

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3

CX/GP 02/3-Add.2

**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
(Canada, Argentina, Morocco, New Zealand, IFAH, BIO)**

CANADA

SCOPE

- 1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
- 2) The primary purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers while having regard to the promotion of 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.

Rationale: The working principles are being developed to provide guidance to the Commission and its subsidiary bodies. The joint FAO/WHO expert bodies and consultations are independent of the Commission, being established by the parent bodies. Therefore, it is not appropriate to indicate that these principles provide guidance to the expert bodies as it would be inconsistent with the title and intent of the working principles. These are intended to be incorporated into the Procedural Manual, not the *Codex Alimentarius*.

- 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 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* (Add footnote)

Rationale: This is the first occasion when these two Statements are referenced. It would, therefore, be appropriate and useful to add a footnote indicating where in the Procedural Manual they can be found.

6) 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 Commission¹, each component being integral to the overall risk analysis process.

7) The three components of risk analysis should be documented fully and systematically in a transparent manner. ~~While respecting legitimate concerns to preserve confidentiality², documentation should be accessible to all interested parties³.~~ Documentation should be made accessible to all interested parties in a manner consistent with rules and procedures on confidentiality which apply to information and documents provided to or prepared by the Codex Alimentarius Commission and its subsidiary bodies.

Rationale: Canada agrees that a definition of “confidentiality” needs to be added to the glossary and is of the view it should include examples of the type of information that would be considered “confidential”. The suggested rewording of the second sentence reflects the fact that there are confidentiality requirements that apply (rather than just concerns) to some information or documents. The associated footnotes would subsequently be reversed.

8) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis process.

9) The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

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 risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.⁴

12) 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 for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13) The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis process.

Risk Assessment Policy

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

15) 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.⁵

¹ Definitions of Risk Analysis Terms Related to Food Safety page 48 11th Edition Codex Alimentarius Commission Procedural Manual.

² A definition should be added at a later stage into the glossary in annex

³ 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 organisations” (see definition of “risk communication” in the Glossary)

⁴ Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

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

16) 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 and transparent.

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

18) Where necessary, risk managers should ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

RISK ASSESSMENT*

~~19) Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.~~

Rationale: Although Canada acknowledges that this paragraph serves as an introduction to the “risk assessment” section, we note that “Codex decisions and recommendations” are actually risk management decisions. It is not appropriate to address risk management issues under principles related to risk assessment and hence suggest it be deleted.

20) 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

21) 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.

22) 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 characterization, exposure assessment and risk characterization.

23) Risk assessment should use available quantitative information to the greatest extent possible and risk assessment results should be presented in a readily understandable and useful form. Risk assessment may also take into account qualitative information.

24) Risk assessment should take into account all available scientific data and relevant production, storage and handling practices used throughout the food chain **including in particular** traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

Rationale: Canada recommends replacing the text “including” with “in particular” in order to emphasize that the list of considerations for risk assessment is not exhaustive.

25) Recognizing that food production in developing countries is largely through small and medium enterprises, risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

26) Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.

27) ~~Any~~ constraints, uncertainties and assumptions ~~and their~~ **having an** impact on the risk assessment should be documented in a transparent manner, including ~~constraints~~ **those** that are likely to influence the quality 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.

Rationale: Canada suggests the above revisions to clarify the need for documentation specific to those constraints, uncertainties and assumptions which are relevant to the risk assessment.

* Reference is made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*

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

29) The conclusion of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable form. They should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

30) To ensure a transparent risk assessment, a formal 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

31) 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 protection to address similar risks in different situations should be avoided.

32) 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*⁶.

33) In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain **including in particular** traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

Rationale: Canada recommends replacing the text “including” with “in particular” in order to emphasize that the list of considerations for risk assessment is not exhaustive. This would make this paragraph consistent with paragraph 24.

34) 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.

35) 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.

~~36) 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.⁷~~

Rationale: The last sentence is a repetition of paragraphs 31 and 32 and therefore can be deleted.

~~37) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. 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. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission should select those which, if adopted by member countries, would not be more trade restrictive than necessary.~~

Rationale: While transparency and consistency are important for avoiding unjustified trade barriers, they, by themselves, cannot fully achieve this desired objective. Canada notes that the issues of

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

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

transparency and consistency are addressed in paragraph 34. It is Canada's view that the first sentence can be deleted so that the focus of the paragraph is on selection of the least trade restrictive option from amongst those options that are equally effective in protecting the health of the consumer.

38) Risk management should take into account the economic consequences and the feasibility of risk management options ~~in particular in developing countries~~. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. **In taking these elements into consideration, risk managers should give particular attention to the circumstances of developing countries.**

Rationale: As currently worded, it is possible to interpret that the special circumstances of developing countries is applicable to the first sentence only. Therefore, by shifting the reference to developing countries to the end of the paragraph, it makes it clear that the special circumstances of developing countries are applicable to both sentences.

39) 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

40) 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 **reciprocal** communication with member countries and all interested parties in all aspects of the process.

Rationale: Canada suggests adding the word "reciprocal" before "communication" in order to strengthen the interactive nature of communication involving member countries and other interested parties. There is a need to seek feedback from member countries and other interested parties rather than simply providing them with information, which is a possible interpretation of this paragraph as it is currently worded.

41) 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.

