codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 3 **CX/GP 00/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Fifteenth Session, Paris, France, 10 - 14 April 2000

RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS

1. Following the request of the 22nd Session of the Commission to elaborate integrated principles for inclusion in the Procedural Manual, the 13th Session of the CCGP (1998) considered a first version of the Proposed Draft Working Principles for Risk Analysis based on the proposals presented to the Commission (ALINORM 97/19-Rev.1). The document was redrafted in the light of the discussion of the 13th Session and considered by the 14th Session of the CCGP (1999).

2. The Committee agreed on a number of amendments to the sections concerning Risk Analysis, Risk Assessment and Risk Assessment Policy, but decided that they could not be finalized at this stage as the Working Principles should be considered as a whole and further discussion was required especially on Risk Assessment Policy (ALINORM 99/33A, paras. 17-26).

3. The Committee discussed the opportunity to include a reference to the precautionary principle in the framework of risk management, and could not come to a conclusion on this issue. It was therefore agreed that the section on Risk Management, as presented in the working document, would be circulated for further comments (paras. 27-34). The Committee also agreed that comments would be sought on a definition of the precautionary principle or a statement of a precautionary approach and the conditions under which it would be applied, and that the Secretariat would prepare an analysis of all relevant aspects and proposals for further consideration. In order to prepare this document and to facilitate the discussion on the Working Principles as a whole, governments and international organizations were 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.

4. The Working Principles have been redrafted in the light of the comments received and in order to clarify or further develop some issues raised in the comments. The last session of the Committee did not discuss the section on Risk Management in its entirety, as the discussion focused mainly on the precaution issue, and no changes were made to that section. It was revised to incorporate some relevant recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety, since the initial draft had been prepared before the Consultation.

5. The present document includes an outline of the main issues and corresponding changes made to the principles and the issues and the revised Working Principles; a specific section on the precautionary principle/approach; and the revised draft of the Working Principles. The redrafted version was prepared to facilitate the discussion and it is not circulated for additional comments. It should be read in conjunction with the comments requested at Step 3 and included in document CX/GP 00/3-Add.1.

WORKING PRINCIPLES FOR RISK ANALYSIS

SCOPE

6. It was proposed in some comments that a general statement clarifying the scope of the principles and their relevance in the framework of Codex should be added. An introductory section was therefore included in order to highlight the importance of risk analysis as related to the objectives of Codex, and the role of such principles in the standard-setting process. It should therefore be clear that the principles are intended to provide an orientation to the work of the Committees while considering issues specific to "protecting the health of consumers".

7. However, the question of the applicability of the principles may need further consideration since several recommendations also relevant for governments when carrying out risk analysis. The 13th Session of the Committee recalled that the mandate given by the Commission was to consider the application of the principles in the framework of Codex. This question was also discussed in relation to the recommendations on risk communication, which needed rewording to ensure that they were appropriate in the context of Codex.

8. It should be borne in mind that the Statutes of the Codex Alimentarius Commission do not encompass all public health issues or food safety per se but refer specifically to "protecting the health of consumers", which may in fact be a wider mandate than strictly public health or food safety issues. The Working Principles should be consistent with the mandate of the Commission as defined in its Statutes.

9. Following the recommendations of the Commission, the Committees responsible for "protecting the health of consumers" have been considering how to integrate risk analysis in their work, and they are currently developing recommendations to this effect. In addition, the Committee on Food Hygiene developed the Principles and Guidelines for the Conduct of Microbiological Risk Assessment adopted by the Commission in 1999, which are directed to government and other interested sectors and is currently developing a similar document on risk management, which is also of general application. In this perspective the Committee may wish to consider the need to develop risk analysis principles for general application, which would be directed to governments and to other interested sectors. These two approaches might be complementary: the current working principles, together with specific guidelines for relevant committees would ensure consistent application of risk analysis throughout Codex and appear in the Procedural Manual. General recommendations on the application of risk analysis could be directed to governments and included in the Codex Alimentarius; this document would be of the same nature as the Principles and Guidelines for the Conduct of Microbiological Risk Assessment or the Principles for Food Import and Export Inspection and Certification .

10. The text in the first Footnote identifying the risk assessors and risk managers in the framework of Codex was transferred to the Scope section for clarification purposes and as proposed in some comments.

RISK ANALYSIS – GENERAL ASPECTS

11. Several working principles applying to the entire process were included in the section on risk analysis; there is no need to repeat them in the individual sections but only to develop them further when specific detail is needed. The recommendation concerning the nature of the process was amended to emphasize the need for a structured approach and was moved to the beginning of the section in view of its importance.

12. The Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters recognized that "risk communication, being an integral part of risk analysis, is a necessary and critical tool to appropriately define issues and to develop, understand and arrive at the best risk management decisions". Several comments also stressed the need for effective communication throughout the risk analysis process and a separate paragraph was added to reflect the importance of communication and consultation with interested parties at all stages.

13. Since the separation between risk assessment and risk management is an essential principle of risk analysis, it should be included in this general section rather than under Risk Assessment. The text was expanded to include the recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety (Principle 5), in order to emphasize the scientific integrity of the assessment. This is also

important to stress that risk assessment and risk management are not conducted sequentially or in isolation, but are part of a common process requiring effective interaction.

