

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 3

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

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RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS GOVERNMENT COMMENTS IN REPLY TO CL 1999/16-GP

AUSTRALIA

General

Australia notes that the proposed draft working principles are intended for the work of Codex Committees and their association with independent expert advisory committees and expert consultations. While the principles may have some benefit for member governments in addressing risk analysis at the national level, it is important that this review process avoid any confusion by maintaining focus on preparing the working principles for application in the Codex decision process only.

In regard to the request for specific comment on reference to “precautionary principle”/“precautionary approach”, Australia acknowledges and supports the precautionary approach inherent in Codex decision processes. We believe that it has provided Codex, in the absence of absolute scientific knowledge, with a coherent approach to decision making.

However, any reference to the application of a precautionary approach, if applicable in working principles on risk analysis, should initially be made in the general introductory section to the text.

A suggested approach to the drafting and other specific comments detailed below are shown in editorial marks on the Proposed Draft Codex Working Principles for Risk Analysis at Attachment 1.

Specific comments on text

Section on Risk Analysis

We believe that the utility of the text could be significantly improved by creating an introductory section in place of the present section entitled “Risk Analysis” (this title is redundant). This could be followed by three further Sections titled: Definitions, Principles, and Documentation.

This Introduction Section could be composed from the present draft text and some additional material so that it covers:

- . a statement on the purpose and outcomes of the risk analysis process in Codex, consistent with outcomes already endorsed by the Commission, eg, *Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995)*;
 - . the scope of the text; ie, the three components (risk assessment, risk management, risk communication) that comprise risk analysis;
 - . specific applications, such as: the needs of developing countries, transparency, etc; and
- See proposed drafting in Attachment 1 (Section 1: paragraphs 1-7).

Risk Assessment

Paragraph 4: “As” and “open” are redundant. The English version should read:

“The risk analysis process used in Codex should be consistent and transparent.”

Bring forward existing paragraph 14 to the Section on Introduction (as a new paragraph 7) to read:

“There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.”

Paragraph 9: Reference to ‘different situations’ should be included under the heading ‘Risk Assessment Policy’ rather than ‘Risk Assessment’. Also the last sentence of this paragraph repeats text included under paragraph 13. Therefore we would suggest that paragraph 9 read:

“Risk assessments should be based on realistic exposure scenarios and include consideration of susceptible and high risk population groups.”

Paragraph 13 is unclear. Suggest it should read:

“Risk assessments recognise as appropriate both acute and chronic (including long-term) adverse health effects.”

Paragraph 14 is an overarching statement that would be better placed in the introduction to the text.

Risk Assessment Policy

Paragraphs 16 and 17 both relate to the mandate given to risk assessors, but it would not be appropriate to include paragraph 17 in the Codex Procedural Manual. Australia also notes that 14 CCGP (1999) considered identification of risk assessors (ie. independent expert committees/expert consultations) and risk managers (ie. Codex Committees) might be included as a footnote after the principles for risk analysis are defined. We would suggest that such footnoting is inserted at this step to avoid confusion occurring at a later stage in the elaboration process.

Risk Management

Paragraph 20 could be clarified to read:

“Risk management decisions should have as their prime objective the protection of human health.”

We would also suggest that paragraph 20 precede paragraph 19 as it relates to the overall objective of the risk management decision process whereas paragraph 19 and paragraphs 21 to the end of the section relate to the process.

Paragraph 24: We do not understand what this paragraph is stating. Suggest deletion.

Paragraph 26: This paragraph is unclear. Australia suggests that it is deleted.

At this point in the text Australia would suggest including a new paragraph that is relevant to the risk management process and that reflects WTO member country obligations under the SPS agreement:

“26. (new). Risk management decisions reflected in standards should be chosen so as to achieve consistency in the level of acceptable risk and be proportional to the risk.”

Paragraph 28. Remove square brackets from paragraph 28 and delete the second sentence. Paragraph 28 hence would read:

“28. The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified.”

Risk Communication

Paragraph 31. Communication of the risk process should include consumers, industry, public interest groups and so on. Therefore suggest this paragraph read:

“31. Risk managers should include an assessment of uncertainty in risk estimates in their communication with the public and other interested parties.”

Documentation

Paragraphs 32 and 33: The drafting of these paragraphs could be improved. Further the notion of flexibility in risk managers would be better associated with the principle of developing food standards that are consistent with new scientific knowledge. Note, however, that the use of the term “consistent” in this context may be confusing with its use in paragraph 32. Therefore we suggest the text reads

- “32. Risk assessment and risk management should be fully documented in a transparent manner. The risk management process should be transparent, consistent, objective, repeatable and fully documented.
33. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Risk managers should be flexible in considering options so as to ensure that food standards utilise contemporary scientific knowledge and other information relevant to risk analysis.”

ATTACHMENT 1 - Australia's Proposed Amendments to the Proposed Draft Codex Working Principles for Risk Analysis
(At Step 3 of the Procedure)

Risk analysis section 1 - introduction

1. The primary purpose of applying risk analysis ~~is within~~ Codex is to ensure that Codex decision processes are governed by principles which will achieve optimal outcomes consistent with consumer protection and facilitation of trade. ~~the protection of public health.~~

~~2.~~ The three components of risk analysis process, namely (risk assessment, risk management and risk communication). Each component is integral to the overall risk analysis and should be documented separately and systematically, with the documentation accessible to interested parties. To use the risk analysis process in an effective way, there is a need for communication and interaction where appropriate between the parties involved in these three components.

~~2, 3.~~ The risk analysis procedures used by Codex and those used by other relevant international intergovernmental [and non-governmental] bodies should be harmonized where appropriate.

4. These principles are intended to apply to the risk analysis procedures used by Codex. However, in order to achieve a harmonised approach to the application of risk analysis other relevant international intergovernmental [and non-governmental] bodies are encouraged to use these Principles where appropriate.

~~3, 5.~~ The needs of developing countries should be specifically identified and addressed in the different stages of the Codex risk analysis process.

~~4, 6.~~ The risk analysis process used in Codex should be as consistent, ~~open~~ and transparent.

7. (paragraph 14 brought forward). There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.

SECTION 2 – DEFINITIONS

SECTION 2 - PRINCIPLES

RISK ASSESSMENT

~~5, 8.~~ Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.

~~6, 9.~~ 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.

~~7, 10.~~ Risk assessment should be based soundly on science, should incorporate the four steps of the risk assessment process and should be documented in a transparent manner, indicating any constraints, uncertainties and assumptions and their impact on the risk assessment.

~~8, 11.~~ Risk assessments should use available quantitative information to the greatest extent possible and risk characterisations should be presented in a readily understandable and useful form.

~~9, 12~~ Risk assessments should be based on realistic exposure scenarios, ~~with consideration of different situations being defined by risk assessment policy. They should be applicable to~~ and include consideration of

susceptible and high risk population groups. ~~Both acute and chronic (including long-term) adverse health effects should be recognized in carrying out risk assessment~~

~~10.~~ 13. Risk assessment should take into account all available scientific data and relevant production processes, methods of sampling and inspection and the prevalence of specific diseases.