42) A major function of risk communication is establishing a process whereby information and opinion essential to effective risk assessment and risk management is exchanged amongst all interested parties.

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

Rationale: Canada suggests changing the word "with" to "involving" in order strengthen the concept risk communication is an interactive process.

44) The guidance on risk communication in this document 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 non-specialists and 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.

The goals of risk communication are to:

- i) **Exchange information and** promote awareness and understanding **amongst interested parties** of the specific issues under consideration during the risk analysis process;

Rationale: Incorporation of the “exchange of information” from sub-paragraph viii makes it possible to simplify the text by deleting the last sub-paragraph. Given that the exchange of information is related to the promotion of awareness and understanding, it is appropriate to include them in the same sub-paragraph.

- 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.~~

Rationale: This sub-paragraph is included in sub-paragraph (i) and hence this sub-paragraph can be deleted.

45) A risk communication strategy should be proactive and include a plan specifying how information and opinion is to be exchanged and considered in the risk analysis process.

ARGENTINA (English version)

SCOPE

46) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

47) The primary purpose of risk analysis in the Codex Alimentarius Commission is protecting the health of consumers ~~while having regard to the promotion of fair practices in the food trade,~~ **using standards based on sufficient scientific data.**

Justification

The SPS Agreement defines risk analysis (for food) as “..the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs”

Similarly, in the Procedural Manual of the Codex Alimentarius Commission (11th edition) risk analysis is defined as “A process consisting of three components : risk assessment, risk management and risk communication”.

The Manual defines risks as “A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food”.

It appears from these definition that neither the SPS nor Codex define risk analysis as an instrument for the promotion of fair trade practices.

While this objective is one of the aims of the Codex Alimentarius, the instrument or mechanisms for its implementation is not risk analysis.

This interpretation is confirmed in points 3,9,19,22,24,etc. of this document whereby it is specified that the objective of the working principles cover food safety, without referring to fair trade practices.

The addition (in bold) is intended to link this para. with the content of para. 11.

48) 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.

49) 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

50) 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*

51) 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 Commission⁸, each component being integral to the overall risk analysis process.

Justification

There is an international agreement on the definition of what should be considered as "confidential information" in Article 39 of the WTO/TRIPS Agreement, and it is not necessary to provide a new definition

52) The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality⁹, documentation should be accessible to all interested parties¹⁰.

53) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis process.

54) The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

55) 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~~ **interactive** process, and interaction between risk managers and risk assessors is essential for practical application.

56) When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.¹¹

57) ~~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,

⁸ Definitions of Risk Analysis Terms Related to Food Safety page 48 11th Edition Codex Alimentarius Commission Procedural Manual.

⁹ ~~A definition should be added at a later stage into the glossary in annex~~

¹⁰ 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 organisations" (see definition of "risk communication" in the Glossary)

¹¹ Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

Justification

We consider that the deleted sentence could cause errors of interpretation. In addition, it has no relationship with the rest of the paragraph, that only refers to the management of uncertainty.

Similarly, we reiterate the comments made by Argentina in the meeting of the Working Group (Paris, December 2001), stressing the difference in scope between precaution in risk assessment and precaution as applied by risk managers, and their different applications.

Precaution applied by scientists-technicians responsible for risk assessment consists in diligence/caution that all technicians should apply in their work. This duty is not linked with sufficient or insufficient scientific evidence, but with the caution that they should exercise while developing their research.

Precaution in risk management is addressed on the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (Article 5.7) as a qualified exception to the obligation for measures to be based on sufficient scientific evidence. It is applicable when it results from scientific evidence that there is a risk for human life and health, but its extent cannot be determined with precision. The measures adopted under the precautionary approach are temporary and it belongs to the country that applies them to justify its adoption.

58) The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis process.

Risk Assessment Policy

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

60) 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.¹²

61) 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 and transparent.

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

63) Where necessary, risk managers should ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

RISK ASSESSMENT*

64) Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as **adequate appropriate** to the circumstances.

65) 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

66) 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.

¹² This paragraph is also included in the Definitions (Annex 1) and might be deleted later if the Definitions are retained in the final text

* Reference is made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*

67) 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 characterization, exposure assessment and risk characterization.

68) Risk assessment should use available quantitative information to the greatest extent possible and risk assessment results should be presented in a readily understandable and useful form. Risk assessment may also take into account qualitative information.

69) 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.

70) Recognizing that food production in developing countries is largely through small and medium enterprises, risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

71) Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process.

72) 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 quality 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.

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

74) The conclusion of the risk assessment including a risk estimate if available, should be conveyed to risk managers in a readily understandable form. They should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors, **who shall follow the requirements of para. 12..**

75) To ensure a transparent risk assessment, a formal 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

76) 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 protection to address similar risks in different situations should be avoided.

Justification

See the justification in para. 2.

77) 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*¹³.

78) 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.

¹³ These criteria have been adopted by the 24th Session of the Commission (see Annex 2)

79) 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.

80) Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer **health** protection they achieve **and the objective of not restricting trade more than necessary to protect the health of the consumer**. The option of not taking any action should also be considered.

81) 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.¹⁴

82) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. 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. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission should select those which, if adopted by member countries, would ~~not be more~~ **be less** trade restrictive than necessary.

83) Risk management should take into account the economic consequences and the feasibility of risk management options in particular in developing countries. Risk management should also recognize the need for flexibility in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health.

