naturaleza internacional del Codex limita la atención que puede prestar a muchas preocupaciones particulares de países o grupos sociales. Esta limitación debe ser claramente incorporada en el texto correspondiente a la gestión de los riesgos del "Anteproyecto de Principios Prácticos sobre el Análisis de Riesgos aplicables en el Marco del Codex", en relación con la consideración de los otros factores legítimos relacionados con las prácticas equitativas en el comercio (párrafos 30 a 39 de la versión actual), quizás insertando un nuevo párrafo en tal sentido a continuación del actual párrafo 30.

Es claro que los gobiernos tienen la potestad de resolver estas cuestiones soberanamente, de acuerdo a lo que consideren necesario para atender las particularidades nacionales<sup>15</sup> y con la amplitud, el grado de especificidad y los matices que requieran los valores y convicciones de cada sociedad. Sin embargo el Codex debe establecer normas atendiendo a criterios de flexibilidad y según un "mínimo común denominador" basado en preocupaciones universalmente compartidas, que no violenten la multiplicidad cultural, social y económica (por tanto multiplicidad de prioridades) de sus miembros.

**b) Los futuros “Principios Prácticos sobre el Análisis de Riesgos aplicables en el Marco del Codex” en relación con la (OMC)**

Uruguay entiende que, por tratarse de un documento destinado a orientar los trabajos del Codex y no los de los gobiernos, no sería un documento a ser tomado como referencia por la OMC. En consecuencia propone que la versión adoptada por la CCA sea encabezada por la siguiente declaración: "*Este texto no está destinado a ser aplicado por los gobiernos de los miembros de la Comisión del Codex Alimentarius.*"

**c) La diferenciación de los conceptos de salud e inocuidad en los párr. 3 y 18**

Uruguay entiende que la distinción entre "salud" e "inocuidad" en los párrafos 3 y 18 de la versión en inglés no es correcta. Los aspectos de inocuidad y nutrición son los aspectos fundamentales de salud a considerar en los alimentos. Uruguay se opondría a que, dentro del concepto de "salud", se pudieran eventualmente incluir cuestiones relacionadas con las declaraciones de propiedades saludables de ciertos alimentos. Adicionalmente Uruguay recuerda que el mandato del Codex se circunscribe a los aspectos de la salud humana relacionados **con los alimentos**. La expresión salud por sí misma incluye otros aspectos no dependientes exclusivamente de los alimentos.

Se propone, en consecuencia, las siguientes redacciones a dichos párrafos:

Pár. 3: *"El objetivo de estos Principios Prácticos es proporcionar directrices a la Comisión del Codex Alimentarius y a los comités y consultas conjuntas de expertos de la FAO y la OMS, de manera que la inocuidad y los aspectos nutricionales de los alimentos contenidos en las normas y textos afines del Codex se basen en el análisis de riesgos."*

Pár. 18: *"La inocuidad y los aspectos nutricionales de los alimentos relativos a las decisiones y recomendaciones del Codex deben basarse en una evaluación de riesgos conforma a las circunstancias."*

**d) La traducción al español**

Uruguay desea hacer notar que la versión en español de este documento contiene varios errores. Se citarán en esta oportunidad los que se consideran más importantes porque cambian el sentido de lo expresado en la versión en inglés (que se toma, en este caso, como versión original):

Pár. 3): Debe decir: "... de manera que *la inocuidad de los alimentos y los aspectos relacionados con la salud* en las normas y textos afines del Codex ...". (Si esta corrección no es realizada los

<sup>14</sup> Ejemplo de ello es el trabajo realizado por el CCFL y el realizado por los Comités de Productos en lo atinente a la identidad y calidad esencial de los productos.

<sup>15</sup> Si así procedieran, la legitimidad de la medida correspondiente estaría determinada por su grado de compatibilidad con el artículo 2.2 del Acuerdo sobre Obstáculos Técnicos al Comercio de la OMC.

comentarios efectuados por Uruguay en el punto c) carecen de sentido para los miembros hispano hablante.)

Pár. 10): Debe decir: *"Cuando hay pruebas de que existe un riesgo para la salud, pero los datos científicos son insuficientes o incompletos, la Comisión no deberá proceder a elaborar una norma sino que examinará la conveniencia de elaborar un texto afin, por ejemplo un código de práctica, siempre que dicho texto está respaldado por los datos científicos disponibles"*

Pár. 14): Debe decir: "... así como para su aplicación en los *puntos* de decisión apropiados ..."

Pár. 18): Debe decir: "Los aspectos de *salud* e inocuidad relativos a las decisiones y recomendaciones del Codex ..." (Si esta corrección no es realizada los comentarios efectuados por Uruguay en el punto c) carecen de sentido para los miembros hispano hablante.)

#### **EUROPEAN COMMUNITY (English version)**

The European Commission and 12 Member States of the European Union participated in the Working Group meeting convened by France in Paris on 5-7 December 2001.

The European Community would like to congratulate France for the excellent organisation of this Working Group and the Group for the goodwill of its members to reach a compromise.

The European Community understands that the participants have made huge efforts to take into account the concerns of some delegations and considers that the result is generally acceptable. However, consensus could not be reached on some paragraphs and like some delegations, the EC has reserved the right to make further comments.

The EC regrets the fact that the Working Group found it impossible to reach a more positive conclusion on the application of the precaution in relation to the work of Codex. Nevertheless, the EC recognises that the Working Group probably identified the widest consensus achievable on this subject within Codex and, on that basis, could reluctantly agree to the adoption of the text produced and the conclusions of the Working Group meeting. However, if substantial modifications are introduced during the discussions at the 17<sup>th</sup> Session of CCGP, the EC may have to reconsider its position.

#### **EUROPEAN COMMUNITY (French version)**

##### **COMMUNAUTE EUROPEENNE (version française)**

La Commission européenne et 12 Etats Membres de l'Union européenne ont participé au groupe de travail organisé par la France (Paris 5-7 décembre 2001). La Communauté européenne voudrait féliciter la France pour l'excellente organisation de ce groupe de travail et le groupe pour la bonne volonté de ses membres à trouver un compromis.

La Communauté européenne comprend que les participants ont fait d'énormes efforts pour prendre en compte les inquiétudes de certaines délégations et considère que le résultat est acceptable en général. Toutefois, un consensus n'a pas pu être atteint sur certains paragraphes et, comme d'autres délégations, la CE a réservé ses droits à faire d'autres commentaires.

La CE regrette le fait que le groupe de travail n'a pas réussi à trouver une conclusion plus positive sur l'application de la précaution dans les travaux du Codex. Néanmoins, la CE reconnaît que le groupe de travail a probablement identifié le plus large consensus réalisable sur ce sujet au sein du Codex et, sur cette base, pourra sans enthousiasme accepter l'adoption de ce texte et les conclusions du groupe de travail. Cependant, si des modifications substantielles étaient introduites pendant la discussion à la 17<sup>ème</sup> session du CCGP, la CE pourrait être amenée à reconsidérer sa position.