~~11.~~ 14. Risk estimates should wherever possible include a numerical expression of uncertainty, and this should be conveyed to risk managers in a readily understandable form¹. Risk assessment should take into account uncertainty in exposure estimates and, if necessary, in the assessment of dose-effect toxicity. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

~~12.~~ 15. Risk assessment may include non-measurable, qualitative data.

~~13.~~ 16. Risk assessments should recognise as appropriate both ~~There should be increased recognition of differences between acute and chronic (including long-term) adverse health effects, in carrying out risk assessments~~

~~14.~~ ~~There should be a functional separation of risk assessment and risk management, while recognising that some interactions are essential for a pragmatic approach.~~

RISK ASSESSMENT POLICY

~~15.~~ 17. Determination of risk assessment policy should be included as a specific component of risk management.

~~16.~~ 18. The mandate given by risk managers to risk assessors² must be clearly specified and delineated.

~~17.~~ ~~[Risk managers should try to ensure that the mandates given to risk assessors are achievable and correspond to the capacity and expertise of the risk assessors].~~

19. Risk managers should invite all interested parties to submit proposals and comments to ensure that the risk assessment process is systematic and complete.

RISK MANAGEMENT

20. Risk management decisions should have as their prime objective the protection of human health.

~~19.~~ 21. Risk management should follow a structured approach.

~~20.~~ ~~Protection of human health should be the primary consideration in risk management decisions.~~

22. Risk management should be focused on agreed outcomes rather than on processes.

~~22.~~ 23. Risk management policies should be documented, and where appropriate *clearly* acknowledged in individual Codex standards so as to foster a wider understanding of risk management concepts, and the particular risk policy used in the elaboration of individual Codex standards.

~~23.~~ 24. Guidelines should be available for the inclusion in risk management decisions of “other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade”.

~~24.~~ ~~If economic analyses have to be used in support of risk management decisions, the process should be subject to consistent and transparent decision-making criteria and should be consistent with fair trade practices.~~

~~25.~~ 25. Where risk management involves selection of options other than (or in addition to) quantitative food standards for the prevention, elimination or control of hazards, each available option should be evaluated according to a relevant risk management framework.

~~26.~~ ~~Issues of a general nature in the elaboration of food standards and related should be clearly identified and consistently addressed texts according to risk analysis principles.~~

¹ Within the framework of Codex, the responsibility for providing advice to governments 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 Committee and Consultations.

² The risk managers in the Codex context are the Codex Committees and risk assessors are the Independent Expert Scientific Committees/Expert Consultations.

26. (new) Risk management decisions reflected in standards should be chosen so as to achieve consistency in the level of acceptable risk and be proportional to the risk.

~~27-27.~~ Risk management decisions should take into account conditions prevailing in all countries, where possible, without affecting the agreed outcome.

~~28-28.~~ The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified. ~~In such situations, it should be possible to apply the precautionary principle.~~

RISK COMMUNICATION ~~RISK communication~~³

29. Risk analysis should include clear, interactive communication, exchange of information and opinions on risk and related factors, between risk assessors and risk managers, and communication with consumers and other interested parties in all aspects of the process.

30. A risk communication strategy should be proactive and include a plan specifying how information is to be communicated.

31. Risk managers should include an assessment of uncertainty in risk estimates in their communication with the public and other interested parties.

Documentation

32. Risk assessment and risk management should be fully documented in a transparent manner. The risk management process should be transparent, ~~flexible, consistent,~~ objective, ~~and~~ repeatable and ~~this requires fully documented.~~ ation.

33. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Risk managers should be flexible in considering options so as to ensure that food standards utilise contemporary ~~Food standards must be consistent with new~~ scientific knowledge and other information relevant to risk analysis.

BRAZIL

The amendments are in italics.

Risk Analysis

We have no comments on item 1.

In item 2 we suggest *to take off the square brackets*, since we understand that we need to harmonize these procedures as much as possible.

In item 3 *we suggest to refer to the foot note number 1* in order to clarify these different stages of the Codex risk analysis process.

In item 4 *we suggest to eliminate the conjunction as*, remaining the text as follows “ *... should be consistent, open and transparent.*”

Risk Assessment

We have no comments on item 5.

We strongly support the wordings on item 6 and we believe that the criteria and the procedures used to select these experts would be available.

We have no comments on items 7, 8 and 9.

In order to cover all the stages in the food chain on item 10, we suggest the following amendments:

“..all available scientific data and relevant production, *distribution and storage* processes *of the food chain*, methods of sampling and inspection...”.

We have no comments on items 11, 12, 13 and 14.

³ Risk communication has yet to be formally addressed by Codex, but the following working principles introduce relevant issues. A major function of risk communication is establishing a process whereby information and opinion essential to effective risk management is made available. All parties interested in the risk management decisions of the CAC should be involved to the extent that is practical and reasonable.

Risk Assessment Policy

We have some comments on this topic:

- Analyzing the content (items 15 to 18) we believe that there is no justification to have this topic separated, since all of them refer to the Risk Management stage. So it would be better to have these four items included in the next topic.
- Furthermore, despite the discussion held in the last meetings of CCGP about the definition of this term, we believe that is necessary to define it.
- We have some specific comments on items 16 and 17:
 - Item 16 – we suggest to add at the end of the sentence *and documented*.
 - Item 17 – we suggest *to take off the square brackets*. Furthermore we understand that risk managers should select the risk assessors according to the capacity and expertise needed to achieve the given mandate. The text suggested in the circular letter brings the opposite situation, which, in our opinion, is not appropriate.

Risk Management

We have no comments on items 19 and 20.

On item 21 we would like to have a clarification on the meaning of the term “agreed outcomes”.

On item 22 we see two new terms that, in our opinion, need to be defined: Risk management policies and risk policy.

We have no comments on items 23 and 24.

On item 25, in order to make the sentence clearer, we suggest to eliminate the word *framework* and conclude the sentence after *relevant risk management*.

On item 26, second line, the word *texts* must be placed in the first line, after related.

On item 27, we suggest to stop the sentence at *where possible*, excluding *without affecting the agreed outcomes. This exclusion could be conditioned on a clear explanation of the meaning of the term “agreed outcomes”*.

On item 28 we will follow the discussions being held, but in this moment we won't comment on it. We suggest that the square brackets be maintained.

Risk Communication

On item 29 we have an alternative proposal, in order to match with the definition of Risk Communication approved by the Commission, which is:

“Risk Analysis should establish clear, interactive and documented communication, with the aim of exchanging information and opinions with all involved and interested parties”.

We have no comments on items 30 and 31.