84) 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

85) 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.

86) 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.

87) A major function of risk communication is establishing a process whereby information and opinion essential to effective risk assessment and risk management is exchanged amongst all interested parties.

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

89) The guidance on risk communication in this document 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 non-specialists and 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.

The goals of risk communication are to:

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

¹⁴ Joint FAO/WHO Expert Consultation on Risk Management and Food Safety

- 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.

90) A risk communication strategy should be proactive and include a plan specifying how information and opinion is to be exchanged and considered in the risk analysis process.

DEFINITIONS: no changes proposed

ARGENTINA (Version española)

ÁMBITO DE APLICACIÓN

- 1) Estos principios sobre el análisis de riesgos están destinados a ser aplicados en el marco del Codex Alimentarius.
- 2) El objetivo primordial del análisis de riesgos en la Comisión del Codex Alimentarius es proteger la salud de los consumidores, ~~teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos.~~ **UTILIZANDO NORMAS BASADAS EN DATOS CIENTÍFICOS SUFICIENTES.**

JUSTIFICACION:

El Acuerdo SPS define a la evaluación del riesgo (en función de los alimentos) como: "...evaluación de los posibles efectos perjudiciales para la salud de las personas y de los animales de la presencia de aditivos, contaminantes, toxinas u organismos patógenos en los productos alimenticios, las bebidas o los piensos.

Asimismo, en el Manual de Procedimiento de la Comisión del Codex Alimentarius (11° Edición) se define al análisis de riesgos como el "Proceso que consta de tres componentes: evaluación de riesgos, gestión de riesgos y comunicación de riesgos."

Dicho Manual define a los riesgos como: "Función de la probabilidad de un efecto nocivo para la salud y de la gravedad de dicho efecto, como consecuencia de un peligro o peligros presentes en los alimentos.

De esta manera, surge claramente que ni en el SPS ni en el Codex se ha pensado en el análisis del riesgo como un instrumento idóneo para promover las prácticas equitativas en el comercio de los alimentos.

Si bien dicho objetivo forma parte de las finalidades del Codex Alimentarius, se considera que el instrumento o el mecanismo para su consecución no es el análisis del riesgo.

Esta interpretación se encuentra ratificada en los puntos 3; 9; 19; 22; 24 etc. de este documento cuando se menciona que los objetivos de estos principios prácticos es aplicable en materia de inocuidad de los alimentos, sin mencionar a las prácticas equitativas de comercio.

El agregado en negrita es para relacionar el texto de este punto con el contenido en el punto 11.

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

4) En el marco de la Comisión del Codex Alimentarius y de sus procedimientos, la responsabilidad de asesorar sobre la gestión de los riesgos incumbe a la Comisión y a sus órganos auxiliares, mientras que la responsabilidad de evaluar los riesgos incumbe normalmente a los Comités y las Consultas Mixtas de Expertos de la FAO y la OMS.

ANÁLISIS DE RIESGOS – ASPECTOS GENERALES

5) El proceso de análisis de riesgos utilizado en el Codex tiene que ser

- aplicado coherentemente;
- abierto, transparente y documentado; y
- efectuado de conformidad con las *Declaraciones de principios referentes a la función que desempeña la ciencia en el proceso decisorio del Codex y la medida en que se tienen en cuenta otros factores* y con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos*.

6) El proceso de análisis de riesgos debe ajustarse a un método estructurado que comprenda los tres componentes, distintos pero estrechamente vinculados, del análisis de riesgos (evaluación de riesgos, gestión de riesgos y comunicación de riesgos), tal como los define la Comisión del Codex Alimentarius¹⁵. Cada uno de estos tres componentes forma parte integrante del proceso de análisis de riesgos en su conjunto.

7) Los tres componentes del análisis de riesgos deben estar plena y sistemáticamente documentados de manera transparente. Sin perjuicio del respeto al legítimo interés por preservar la confidencialidad¹⁶, la documentación debe ser accesible a todas las partes interesadas¹⁷.

JUSTIFICACION:

La definición de qué se considera como “información confidencial” ya ha sido acordada internacionalmente en el art. 39 del Acuerdo TRIPS/OMC, por lo que no corresponde dar una nueva definición.

8) Se deben garantizar una comunicación y una consulta eficaces a lo largo de todo el proceso de análisis de riesgos.

9) Los tres componentes del análisis de riesgos deben aplicarse en un marco global para la gestión de los riesgos que los alimentos entrañan para la salud humana.

10) Debe existir una separación de funciones entre la evaluación de riesgos y la gestión de riesgos, a fin de garantizar la integridad científica de la evaluación de riesgos, evitar el riesgo de confusión entre las funciones que deben desempeñar los encargados de la evaluación de riesgos y las que corresponden a los encargados de su gestión, y atenuar cualquier conflicto de intereses. No obstante, se admite que el análisis de riesgos es un proceso ~~iterativo~~ **INTERACTIVO** y, para aplicarlo en la práctica, es esencial que exista una interacción entre los encargados de la gestión de riesgos y los encargados de la evaluación de riesgos.

11) Cuando hay pruebas de que existe un riesgo para la salud humana, aunque los datos científicos sean insuficientes o incompletos, la Comisión no debe elaborar una norma, sino contemplar la elaboración de un texto afín, por ejemplo un código de prácticas, a reserva de que dicho texto se base en las pruebas científicas disponibles¹⁸.

~~12) La precaución es un elemento inherente al análisis de riesgos.~~ En el proceso de evaluación y gestión de los riesgos que entrañan los alimentos para la salud humana, hay múltiples fuentes de incertidumbre. El grado de incertidumbre y variabilidad de la información científica disponible debe tomarse explícitamente en consideración en el proceso del análisis de riesgos. Cuando haya pruebas científicas suficientes para que el Codex pueda elaborar una norma o texto afín, las hipótesis utilizadas para la evaluación de riesgos y las opciones en materia de gestión de riesgos deben reflejar el grado de incertidumbre y las características del peligro.

JUSTIFICACION:

Se considera que la frase tachada podría dar lugar a interpretaciones erróneas. Además, no mantiene relación alguna con el resto del artículo, el cual sólo hace mención al manejo de la incertidumbre.

¹⁵ Definiciones de los Términos del Análisis de Riesgos Relativos a la Inocuidad de los Alimentos (pág.49 del Manual de Procedimiento de la Comisión del Codex Alimentarius, 11ª edición).

¹⁶ ~~En una etapa ulterior se incluirá una nueva definición en el glosario que se adjunta en el Anexo 1.~~

¹⁷ En el presente documento, se entiende que las “partes interesadas” son las siguientes: “las personas encargadas de la evaluación de riesgos, las encargadas de la gestión de riesgos, los consumidores, la industria, la comunidad académica y otras partes interesadas” (consúltese la definición de la comunicación de riesgos que figura en las *Definiciones*).

¹⁸ Declaración adoptada en el 24º Periodo de Sesiones de la Comisión (ALINORM 01/41, párrs. 81-83).

Asimismo, se reiteran los comentarios presentados por la Argentina en la reunión del Grupo de Trabajo (Paris, Diciembre de 2001), a través de los cuales se precisa las diferencias de alcance entre la cautela del evaluador del riesgo y la aplicada por el gestor del riesgo, y sus diferentes alcances.

La precaución aplicada por los científicos-técnicos encargados de la evaluación del riesgo consiste en la diligencia/cautela que todo técnico debe aplicar en su trabajo. Es un deber de diligencia que no se relaciona con la suficiencia o insuficiencia de evidencia científica, sino con el cuidado y la cautela que los técnicos deben tener en el desarrollo de sus investigaciones.

La precaución en la gestión del riesgo ha sido prevista en el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias de la OMC (art. 5.7.) como una excepción cualificada a la obligación de basar las medidas en evidencia científica suficiente. La misma es aplicable cuando, del resultado de la evaluación del riesgo surja evidencia científica de la existencia de un riesgo para la salud y vida de las personas, pero cuyo alcance aún no puede ser precisado con exactitud.

Las medidas adoptadas al amparo del enfoque precautorio son temporarias y, corresponde al país que las aplica, justificar las razones que motivan su adopción.

13) Las necesidades y situaciones de los países en desarrollo deben ser objeto de una identificación específica y han de ser tomados en cuenta por los órganos responsables en las distintas fases del proceso del análisis de riesgos.

Política de evaluación de riesgos

14) La determinación de una política de evaluación de riesgos debe ser un componente específico de la gestión de riesgos.

15) La política de evaluación de riesgos consiste en directrices documentadas para las opciones de políticas y juicios conexos, así como para su aplicación en los centros de decisión apropiados durante la evaluación de riesgos, de manera que se mantenga la integridad científica del proceso.¹⁹

16) Los encargados de la gestión de riesgos deben establecer la política de evaluación de riesgos con antelación a la evaluación de riesgos, en consulta con los encargados de la evaluación de riesgos y todas las partes interesadas, a fin de garantizar el carácter sistemático, completo y transparente del proceso de evaluación de riesgos.

17) El mandato encomendado por los encargados de la gestión de riesgos a los encargados de la evaluación de los riesgos debe ser lo más claro posible.

18) En caso de necesidad, los encargados de la gestión de riesgos deben pedir a los encargados de la evaluación de los riesgos que evalúen la posible disminución de los riesgos que resulte de las distintas opciones de gestión de riesgos.

EVALUACIÓN DE RIESGOS*

19) Los aspectos de higiene e inocuidad relativos a las decisiones y recomendaciones del Codex deben basarse en la evaluación de riesgos ~~en~~ conforme ADECUADA a las circunstancias.

20) El alcance y el objetivo de una evaluación de riesgos específica se deben enunciar claramente. La expresión de los resultados y otros resultados posibles de la evaluación de riesgos se deberán definir claramente.

21) La selección de los expertos encargados de la evaluación de riesgos debe ser transparente y ha de efectuarse en función de su competencia e independencia con respecto a los intereses involucrados. Los procedimientos utilizados para elegir a esos especialistas se deben documentar, incluyendo una declaración del posible conflicto de intereses. Esta declaración debe también identificar y detallar su competencia individual y experiencia. Siempre que sea posible, los comités y consultas de expertos deben velar por una participación efectiva de especialistas de las distintas regiones del mundo, incluidos los países en desarrollo.