Documentation

We understand that there is no justification to have a topic on documentation, since the text refers to the stages of risk management and risk assessment. So, at first it would be better to have item 32 and 33 changed in the following manner:

32 *Risk assessment should be fully documented in a transparent manner.*

33 *Risk management should be fully documented in a transparent manner.*

34 *Risk management should be transparent, flexible, objective and repeatable and this requires full documentation.*

35 *Risk management should be a continuing process that takes in account all newly generated data in the evaluation and review of risk management decisions. Food standards must be consistent with new scientific knowledge and other information relevant to risk.*

The item 32 would be included on topic Risk Assessment, and items 33, 34 and 35 would be included on topic Risk Management.

CANADA

PRINCIPLES RELATED TO RISK ASSESSMENT

Principle #7 makes reference to the four steps of risk assessment. It is suggested that the four steps actually be identified (i.e. hazard identification, hazard characterization, exposure assessment and risk characterization) in the text, similar to the approach taken in principle #1.

The current text in principle #11 tends to place an emphasis on chemical toxicity rather than a general hazards approach. It is recommended that the end of the second sentence in principle #11 be changed from “...*the assessment of dose-effect toxicity.*” to “...*the assessment of dose-response*”. This wording will encompass both chemical and microbiological hazards.

PRINCIPLES RELATED TO RISK MANAGEMENT

Principle #24 states that, “*If economic analyses have to be used in support of risk management decisions, the process should be subject to consistent and transparent decision-making criteria and should be consistent with fair trade practices.*”. It is not clear how economic analyses can be “consistent with fair trade practices”. Perhaps it is the decision to use economic analysis that should be evaluated for consistency with fair trade practices. It is suggested that the text, “...*and should be consistent with fair trade practices*” should be replaced with “...*and should not result in unfair trade practices.*”

Principle #26 states that, “*Issues of a general nature in the elaboration of food standards and related texts should be clearly identified and consistently addressed according to risk analysis principles.*” Canada agrees with this principle although clarification is sought regarding what types of issues would be considered “ISSUES OF A GENERAL NATURE”.

Principle #28 states, “[*The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified. In such situations it should be possible to apply the precautionary principle.*]”. Canada supports the concept of a principle allowing for risk management measures to be implemented in cases where a risk to health has been identified but the cause/effect relationship has not been scientifically verified. Therefore, Canada supports the inclusion of a reference to “*precaution*” or “*a precautionary approach*”. It is Canada’s opinion that a “precautionary approach” is not new to the Codex risk analysis process. “Precaution” has always been a fundamental element in the work of Codex. Inclusion of a reference to “precaution” in the *Working Principles of Risk Analysis* would not really change the risk analysis process but would serve to make explicit an approach that has been implicit in the Codex process for a number of years. Furthermore, inclusion of guidance on the application of “precaution” or a “precautionary approach” would serve to enhance a consistent application of the concept and strengthen the transparency of the risk management process. However, it is Canada’s opinion that the phrase “*the precautionary principle*” itself is not an appropriate reference due to the confusion and misinterpretations associated with the environmental principle with the same name. As currently worded in the CL, principle #28 only promotes a continuation of this confusion. Canada would suggest that this working principle be reworded as follows;

“Situations should be clearly identified where scientific evidence is insufficient or where there is evidence to suggest that negative effects will occur but it is difficult to evaluate their nature and extent. In such situations, a precautionary approach should be taken to protect the health of the consumer.”

It must be recognized that a precautionary approach is intended for application where there is evidence that there is a risk, but the nature of the risk, or the seriousness of the negative effects on health are not known. It should also be acknowledged that scientific knowledge is never complete - it is always advancing. Hence, there will be situations where the best available science at a point in time indicates no risk, but there is always a possibility that there is a new or unknown element that science was not aware of and has not been assessed. Since no actual risk has been identified, taking action such as the prohibition of the sale of a food would not be appropriate. Nevertheless, these types of situations need to be addressed through the elaboration of policies and guidelines.

A “precautionary approach” or “precaution” would be therefore be defined as an approach or actions taken to initiate measures to ensure public protection in situations where there is evidence that a risk exists or there are reasonable grounds to believe that exposure to an agent may cause serious or irreversible damage to human health, even if some cause and effect relationships are not fully established scientifically.

PRINCIPLES RELATED TO RISK COMMUNICATION

Principle #31 states that, “*risk managers should include an assessment of uncertainty in risk estimates in their communication with the public.*”. It is suggested that this principle should be expanded to include, “*...and other stakeholders.*” The assessment of uncertainty in risk estimates is an important concept that all stakeholders should be apprised of, not just the consumer.

Principle #32 states that, “*Risk assessment and risk management should be fully documented in a transparent manner. Risk management should be transparent, flexible, objective and repeatable and this requires full documentation.*” Canada agrees with this principle. However, reference to “flexible” could be interpreted in such a way as to foster the perception that risk management decisions are inconsistent. Consideration should be given to rewording the principle to reflect that for similar situations, with similar risks and the results of the risk assessments are similar, then there should be consistency in the risk management actions taken. Risk managers need to be flexible in considering various options, but once a decision has been taken, it should be consistent with decisions taken under similar circumstances.

NEW ZEALAND

Section on Risk Analysis

The general principles on risk analysis do not currently provide an adequate food safety context for the following principles on risk assessment and risk management.

This general section should clearly dispel the notion that “risk analysis” consists of the **serial** application of three components: risk assessment, risk management and risk communication. Pragmatic application of a risk-based approach to food control is predicated by the need for a generic risk management framework. This was clearly established by the Joint FAO/WHO Consultation on risk management and food safety, and needs to be developed here as either a principle or as a preambular statement. (It should be noted that the 22nd Session of the CAC in 1997 agreed that the “Elaboration Procedures” section of the Procedural Manual, in addition to containing principles, should contain an introductory narrative on risk analysis).

Risk management provides the process whereby risk estimates and other information relevant to health protection of consumers and the promotion of fair trade practices are used to choose and implement appropriate sanitary measures. It should be made clear in this section that in cases where adequate scientific information on risks is available, utilisation of qualitative or quantitative risk assessments will considerably strengthen decision-making. (In some food safety situations e.g. standard setting, risk management policy may require a risk assessment as a mandatory procedure). However, it is essential to acknowledge that in other cases, food-borne risks to human health can be managed in a systematic way **without** necessarily having to commission a formal risk assessment or define (or make a decision on) an appropriate level of protection.

Further, the entry point to the risk management framework can be a range of food safety issues. These include: identification of a specific food safety problem, the routine need to develop food standards for chemical hazards, development of food safety policy that achieves broad food safety goals, and development of sanitary measures that are required to meet specific food safety goals e.g. demonstration of equivalence.

Application of a risk management framework provides a mechanism for arriving at decisions on appropriate levels of consumer protection and assuring their achievement on an on-going basis. This tenet of risk management is not specifically addressed in the principles of “risk analysis” or in the principles of risk management in the current document.

Communication and consultation are essential activities at all steps in the risk management framework (including risk assessment). In the general section on “risk analysis”, this needs to be explicitly stated.

New Zealand considers that it is very important to address the above issues, either as preambular narrative or as principles in the section on “risk analysis”, so as to give an appropriate context to the following principles for risk assessment and risk management.

Section on Risk Assessment

Editorial changes need to be made to paragraphs 9, and 13 (repeat of material in paragraph 9).
The intent of paragraph 18 is unclear.

Section on Risk Management

Principles developed here should reflect the general comments made above on a generic risk assessment framework.

Editorial changes need to be made to paragraphs 22 and 26.

It should be stated in principle that where a risk assessment is commissioned by the risk manager, the scope and purpose of that risk assessment should be clearly defined.

Paragraph 28 in its present form should be deleted. Reference to application of a precautionary approach, if applicable in working principles on risk analysis, should initially be made in the general section on risk analysis.

Risk Communication

At the time of the original elaboration of the working principles, the Joint FAO/WHO Expert Consultation on risk communication had not taken place. In light of the output of this Expert Consultation and the increasing recognition that risk communication is a key function in the effective implementation of a generic risk management framework, the section on risk communication needs to be considerably expanded and reworked.

NORWAY

Norway considers the inclusion of the precautionary principle/approach in the working principles very important. The term is widely used, but the use is not uniform and interpretations differ considerably.

The concept of precaution is linked to scientific uncertainty as well as to the lack of satisfactory data. Taking into account that uncertainty exists to some degree in almost every case, we find it important that this situation is discussed internationally. If there are serious risks involved, it might be necessary to take measures to protect the health of the consumers without having to wait for all adequate data. It is important however, to ensure a scientific and consistent approach in those situations where the data are insufficient.

Norway considers it very important that the Codex working principles include provisions for dealing with uncertainty and insufficient data. Since the term precautionary principle or words having the same meaning are in use, Norway find that the best way to ensure appropriate and consistent use of these concepts is to include them in the working principles. Otherwise there is a possibility that some kind of parallel terminology might be established, formally or informally.

To ensure that risk management measures are correctly carried out and documented, it is important to develop a common understanding of the meaning and use of precautionary principle/approach within the risk analysis framework.

Norway are therefore in favour of deleting the square brackets of para. 28 in the proposed draft Codex working principles for risk analysis.

The definition should however be discussed further as should the possible elaboration of more specific guidelines. We would recommend that it is stated explicitly that the principle/approach should be applied when a preliminary risk assessment indicates a possible threat to health, that the measures should be of a provisional nature and that efforts should be made to obtain sufficient data to perform a comprehensive risk assessment. We would also like to see references to proportionality and consistency of measures, involvement of stakeholders etc..

REPUBLIC OF KOREA

1. We recall that in 14th session of General Principles there was a discussion whether these principles were used for both of nation and Codex, otherwise for only Codex levels. We consider that the introductory statement should be inserted so as to prevent Codex member from interpreting these principles differently. We suggest new paragraph as follows;

We recognize that these principles should be applied and implemented in Codex framework.

2. For second paragraph under section of Risk Analysis, the sentence should be changed to make it smooth
The risk analysis procedure used by Codex ~~and those used by other relevant international intergovernmental [and non-governmental] bodies~~ should be harmonized ***with those which were used by other relevant international intergovernmental [and non-governmental] bodies*** where appropriate.
3. In paragraph 7, to describe risk assessment process accurately, it should be rewritten as follows;
Risk assessment should be based soundly on science, should incorporate the four steps of the risk assessment process ***which consist of hazard identification, hazard characterization, exposure assessment and risk characterization*** and
4. In paragraph 8, as quantitative information was presented by numerical expression, it should be replaced with data.
5. In paragraph 10, as aspect of production processes, etc., indicate criteria rather than numerical expressions, the ‘data’ should be substituted with ‘information including’.
6. The recommendation of 23th Commission should be reflected in this principle and then new paragraph should be added under section of Risk Assessment.

Risk assessment should be based on global data, including that from developing countries.

7. Regarding the legal position of Codex standards under WTO/SPS agreement, we would like to refer that Codex standard and related texts should be prepared with providing consistently an appropriate level of protection against risk in line with provision of SPS agreement. New paragraphs should be included under section of Risk assessment policy as follows;

Risk assessment policy should be considered and established in the terms of ensuring to provide appropriate level of protection for risk to human life or health. An appropriate level of protection should be indicated as numerical expression, if possible.

Risk assessment policy should be consistently applied to risk of human life or health in the risk assessment process.

8. Where food-born illness happens urgently around the world and then Codex members make consensus for handling that matter, Codex Alimentarius needs to establish the specific limit to an identified risk, even though scientific data of an emerging risk are insufficient. Therefore we support that paragraph 28 should be included in the risk management process.

EUROPEAN COMMUNITY

Risk Analysis

The European Community recommends that the first four opening paragraphs are re-ordered and amended as follows:

- “1. The primary purpose of risk analysis in Codex is the protection of public health.
2. The risk analysis process used in Codex should be consistent, open and transparent and follow a structured approach.
3. The 3 components of risk analysis (risk assessment, risk management and risk communication) are separate but interdependent steps and risk communication must cover the whole process from the beginning to the end.
4. There is a need for communication and interaction where appropriate between the parties involved in risk analysis in order for the process to be carried out effectively.
5. The risk analysis procedure used by Codex and those used by other relevant international, intergovernmental and non-governmental bodies should be harmonised where appropriate.
6. The needs of developing countries should be specifically identified and addressed in the different stages of the Codex risk analysis process.”

Risk Assessment

Para 7: The European Community recommends that the meaning of the three terms “constraints”, “uncertainties” and “assumptions” is clarified.

Para 8 and 12

The European Community recommends that the paragraphs 8 and 12 be merged to the following paragraph 8:

“Risk assessment should use available quantitative information to the fullest extent possible and may include consideration of non-measurable or qualitative data..”

Para 9:

The European Community recommends that a new sentence is added at the end of paragraph 9:

"Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be recognised in carrying out risk assessment"

Para 10:

The European Community suggests redrafting this paragraph as follows:

“Risk Assessment should take into account all available scientific data and other relevant information .”

Para 11:

The European Community recommends that this paragraph is re-ordered and amended as follows:

“Risk assessment should take into account uncertainty in exposure estimates and, if appropriate, in the assessment of dose-effect toxicity. Risk estimates should include an expression of uncertainty which may be qualitative or quantitative. The conclusions of the risk assessment should be conveyed to the risk managers in a readily understandable form. Responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.”

Para 12

The European Community recommends that this paragraph 12 is deleted because it has been incorporated in para 8.

Footnote 1 (para 11)

The European Community strongly endorses the content of this footnote and would like to stress that this division of responsibilities between the Codex Alimentarius Commission (CAC) and its subsidiary bodies, on the one hand, and expert committees, on the other hand, is always respected.

Risk Assessment Policy

The European Community recommends that paragraphs 16 and 17 are re-ordered and amended as follows:

“16 Risk assessment policy should be established following communication between risk managers and risk assessors. Risk managers should encourage communication with stakeholders in the establishment of risk assessment policy.