¹⁹ Este párrafo está también incluido en las Definiciones (Anexo 1) y se podría suprimir después si las definiciones se mantienen en el documento final

* Se refiere a las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos s.*

22) La evaluación de riesgos debe efectuarse de conformidad con las *Declaraciones de principios relativos a la función de la evaluación de riesgos respecto de la inocuidad de los alimentos* y debe comprender las cuatro fases de la evaluación de riesgos, es decir, identificación de los peligros, caracterización de los peligros, evaluación de la exposición a los peligros y caracterización de los riesgos.

23) Las evaluaciones de riesgos deben utilizar, en la mayor medida posible, los datos cuantitativos disponibles y los resultados de la evaluación de riesgos deben presentarse de manera fácilmente comprensible y utilizable. Las evaluaciones de riesgos pueden también tener en cuenta datos cualitativos.

24) La evaluación de riesgos debe tomar en cuenta todos los datos científicos disponibles y las prácticas de producción, almacenamiento y manipulación utilizadas a lo largo de toda la cadena alimentaria, comprendidas las prácticas tradicionales, así como los métodos de análisis, muestreo e inspección, y la incidencia de los efectos perjudiciales específicos para la salud.

25) Reconociendo que la producción de alimentos en los países en desarrollo se realiza sobre todo en pequeñas y medianas empresas, para la evaluación de riesgos se debe buscar e incorporar información procedente de las distintas partes del mundo, comprendida la suministrada por los países en desarrollo. Esa información debe comprender en especial datos de control epidemiológico y estudios sobre exposiciones a los riesgos.

26) Se deben tomar explícitamente en consideración la variabilidad y otras fuentes de incertidumbre en cada etapa del proceso de evaluación de riesgos.

27) Cualquier limitación, incertidumbre e hipótesis, así como su repercusión en la evaluación de riesgos se deben documentar con transparencia, comprendidas las limitaciones que puedan tener repercusiones en la calidad de la estimación de los riesgos. La expresión de la incertidumbre o de la variabilidad en la estimación de los riesgos podrá ser cualitativa o cuantitativa, pero tendrá que cuantificarse en la medida en que ello sea científicamente posible.

28) Las evaluaciones de los riesgos deben basarse en hipótesis de exposición realistas y el examen de las distintas situaciones se debe definir en función de la política de evaluación de riesgos. Se deben tomar en consideración los grupos de población propensos a riesgos o de alto riesgo. Los efectos perjudiciales agudos, crónicos (comprendidos los efectos a largo plazo), acumulativos y/o combinados para la salud se deben tomar en cuenta en la realización de la evaluación de riesgos, cuando sea pertinente.

29) Las conclusiones de la evaluación de riesgos, incluida una estimación del riesgo, cuando se disponga de ella, se deben comunicar a los encargados de la gestión de riesgos de forma fácilmente comprensible. Deben indicar todas las limitaciones, incertidumbres e hipótesis, así como sus consecuencias sobre la evaluación de los riesgos, y también las opiniones minoritarias. La cuestión de resolver la incidencia de la incertidumbre en la decisión de gestión de riesgos no incumbe a los encargados de la evaluación de los riesgos, sino a los encargados de la gestión de riesgos, **QUIENES OBSERVARAN LAS PRESCRIPCIONES CONTENIDAS EN EL ART. 12.**

30) Para garantizar la transparencia de la evaluación de riesgos se debe preparar un documento oficial, que incluya un resumen, y se ha de poner a disposición de los demás encargados de la evaluación riesgos, así como de las partes interesadas, a fin de que puedan examinar la evaluación.

GESTIÓN DE RIESGOS

31) El objetivo esencial de las decisiones y recomendaciones del Codex en materia de gestión de riesgos debe ser la protección de la salud de los consumidores, ~~teniendo en cuenta a la vez la promoción de prácticas equitativas en el comercio de alimentos~~. Se deben evitar diferencias injustificadas en el nivel de protección del consumidor riesgo al tratar riesgos similares en situaciones diferentes.

JUSTIFICACION:

Ver justificación relativa al art. 2.

32) La gestión de riesgos debe ajustarse a un método estructurado, que comprenda la evaluación de los riesgos, la evaluación de las opciones de la gestión de riesgos, el seguimiento y la revisión de las decisiones adoptadas. Las decisiones se deben basar en una evaluación de riesgos que resulte adaptada a las circunstancias y tenga en cuenta, cuando corresponda, otros factores legítimos que atañen a la protección de la salud de los consumidores ~~y a la promoción de prácticas equitativas en el comercio de alimentos~~, de

conformidad con los *Criterios para tomar en cuenta los otros factores mencionados en la Segunda Declaración de Principios*²⁰.

33) En el logro de los resultados acordados, la gestión de riesgos debe tener en cuenta los procesos pertinentes de producción, almacenamiento y manipulación a lo largo de toda la cadena alimentaria, incluidas las prácticas tradicionales, así como los métodos de análisis, muestreo e inspección, y la incidencia de los efectos perjudiciales específicos para la salud.

34) El proceso de gestión de riesgos debe ser transparente y coherente y estar completamente documentado. Las decisiones y recomendaciones del Codex sobre gestión de riesgos deben documentarse y, cuando proceda, deben estar claramente identificadas en las distintas normas y textos afines del Codex para facilitar que todas las partes interesadas entiendan mejor el proceso de gestión de riesgos.