17. The mandate given to risk assessors must be clearly specified and delineated. This mandate should be achievable and correspond to the capacity and expertise of the risk assessors and take into consideration any constraints for/on the risk assessment process.”

Para 18

Replace 2nd line as follows: “...the risk assessment process is systematic, complete, transparent and objective”.

Risk Management

Para 19

The European Community considers that this paragraph is superfluous, as the revised text on Risk Analysis requires a structured approach for all stages of the risk analysis process.

Para 21

The European Community recommends that this paragraph be modified as follows:

“Risk management should be focused on defining measures aimed at achieving the appropriate level of protection and may take into account agreed outcomes as well as relevant processes and production methods”

Para 22

The European Community recommends that this paragraph modified as follows:

“The principles and factors taken into consideration in Codex risk management decisions should be clearly acknowledged and documented in individual Codex texts. This will encourage a wider understanding of the application of risk management.”

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Para 24

The European Community recommends adding at the end of the 1st line: “to the extent possible”.

Para 25

The European Community recommends that this paragraph be modified as follows:

“Risk management should involve (consistent) appraisal of all available options.”

Para 26

The European Community recommends that this paragraph be modified as follows:

“In the elaboration of food standards and related texts, issues that have been identified as being of a general nature should be referred to the General Principles Committee (CC GP) for consideration, in order to ensure that such matters are dealt with consistently in all Codex texts.”

Para 28

The European Community recommends the deletion of the brackets and has sent separate comments to the Codex Secretariat.

Risk Communication

Footnote 2:

The European Community recommends that, in this footnote, the words “to the extent that is practicable and reasonable” at the end of this paragraph should be deleted in order to give real meaning to the desired objective of increasing transparency and participation of the civil society in Codex’s work.

Para 29: The European Community recommends that this paragraph be modified as follows:

“Risk analysis should include clear, interactive communication, exchange of information and opinions on risk and risk-related factors among risk assessors, risk managers, consumers and other interested parties in all aspects of the process”

Para 31: The European Community recommends that this paragraph be modified as follows:

“In their communication with the public, risk managers should include a transparent explanation of the risk assessment policy and the uncertainty in risk estimates. The need for the measures and the procedures followed to determine them should also be clearly explained”.

Documentation

Para 32

The European Community recommends that this paragraph should be deleted, because the first sentence is a repetition of the paragraph 2 and 3 and the second sentence describes what the risk management should be and is not relevant here.

Para 33

The European Community recommends the removal of this paragraph because it does not relate to documentation. The idea of a continuing process and consistency are good, but this paragraph should be addressed to risk assessment and risk management. The content should be transferred to the Risk Analysis chapter (for example to a new point 6).

Comments on the Precautionary Principle

Response of the Member States of the EC to Circular Letter CL 1999/16 – GP

In order to help the Codex Secretariat to prepare a document on the Working Principles for Risk Analysis, governments and international organisations have been invited to present specific comments on the precautionary principle or approach, which should be distinct from the comments concerning the other sections of the Working Principles.

The Member States of the European Community welcome the opportunity to comment on the inclusion of the Precautionary Principle in the context of the discussions in the Codex Committee on General Principles (CCGP) on the Working Principles for Risk Analysis.

The square brackets around the sentence referring to the Precautionary Principle in the Proposed Draft Codex Working Principles for Risk Analysis (paragraph 28) should be removed.

In addition, the Member States of the European Community recommend that the CCGP continue working on the Precautionary Principle, as already initiated in April 1999 (Paris), in order to arrive at a general understanding of the conditions under which it would be applied, including guidelines for its application.

In this respect the Member States of the European Community recommend the following definition/statement and key requirements for the application of the Precautionary Principle in relation to food safety issues:

When a preliminary risk assessment indicates the likelihood of unacceptable effects on human health from hazards present in food, lack of full scientific information shall not be used as a reason to postpone the introduction of appropriate, proportionate measures which are intended to prevent such effects.

Following the recommendations of the FAO Conference on International Food Trade beyond 2000 (Melbourne), the Member States of the European Community recommend that the CCGP considers the following key points in the development of Guidelines for the Application of the Precautionary Principle in the food safety area:

- The Precautionary Principle is a risk management tool and may be invoked to develop measures in those specific circumstances where, following **preliminary scientific assessment** there are indications that possible consequences on health may be unacceptable and that the data are insufficient for a full risk assessment to be carried out. The Precautionary Principle is part of the overall risk analysis approach **and the measures taken should be based on information provided by the preliminary risk assessment.**
- The Precautionary Principle should **not be confused with a precautionary approach** used by scientists in the risk assessment process (e.g. in relation to dietary exposure levels, safety factors etc.)
- Measures should be **proportionate** to the nature and magnitude of the health risks and extent of the uncertainties.
- Measures should be **non-discriminatory** and **the least trade restrictive.**
- Where possible, **all interested parties should be involved** in the decision-making process.
- There should be a **transparent** explanation of the need for the measures and the procedures followed in determining them.
- **Additional data** should be collected to enable a full risk assessment to be performed. The data needed, and responsibility for collecting them, should be clarified.
- The measures taken should be regarded as **provisional** and subject to **review** and, if justified, modified in the light of new findings.
- Examination of the **full range of management options** should be undertaken. This should include an assessment of the potential advantages and disadvantages of various possible measures, including cost/effectiveness considerations.

CONSUMERS INTERNATIONAL

1. Introduction

2. Consumers International welcomes this opportunity to submit comments on the proposed Working Principles for Risk Analysis (CL 1999/16 – GP) and to provide our initial comments on a definition of the precautionary principle or a statement of a precautionary approach and the conditions under which it would be applied.⁴

3. The Precautionary Principle

4. The debate around the precautionary principle within Codex has centred around the following issues:

- Whether it is appropriate to apply the precautionary principle to food safety standards
- How the principle should be defined
- How the principle should then be applied in practice and whether precaution is already built into the risk analysis process

⁴ We also want to draw attention to the report by Consumers Association (1999), *Confronting Risk: A New Approach to Food Safety*, CA, London.

5. It is clear that some delegations perceive the precautionary principle to be a protectionist measure at odds with the need to promote trade. Consumers International believes that clearly defining when and how precaution is used in the Codex context should ensure that the precautionary principle and approach is used appropriately to protect consumers and promote fair trade practices. CI considers that it is essential that the precautionary principle is recognised and upheld within Codex. We consider it to be of such fundamental importance that we believe the Committee should consider its incorporation into the Procedural Manual.

The wording that we would suggest is as follows:

‘The precautionary principle should apply in cases when the scientific evidence is not conclusive enough to establish control measures based on a sound and accurate risk assessment, but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment’.

The wording proposed by the delegation of Sweden at the Fourteenth Session of the Codex Committee on General Principles was very much in line with our own interpretation of the principle, and we could support their proposed wording as set out in paragraph 28 of the report of the meeting.