35) Las opciones de gestión de riesgos se deben evaluar en función del ámbito y de la finalidad del análisis de riesgos, del grado de protección **DE LA SALUD** del consumidor que proporcionen **Y DEL OBJETIVO DE NO RESTRINGIR EL COMERCIO MAS DE LO NECESARIO PARA PROTEGER AL CONSUMIDOR**. Se debe también considerar la opción de no emprender acción alguna.

36) El resultado del proceso de evaluación de riesgos debe asociarse con la evaluación de las opciones de gestión de riesgos disponibles, a fin de adoptar una decisión sobre la gestión del riesgo. Cuando se adopte esa decisión, la consideración primordial debe ser la protección de la salud de los consumidores **y los demás factores se han de tomar en consideración según proceda**²¹.

37) Para evitar la creación de obstáculos injustificados al comercio, la evaluación de riesgos debe garantizar la transparencia y coherencia del proceso de decisión en todos los casos. El examen de todas las opciones de gestión de riesgos debe, en la mayor medida posible, tener en cuenta una evaluación de los ventajas y **E** inconvenientes. Cuando se haga una selección entre varias opciones de gestión de riesgos, que sean igualmente eficaces para proteger la salud del consumidor, la Comisión debe seleccionar las opciones que ~~no serían más~~ **SERIAN MENOS** restrictivas al comercio ~~que necesario~~, una vez adoptadas por los países miembros.

38) La gestión de riesgos debe considerar las consecuencias económicas y la viabilidad de las opciones de gestión de riesgos, especialmente en los países en desarrollo. La gestión de riesgos debe reconocer también que es necesaria la flexibilidad en el establecimiento de normas, directrices y otras recomendaciones, en consonancia con la protección de la salud del consumidor.

39) La gestión de riesgos debe ser un proceso permanente que tenga en cuenta todos los datos nuevos que aparezcan en la evaluación y revisión de las decisiones relativas a la gestión de riesgos. Las normas alimentarias y los textos afines deben ser revisados y actualizados periódicamente, cuando sea necesario, para tener en cuenta los nuevos conocimientos científicos y otra información pertinente para el análisis de riesgos.

COMUNICACIÓN DE RIESGOS

40) El análisis de riesgos debe comprender una comunicación clara, interactiva y documentada entre los encargados de la evaluación de riesgos (comités y consultas conjuntos de expertos) y los encargados de su gestión (Comisión del Codex Alimentarius y sus órganos auxiliares), así como una comunicación con los Países Miembros y todas las partes interesadas en todos los aspectos del proceso.

41) La comunicación de riesgos no se limita a la mera difusión de la información. Su función principal consiste en garantizar que en el proceso de elaboración de las decisiones se tiene en cuenta toda información o dictamen que sean esenciales para la gestión eficaz de los riesgos. La comunicación recíproca permanente entre todas las partes interesadas forma parte integrante del proceso de análisis de riesgos.

42) Una función fundamental de la comunicación de riesgos es establecer un proceso mediante el cual se intercambian entre todas las partes interesadas informaciones y opiniones que son esenciales para una evaluación de riesgos y una gestión de riesgos eficaces.

43) La comunicación de riesgos con las partes interesadas debe comprender una exposición transparente de la política de evaluación de riesgos y de la evaluación del riesgo, incluida la incertidumbre. También se deben

²⁰ Estos criterios se adoptaron en el 24º Periodo de Sesiones de la Comisión (véase el Anexo 2).

²¹ Consulta Mixta de Expertos FAO/OMS sobre Gestión de Riesgos y la Inocuidad de los Alimentos. En el marco del Codex, el "componente" de Aplicación no es pertinente.

explicar claramente la necesidad de adoptar normas o textos afines específicos y los procedimientos que se han seguido para determinarlos, comprendida la manera en que se ha tratado la incertidumbre. Se deben indicar asimismo todas las limitaciones, incertidumbres e hipótesis y sus correspondientes repercusiones en el proceso del análisis de riesgos, así como las opiniones minoritarias.

44) En el presente documento, las directrices sobre la comunicación de riesgos están destinadas a todos los que participan en la realización del análisis de riesgos en el marco del Codex Alimentarius. No obstante, es importante que esta labor tenga la mayor transparencia y accesibilidad posibles para los que no son especialistas o no participan directamente en el proceso, comprendidos los consumidores y sus organizaciones representativas, así como los que intervienen en la producción, transformación y distribución de alimentos, y otras partes interesadas.

Los objetivos de la comunicación de riesgos son:

- (i) promover la concienciación sobre las cuestiones específicas que se toman en consideración a lo largo del proceso del análisis de riesgos, así como la comprensión de las mismas;
- (ii) promover la coherencia y la transparencia en la formulación de las opciones y recomendaciones relativas a la gestión de riesgos;
- (iii) suministrar una base sólida para el entendimiento de las decisiones que se proponen en materia de gestión de riesgos;
- (iv) mejorar la eficacia y eficiencia globales del proceso del análisis de riesgos;
- (v) reforzar las relaciones de trabajo entre los participantes;
- (vi) promover el entendimiento del proceso por parte del público, a fin de consolidar la confianza en la seguridad de los abastecimientos de alimentos;
- (vii) promover la adecuada participación de todas las partes interesadas;
- (viii) intercambiar información sobre las cuestiones que preocupan a las partes interesadas en relación con los riesgos relativos a los alimentos.

45) Una estrategia de comunicación de riesgos debe ser anticipante y comprender un plan en el que se especifique cómo se han de intercambiar y considerar las informaciones y las opiniones en el proceso del análisis de riesgos.

DEFINICIONES: sin cambios

MOROCCO (English version)

The following Table presents the amendments to be made to the relevant paragraphs in the Proposed Draft Working Principles for Risk Analysis (CX/GP02/3):

para.	Proposed Amendments
	SCOPE
4	The term "expert" should be added to distinguish between subsidiary bodies that are Codex Committees and regional Coordinating Committees (Rule IX of the Rules of Procedure) (change only for French version)
	RISK ANALYSIS – GENERAL ASPECTS
10	In order to ensure consistency with the 3 rd Statement of Principle Relating to the Role of Food Safety Risk Assessment, " essential " should be replaced with " indispensable " and " practical " by " pragmatic ". " However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is indispensable for a pragmatic application."
13	Replace the term " responsible bodies " with " Codex Alimentarius and developed countries "
	RISK ASSESSMENT
19	Change in the French version Replace « en fonction des circonstances » with « ... adaptés aux circonstances. »

21	Replace " different parts of the world " with " regions of the world "
23	In order to ensure consistency with the 4 th Statement of Principle Relating to the Role of Food Safety Risk Assessment, the term " risk assessment results " should be replaced with " risk characterizations ".
	ANNEX 1
	Translation into French of "adverse to health" . Replace « adverse pour la santé » with « néfaste sur la santé».

MOROCCO (French version)

Le tableau suivant présente les différents amendements à apporter aux paragraphes concernés de l'avant-projet de principes de travail pour l'analyse des risques (CX/GP02/3):

§	AMENDEMENTS PROPOSES
	CHAMP D'APPLICATION
4	On doit rajouter le terme expert pour distinguer entre les organismes subsidiaires qui sont les comités du codex et le comités de coordination pour les régions (Article IX du règlement intérieur de la Commission du Codex Alimentarius) : «tandis que la responsabilité de l'évaluation des risques incombe normalement aux comités d'experts... ».
	ANALYSE DES RISQUES – ASPECTS GENERAUX
10	Pour être conformes aux termes de la 3 ^{ème} déclaration de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments, On doit remplacer le terme « essentielle » par « indispensable » et le terme « concrète » par « pragmatique » : « Cependant, il est reconnu que l'analyse des risques est un processus itératif, et l'interaction entre les responsables de la gestion des risques et les responsables de l'évaluation des risques est indispensable pour une application pragmatique. »
13	Remplacer l'expression « ... organes responsables... » par « ... les instances du Codex Alimentarius et les pays développés... »
	EVALUATION DES RISQUES
19	Pour être conforme aux termes de la 1 ^{ère} déclaration de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments on doit remplacer « en fonction des circonstances » par « ... adaptés aux circonstances. »
21	Remplacer le terme « ... parties du monde... » par « régions du monde.... »
23	Pour être en conformité avec les termes la 4 ^{ème} déclaration de principes sur le rôle de l'évaluation des risques en matière de salubrité des aliments, on doit remplacer l'expression «... les résultats de l'évaluation des risques... » par « ... la caractérisation des risques.... ».
	ANNEXE 1
	Au niveau de toutes les définitions, il serait préférable de remplacer le terme « adverse pour la santé » par « néfaste sur la santé».

NEW ZEALAND

New Zealand congratulates the Working Group for an excellent job of incorporating government comments and recasting the draft Working Principles. We support the revised text, and suggest the following amendments to strengthen the document.

Paragraph 6

New Zealand believes that it is not appropriate for this principle to refer to a “structured approach” in the context of the three components of risk analysis. A “structured approach” is properly referred to in paragraph 32 in the context of a process for risk management. A better phrasing might be, “*Risk analysis should incorporate the three distinct but closely linked components of risk assessment, risk management and risk communication, each being integral to the overall risk analysis process*”.

Paragraph 11

New Zealand supports the revised text's conformance with the Commission's direction that Codex should not elaborate standards without sufficient scientific evidence, as noted in paragraph 10.

New Zealand also supports the revised text's linking of precaution to uncertainty in risk assessment. However, the paragraph appears to address two different issues: (1) how risk assessors handle and communicate uncertainty and variability in the scientific process (“assumptions used for risk assessment”) and (2) how risk managers respond to uncertainty and variability (“risk management options selected”),

presumably in the latter case as a consequence of the degree of uncertainty and variability expressed in the risk estimate. The CCGP may wish to debate whether these two issues need to be clearly separated in a statement of principle, so as to reinforce the functional separation of risk assessment from risk management activities. It is New Zealand's opinion that the exercise of precaution should be primarily recognised as a risk management function.

From an editorial perspective, New Zealand notes that further amendments are necessary in order to turn this paragraph into a principle. Currently, the first two sentences are statements of fact. If it is necessary that they remain, they should be rewritten as a principle.

Paragraph 17

New Zealand suggests changing the phrase “potential risk reduction” to “potential changes in risk”, as this is a more inclusive phrase.

Paragraph 23

New Zealand notes that this paragraph is still almost identical to paragraph 32. We suggest revising this paragraph to both distinguish it and focus it more clearly on risk assessment. New Zealand suggests the following words: “*Subject to available data and technical resources, exposure assessment should involve the whole food chain so as to enable evaluation of risk management options that provide optimal control of hazards.*”

Paragraph 27

New Zealand notes that this paragraph does not recognise that while the types of data described are highly desirable, they are often lacking. We suggest adding to the beginning of the second sentence: “Wherever possible, they should include...”.