Rather than being at odds with an approach to risk analysis based on sound science – the precautionary principle complements and reinforces this approach. It works to ensure that uncertainties are adequately and appropriately acknowledged and addressed by risk assessment and risk management. In the risk management context, it calls for measures in the short term to ensure that public health is not put at risk in the longer-term. The principle is based on the idea of prevention and it can therefore work to assist trade and economic interests, by aiming to ensure that food safety issues do not arise in the longer-term. Its basic premise is that we should not wait for conclusive evidence of the causes of a risk before putting control measures in place designed to protect consumers or the environment. This is consistent with the approach that has been taken by governments for example in introducing controls covering Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt Jakob Disease (CJD). The European Union has explicitly acknowledged the importance of the precautionary principle in recent years after a succession of food scares which reinforced the costs – both public health and economic – of failing to take such an approach.

It is often assumed that to acknowledge the precautionary principle automatically means that products will be banned from trade. This is not necessarily so. Precautionary action can involve a whole range of measures, from assessing the risks of alternative products, implementing more thorough monitoring and inspection programmes, restricting the sale of a product, introducing legislation, encouraging the industry to take voluntary measures or follow a particular research or marketing approach, or requiring labelling on products, for example. A balance will still need to be achieved between ensuring that consumers have a choice of foods and also ensuring that they are safe. An evaluation of the risks and benefits of taking action or not taking action will therefore be required. However, for this to be done effectively, stakeholders will have to be fully involved and there will need to be openness about the current state of knowledge and where uncertainties may lie. Applying the precautionary principle, does not therefore remove the need for measures to be proportionate. In addition, in situations where precautionary action is taken, priority should be given to developing the scientific data necessary to support a sound and accurate risk assessment in the future.

Although general guidelines will need to be developed by Codex for the practical application or ‘operationalisation’ of the precautionary principle, decisions about when to act or not to act, will ultimately still need to be taken by risk managers, together with all relevant stakeholders, on a case by case basis.

We do not therefore consider that it is necessary to debate whether we need to refer to a precautionary principle or to a precautionary approach. Both are necessary. The precautionary principle is, as it suggests, a statement of principle. Codex therefore also needs to consider the approach that is taken to risk analysis that will ensure it is practically applied.

A precautionary approach

Implementation of the principle, requires the adoption of a precautionary approach throughout the risk analysis process based on :

- two-way risk communication with stakeholders throughout the process ; and
- openness and transparency

Although the on-going work that Codex is doing in relation to risk analysis principles is making progress in this respect, we do not consider that precaution is sufficiently incorporated into Codex's current approach to risk assessment and risk management. Work in this area should continue to be a priority as it is essential that working principles are established and then implemented.

Our following comments on the most recent draft of the Working Principles for Risk Analysis expand on how we consider precaution can be incorporated into risk analysis procedures.

Proposed draft Codex working principles for risk analysis

We support the work of the Committee on this important and excellent document and offer the following comments.

Risk analysis

Although the three components of risk analysis should be documented separately and systematically, we consider that the working principles should emphasise the importance of ensuring that risk communication is integral to the whole process – and therefore the three stages of risk analysis will not necessarily follow one after another, although they should remain distinct. For example, in practice, the process begins with risk managers determining a risk assessment policy together with relevant stakeholders, ie. risk communication (please see our comments more specifically in relation to these stages).

We fully support Principle 4 that the risk analysis process used in Codex should be consistent, open and transparent.

Risk assessment

We fully support the emphasis on ensuring that risk assessment is conducted openly and transparently and that any uncertainties and assumptions will be documented. This documentation should be presented along with the conclusions of the risk assessors.

It would be very helpful if the working principles explicitly stated at the beginning of each section who will have responsibility, rather than putting this in a foot note.

We suggest that (6) is re-worded to state that : Experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, *and a declaration of any interests should be publicly available.*

We suggest that (11) is reworded by adding a second sentence to read : *Risk assessors should also clearly set out and communicate any assumptions that have been made or any judgements that have been included as part of their assessment.* We also strongly agree with the last sentence that the responsibility for resolving the impact of uncertainty should lie with the risk manager and not the risk assessor.

We suggest that (12) is reworded : Risk assessment may include non-measurable, qualitative information *and where this is included it should be clearly documented.*

We also suggest that an additional point is added:

(new 15) Consumer INGOs should be invited to attend meetings of the risk assessors in their capacity as observers. This should help to aid transparency, help ensure that the assessors can communicate their conclusions in a form that is meaningful and should ensure that lay perceptions of risk are also taken into account.

Risk assessment policy

This should clearly state that as a risk management responsibility in the Codex context, risk assessment policy will be determined by the Codex Committees and the Commission, in consultation with risk assessors and relevant stakeholders including consumer INGOs.

We consider that (17) currently in square brackets does not provide the right emphasis. Risk managers should identify the issue to be considered and the questions that need to be addressed, as well as the type of expertise that is needed. The risk assessors should then be appointed to match their requirements. We do not agree that

the question should be framed to suit the make-up of the risk assessors and their way of working, as this will not result in robust decisions and may not mean that the most appropriate expertise is included. If a situation arises where the task is beyond the capacity of an existing committee, the risk managers should consider how this can be most appropriately addressed.

(18) should be amended to read 'Risk managers should invite all interested parties to submit proposals and comments *to the risk assessors* to ensure that the risk assessment process is systematic and complete.'

Risk management

(21) should read: 'Risk management should *normally* be focused on agreed outcomes rather than on processes.' We are concerned that in some situations it may be necessary for risk managers to be more prescriptive in the interests of public health protection, and therefore this option should not be excluded.

(23) We fully support the inclusion of this point and will prepare detailed comments prior to the CCGP meeting in April 2000.

Reference to the precautionary principle

(28) In line with our comments above, we fully support the inclusion of this statement and therefore consider that the square brackets should be removed. We would however, suggest a slight amendment to the second sentence to read: *In such situations, decisions should take account of the precautionary principle.*

Risk communication

We fully support (29). This is consistent with the conclusions and recommendations of the Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters.

We would also suggest that the working principles should highlight the importance of enhancing consumer involvement within Codex and therefore suggest the following addition :

(new 30) *Codex should seek to ensure that consumer involvement within Codex is encouraged and enhanced. Measures should include encouraging consumer INGO participation in committees and conducting consumer research to ensure that risk assessment and risk management are informed by a clearer understanding of consumer attitudes, perceptions and behaviour.*

(31) This will be essential for ensuring the credibility of Codex's work.

Documentation

We support (32) and recommend that it is strengthened as follows, in line with a document elaborated by the Codex Committee on Food Hygiene and already adopted by the Commission at its 23rd Session: Risk assessment and risk management should be fully *and systematically* documented in a transparent manner. *To ensure a transparent risk assessment, a formal record, including a summary, should be prepared and made available to interested and independent parties so that other risk assessors can repeat and critique the work. The formal record and summary should indicate any constraints, uncertainties and assumptions and their impact on the risk assessment.* Risk management should be transparent, flexible, objective and repeatable and this requires full documentation.