Paragraph 35

New Zealand notes that this paragraph mentions “other legitimate factors”, and thus should refer to the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*, as per paragraph 31 and footnote 18. We suggest that the Criteria reference be added to footnote 19.

Paragraph 41 bis

New Zealand notes that this paragraph is currently written as statements of fact, and should be rewritten as a principle.

Paragraph 43 bis

New Zealand notes that this paragraph is currently written as statements of fact, and should be rewritten as a principle.

Annex 1, Definition of risk assessment policy

New Zealand suggests that this definition would be enhanced by referring to consistency as a benefit, i.e. “scientific integrity and consistency of the process...”.

IFAH (International Federation for Animal Health)

With regard to the revised text at Step 3 of the procedure following the working group held 5-7 December 2001, IFAH wishes to emphasise the following points:

Paragraph 7)

IFAH continues to have concerns that there is potential conflict between preservation of confidentiality and “documentation should be accessible to all interested parties”. We note that there is no definition provided yet as to what constitutes “confidentiality” and IFAH awaits further clarification.

Paragraph 11)

IFAH prefers to amend the first sentence to “Precaution is an inherent element of risk management”. We believe that the final word of this paragraph should read “risk” rather than “hazard”.

Paragraph 12)

“Specifically identified” for developing countries is placing a burdensome requirement and IFAH recommends deletion of this phrase to read “... should be taken into account ...”

Paragraph 15)

IFAH suggests the following modification: “Risk assessment policy should be established in advance of risk assessment through consultation with risk managers, risk assessors and other interested parties in order to ensure that the risk assessment process is transparent, systematic, unbiased and complete.”

Paragraph 27)

IFAH recommends insertion of “Where relevant” at the beginning of this final sentence. We believe that the qualifying language is very important in this sentence.

Paragraph 43)

IFAH suggests inserting the phrase “where appropriate” after the final phrase “minority opinions”. This should not be mandatory but at the discretion of the risk managers/ communicators).

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

The Biotechnology Industry Organization (BIO) represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 US states and 33 other nations. BIO members are involved in the research and development of health care, agricultural, industrial and environmental biotechnology products.

BIO participated, as one of the international nongovernmental organizations, in the working group meeting wherein the draft document was prepared. As such, we participated in discussion as the document developed. Given that history, we provide the following suggestions and comments we hope will assist in clarification for discussion next month.

We strongly support the amended Scope language that confines the work in the CCGP to the work of Codex with respect to risk analysis. The work of national governments should be separate from considerations for Codex as expressed in this document. Overall, we assess the draft document as an improvement from the original text. However, we have several comments regarding the language used and will delineate those below.

Risk Analysis- General Aspects

We believe that paragraphs #10 and #11 both cover the issue of scientific certainty/uncertainty in risk analysis. Therefore, we believe they should be revised and combined. We recommend the following language:

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 elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the risk(s). When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code or practice, provided that such a text would be supported by the available scientific evidence.²²

Risk Assessment Policy

Para 16- we recommend deleting the ending of the sentence, “as possible.” We believe that the mandate should be clear.

Para 17- How is “necessary” or “where necessary” defined? Who would determine when or where it is necessary to evaluate potential risk reduction from different options?

²² Adopted by the 24th Session of the Codex Alimentarius Commission (ALINORM 01/41).

Risk Assessment

Para 22, the word “scientifically” should be added so that the statement reads, “...also takes into account qualitative scientific information.”

Para 23- the language regarding relevance of information should be made consistent with that in paragraph 32. The statement might read, “...handling practices used throughout the food chain where relevant, including tradition...”

Para 24- epidemiological surveillance data and exposure study data may not exist from developing countries. Therefore, the statement should read, “This data *may* include epidemiological surveillance data and exposure studies.”

Para 25- insert wording, “Explicit consideration should be given to variability and other sources of *relevant, scientifically-based* uncertainty at each step in the risk assessment process.”

Para 27- insert wording, “*Where relevant* they should include consideration of susceptible...”

Para 28- the term “They” in the second sentence is unclear. Does that mean, “The conclusion should indicate any constraints...?”

Para 29- delete. This issue is already addressed in paragraphs 5 and 15.

Risk Management

Para 34- this more correctly should refer to Risk management options should be “evaluated” rather than assessed in order to be consistent with Para 35. Also, the level of consumer protection is, “intended to be achieved.”

Para 37- should discussion of “potential advantages and disadvantages” be characterized as costs and benefits rather than advantages/disadvantages? Also, options should be “the least trade restrictive possible,” rather than not more trade restrictive than necessary.

Para 38- last sentence should say, “...recommendations, consistent with the *appropriate level of* protection of consumers’ health.”

Risk Communication

Para 41 and 42 are more general to Risk Analysis and should be moved to that general section.

Para 43bis- this should be moved to the first paragraph under risk communication because it states what are the goals of the risk communication function. This should be the new #41.

Within 43bis, “vii” should be moved to “ii” owing to its importance in the process.

We appreciate the opportunity to provide comment on this important document and look forward to thorough discussion during the CCGP meeting in Paris next month. Please feel free to contact me directly if you have questions or need clarification on any of the items that we have highlighted.