We fully support (33) and consider it important that standards are kept under review in the light of new scientific evidence.

We note that documentation of the constraints, uncertainties and assumptions and their impact on the risk assessment is an important and necessary prerequisite for risk managers in deciding whether to take precautionary action. In addition, the gathering and evaluation of new data is particularly important when existing evidence is incomplete and precautionary measures are applied as a result.

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

IACFO agrees with the statement in paragraph 23 that "Guidelines should be available for the inclusion in

risk management decisions of 'other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.'"

In response to the Committee's invitation to provide specific comments on the "precautionary principle or approach," IAFCO recommends that the Committee develop a guideline specifying that when scientific evidence is insufficient to make a determination of risk, risk management decisions should be based on the principle that nondiscriminatory health standards should be maintained until it is demonstrated that such standards are scientifically unjustified.

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

It is reassuring to see that the circular letter correctly acknowledges that the CCGP has not decided to define the precautionary principle for food safety policy. The statement that the Secretary would seek comments on a definition of the precautionary principle **or** a statement of a precautionary approach as it might apply to risk analysis for food is appropriate, because it clearly indicates that the decision has not yet been made.

Our comment will clearly demonstrate that a precautionary approach to food safety policy already exists within Risk Analysis (both in Risk Assessment and Risk Management) and, therefore, an additional precautionary principle is not needed.

The Council for Responsible Nutrition appreciates this opportunity to comment on these important issues. We look forward to working, as a recognized INGO, with government delegations and the Secretariat to help in the elaboration of Codex guidelines that will help provide to consumers the generous availability of a wide variety of safe, properly produced nourishing foods that inspire confidence.

Risk Analysis

The three components of risk analysis are correctly identified as risk assessment, risk management, and risk communication. Codex risk analysis procedures should be harmonized, where appropriate. If risk analysis is based on objective guidelines, the Codex principles and procedures for risk analysis should be as similar as possible to those used by other authoritative bodies, whether they are governmental or not. The strengths of any system of risk analysis should be employed by Codex, as appropriate. This is especially important when one authoritative body has taken a clear lead in a unique and important application of a component of risk analysis, such as the risk assessment method adapted especially for essential nutrients by the United States National Academy of Sciences (U.S. NAS) (Ref 1).

It is important to recognize that the scientific component of risk analysis, i.e., risk assessment, should be universal. Even though developing countries, by definition, have special financial considerations, it is crucial that the basic elements of risk analysis should apply to all countries without regard to financial, cultural, or political considerations. It is important for public confidence that the risk analysis process used in Codex (and all public groups) be consistent, open, and transparent.

Risk Assessment

Codex decisions and recommendations should be based on risk assessment. Other legitimate factors may be considered in risk management decisions at the national level but must not be used as an excuse to overrule the scientific evidence. Of equal importance, the risk assessment should employ the most appropriate authoritative adaptation to a specific use, e.g., the U.S. NAS method for vitamins, minerals, and other nutrients.

Risk assessment must treat uncertainty in a manner that is consistent with all aspects of the science related to the substance under consideration. For example, the large uncertainty factors and safety factors (usually multiples of 10) that are used for pesticides, heavy metals, and many food additives are impossible for application to nutrients—there is less than a 10-fold difference between adverse intakes and deficient intake for some nutrients, e.g., iron, zinc, copper, and perhaps vitamin D. Thus, it is essential that risk assessment for nutrients use a method that has been specifically adapted for that application.

The draft statement (CL, paragraph 12) that "Risk assessment may include non-measurable, qualitative data" needs further elaboration to provide confidence that it will not be misinterpreted. A statement is needed, that quantitative evidence will be used when available, and that qualitative evidence is considered supplementary

or secondary. If additional description and appropriate examples are not given, this paragraph should be deleted.

The request (CL, paragraph 13) for additional recognition of the differences between acute and chronic adverse health effect is not needed because well-defined and executed risk assessment considers both acute and chronic effects and exposures. Consideration of the differences between acute and chronic adverse health effects, i.e., between immediate and delayed effects, and between transient and persistent effects, is a fundamental part of risk assessment as defined and performed by the U.S. NAS, U.S. Environmental Protection Agency, and the Organisation of Economic Co-Operation and Development (OECD). Similarly, the differences in effect and potency in response to both acute and chronic *exposure* is also recognized in these authoritative descriptions of risk assessment methodology.

The support for a pragmatic approach (CL, paragraph 14) should not give the risk managers so much control of risk assessment that they can predetermine the outcome of the scientific process. Guidelines should be developed to assure that politics will not seize control of science. Examples of political rejection of scientific conclusions when those conclusions do not support the political agenda include the European Union's rejection of the Joint Expert Committee on Food Additives (JECFA) conclusions on the safety of bovine somatotrophin (BST) and the EU's ordering of additional studies on hormone-fed beef when the initial studies indicated safety.

Risk Assessment Policy

The separation of risk assessment and risk management addressed in CL paragraph 14 should be included in Risk Assessment Policy. Much of the description of Risk Assessment Policy easily could be construed to give risk managers complete control not only of whether risk assessment on a specific substance is needed and funded, but also control of the scientific procedures, standards, and possibly the outcomes. Risk assessment goals must be achievable, and this is impossible if the goal, either explicit or implied, is to demonstrate complete safety, i.e., zero risk. Broad participation in the development of risk assessment policy and all components of risk analysis will help assure that the process is systematic, complete, logical, and possible.

If "other legitimate factors" (OLFs) are included in Risk Management, guidelines must be developed that will assure that it is *risk* that is being managed. Technical factors such as good agricultural practices and good manufacturing practices are valuable OLFs, and they help manage risk. Cultural and even religious preferences are valuable human and philosophical attributes, but they generally do not manage health *risk*.

Risk Management

Risk managers should not set any OFL that does not influence health risk. It is logical to include environmental and resource considerations in risk management decisions, but human health considerations should remain paramount. Economic considerations included in risk management decisions must not be discriminatory or impede fair trade.

Clear risk management guidelines are needed to assure that the management option selected does not imply an unreasonable or impossible goal. For example, complete "elimination" of many hazards is impossible because zero risk would require zero exposure, an impossible goal for substances such as certain trace elements in food.

Risk management guidelines from Codex should clearly recognize that precaution has long been, and continues to be, a basic component of both risk assessment procedures and risk management authorities. A failure to utilize an existing authority to exercise precaution should not be confused with or misconstrued as a lack of the authority. A separate "precautionary principle" is not needed, and it would be harmful because it would be redundant and falsely imply that there is no precaution in risk management without it. Furthermore, a separate precautionary principle would be an open invitation to erect unjustified technical barriers to trade.

It should be clearly understood that the FAO/WHO/WTO International Conference on Food Trade Beyond 2000, held in Melbourne on 11-15 October 1999, did not recommend that the CCGP define and adopt the precautionary principle into food policy. It merely remanded the controversy over whether or not this should be done back to the CCGP for further consideration.

Risk Communication

Risk Communication must not take actions that cause paranoia or generate demand for goals that risk assessment and risk management could never achieve. For example, a communication that a food product “contains arsenic” would certainly be true. Arsenic is a natural component of soil, and therefore no food product can be totally, absolutely free from all traces of arsenic. The traces may be vanishingly small but they are inevitably there. Risk Communication actions should be **proportionate** to the risk. Simple scientific truth can be used in a manner that is misleading with false implications. Food labeling regulations in many countries prohibit misleading labels. Similarly, misleading risk communication should be rigorously avoided.

Additionally, risk communications should not oversimplify and mislead about “uncertainty” in the scientific evidence related to safety of foods. Science can provide a high level of confidence, but never “certainty.” Assessment of uncertainty is a fundamental part of properly defined and performed risk assessment, and consideration of uncertainty is a proper component of risk management. Risk management must not set impossible goals for implied total elimination of uncertainty as camouflage for unjustified trade barriers, and risk communications must not be used to generate alarm that would demand impossible total elimination of all risk.

Documentation

Risk Communication as well as Risk Assessment and Risk Management should be fully documented. For Risk Communication, documentation should include an assessment of whether the communications are consistent, and also congruent with both the scientific evidence and procedures (risk assessment) and with laws and regulatory practices (risk management). Codex should elaborate guidelines that would help prevent abuses in risk management.

CRN’S Summary: For food safety policy, **an additional or separate precautionary principle should not be defined** and adopted because it would (1) be redundant, (2) be misleading, (3) demand impossible proofs of safety, (4) not improve consumers’ safety, and (5) lend itself to the support of unjustified trade barriers.

EUROPEAN FOOD LAW ASSOCIATION (EFLA)

Point 3.2. The precautionary principle

The European Food Law Association (EFLA) enrolls professionals working in all branches of the Food sector, including executives from the industry or trade and officials in National or European administrations, academics, consultants and lawyers. As EFLA dealt with the precautionary principle on the occasion of its International Congress which was held in Brussels in October 1998 and was devoted to Food Safety, it is happy to express its point of view and to cooperate in the discussion about risk analysis and, more specifically, regarding the use of the "Precautionary Principle" as a tool for risk analysis.

EFLA is not convinced at this stage that a new legal concept such as the "precautionary principle" should be introduced in the international decision making process.

However, in any event, EFLA considers that if the precautionary principle were to be officially introduced in the risk analysis, there should be very clear definitions of :

- the principle itself,
- the circumstances under which the said principle would apply
- the conditions under which it should be implemented

In any case, the following considerations rely on the hypothesis that the subject matter is the use of the principle to justify measures taken by public authorities. The use of this principle to justify any private decision or any decision made in the assessment of the responsibility of producers is not contemplated in this paper.

1. As to the definition of the principle itself :

It is generally acknowledged that a "precautionary approach" has always been adopted, and should always be, when elaborating Food regulations dealing with public health. EU Law on additives, governed by the principle of "positive lists", is a good example of such an approach.

Therefore, it is necessary to determine very clearly if the "precautionary principle" is just a codification of this traditional approach, i.e. an attempt to standardise how caution is used. If this is the case, it will still be present in all decision making processes and no new principle has to be introduced.

If this is not the case, it means that a new "principle", aimed at justifying barriers to trade or even internal restrictive measures within States, is contemplated. In this hypothesis, very clear and precise definitions have to be established.

In any case, the introduction of a new principle should only be considered by International bodies once it has been clearly and concretely established what weaknesses currently exist in the decision-making process and how a new approach can help overcome these weaknesses.

In other words, a new principle should only be introduced if it can be demonstrated that the current Risk Analysis procedures are not sufficient to protect human health. ~~-(a);~~

2 - As to the circumstances under which the principle would apply

2.1. EFLA has noticed that a majority considers that the precautionary principle, if introduced, must apply **at the risk management level and not at the risk assessment level**. This position is based on the idea that the scientists must remain free to give fully independent statements, whereas the decisions taken on the basis of these statements are of a political nature.

Whether this approach is approved would have to be clearly stated.

2.2. As far as it is acknowledged that the principle would only apply when the results of scientific research are "uncertain", it should be borne in mind that a scientific result is never 100% "certain".

Therefore, what constitutes "uncertainty" within the meaning of the "Precautionary Principle" has also to be clearly defined.

The risk assessment has to define if uncertainty is the result of uncompleted work, or if uncertainty is due to be permanent.

Also, the category and the magnitude of the risk derived from uncertainty has to be determined, in order to assess in which cases the "Precautionary Principle" is to be implemented. The meaning of "health risk" has also to be defined. Health risk must be real, not just hypothetical and must be a real threat to human health.

EFLA strongly supports the opinion according to which, in any case, the Precautionary Principle must apply at the risk management level for an actual risk, and not for a perceived risk which would be dealt with at the risk communication level.

3. As to the conditions under which the principle should be implemented

3.1. The implementation of the Precautionary Principle should in any case be balanced with the fundamental and well assessed **principle of proportionality**, according to which the most appropriate measures are those taken, with a view not to put more burden than strictly necessary on the producer. Information to the consumers for example may be sufficient if the risk at stake is only for a small and well defined part of the population.

3.2. EFLA also believes that when a measure is taken under the precautionary principle there must be no shift whatsoever of the burden of proof.

A company should in any case have the opportunity to collaborate with the public authorities before being exposed to bans or other drastic measures.

One of the general principles of law is that the burden of proof lies on the party who takes a measure. Therefore, the rules must clearly remain that public authorities, when taking measures under the precautionary principle, must prove⁵ :

- that all conditions are met, namely that there is a scientific uncertainty entailing one of the risks which are recognised as justifying the implementation of the Precautionary Principle.

To this purpose, due consideration should be given to cases where public authorities are bound to take measures, because in the absence of said measures, they would be liable vis à vis the consumers. In this case (if proven), it seems obvious that the authorities should be allowed to take proportionate and temporary measures based on the Precautionary Principle without bearing any responsibility vis à vis the producer/importer.

- that the measure is proportionate to the risk at stake. If it is to be decided that the Precautionary Principle would only justify temporary measures, it would also be necessary to prove in that case that scientific certainty is being sought in the meantime.

It is obvious that in many cases, the producer will be active, trying to prove that the restrictive measure is not justified and that, therefore, this measure should be abolished. However, as a legal principle, EFLA believes it is important not to shift the burden of the proof, and recommends to state clearly that the authority

⁵ This mechanism of the burden of the proof applies if the Precautionary Principle is seen as a justification for temporary restrictive measures. If it is a mere "codification" of the traditional precautionary approach when a decision is taken, the burden of the proof for the admission of a new substance on a positive list should remain, naturally, on the producer who claims for this admission.

who has taken the restrictive measure remains responsible for proving that the said measure was, and remains, justified.