14. The last session of the Committee recognized that a precautionary approach had been consistently taken in health protection matters in the framework of Codex and a specific statement might be useful to reflect that precaution is as an integral part of the risk analysis process. The Committee should decide as a matter of principle if there is a need for an additional section on precaution in the context of Risk Management context to address different issues, as discussed below.

15. The relevance of the requirement for harmonization with other organizations in the context of the risk analysis principles may be questioned and it is perhaps not necessary to discuss this question at length, since the mandate of the Committee is to establish principles for application in Codex. Other international organizations participate in Codex work and their proposals are taken into account in the development of standards and related texts as an integral part of the elaboration procedure. It may therefore be superfluous to introduce this question in working principles. Moreover, the role of Codex as regards coordination with other organizations is explicitly stated in Article I (b) of the Statutes of the Codex Alimentarius Commission "promoting coordination of all food standards work undertaken by international governmental and non governmental organizations" and this applies to risk analysis as to other aspects of food safety and quality.

16. Unless there is clear consensus that this provision can be included with one or other of the wording proposed, it is suggested to delete it since it not of primary importance. If it is retained, a reference to "expert bodies" could be added since these bodies are not strictly speaking intergovernmental, although experts may be from government agencies. As an alternative, reference could be made to "coordination" with other organizations since this terminology might be more generally acceptable to the Committee.

RISK ASSESSMENT

17. A recommendation concerning the need to state clearly the scope and purpose of risk assessment, and to define its possible output, appears is the Principles and Guidelines for the Conduct of Microbiological Risk Assessment and this principle was included in the text in view of its general relevance for risk analysis (para.14).

18. A reference to the procedures used to select the experts was included in order to reflect the general requirement for transparency, and as proposed in the comments from Brazil. This also corresponds to earlier discussions in the CCGP and the Commission on this question and is intended to cover all aspects of the selection process.

19. The identification of uncertainty and variability represents an important issue in the framework of risk analysis and specific provisions were introduced to address their description in hazard identification and characterization, on the basis of the recommendations of the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues (paras. 16 and 17).

20. The text was reorganized in order to avoid duplication and to combine the recommendations that reflected the same concept, such as type of data and the nature of the adverse health effects. As it is recognized that risk assessment should consider susceptible population groups, and take into account all types of adverse health effects, these provisions were included in the same paragraph (19) to emphasize the need for a thorough risk assessment, and as proposed in the comments (EC).

21. A recommendation concerning the use of global exposure assessment data was included, following earlier discussions on how to address the needs of developing countries, and take them into account while developing international standards (para. 20).

22. In para. 21, the text was amended to reflect that the whole food chain should be covered, as proposed in the comments, and to replace a reference to "diseases" with "adverse health effects" since the principles are intended to cover all risks to the health of consumers, whether chemical or microbiological.

23. As it is recognized that risk assessment should be clearly recorded, a recommendation to this effect was included on the basis of the text included in the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (para. 23).

RISK ASSESSMENT POLICY

24. This section was redrafted in the light of the comments received, especially to address the issue of as regards the selection of risk assessors: it was noted that the mandate should not be defined by the expertise of the risk assessors, but that the selection of risk assessors should rather correspond to the mandate proposed. However, the mandate should be achievable in view of current scientific evidence, and the revised texts intends to take both aspects into account. It was also stressed that risk managers should clearly identify the scope and purpose of the risk assessment.

25. The last session of the Committee agreed to defer consideration of the definition for "risk assessment policy" since further work on risk analysis principles was needed to clarify the concepts involved. The Committee may wish to reconsider the need for a definition in the light of the discussion on the principles, since most terms referring to risk analysis have already been defined.

26. The need for effective communication between risk managers and risk assessors, and with interested parties, was explicitly stated since this is essential to ensure the efficiency and transparency of the process, and the initial text was too vague in this respect.

27. The last paragraph in the Section is intended to reflect current practice as the evaluation of risk reduction corresponding to different options may be an important element of the decision taken by risk managers. This approach was taken in the case of the risk assessment of aflatoxins and it is proposed to follow a similar procedure in the case of certain contaminants and of emerging pathogens.

RISK MANAGEMENT

28. This section, which had not been discussed in detail by the last session of the Committee, was redrafted to take into account the recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety, in addition to the comments received. Among these, the reference to the protection of consumers' health was emphasized as the general objective of risk management (instead of the earlier reference to primary consideration).

29. The elements of risk management, as defined by the Consultation, were specified in order to clarify the reference to a structured approach for risk management (para. 31). In this respect, the Committee will need to consider an important issue of principle, raised in the comments of New Zealand: the need for the risk management process to follow a structured approach even when a formal risk assessment is not requested.

30. The need for a specific risk assessment may be considered from different perspectives according to the nature of the risk management decision. It may take the form of a quantitative requirement affecting the end product or it may consist of control measures applying to different stages of the production or processing chain. This is especially the case with food hygiene and microbiological contamination issues, which are addressed in codes of practice following the whole food chain, or with source-directed measures against mycotoxins or other contaminants, which may be taken in addition to a numerical limit. All risk management measures, whether quantitative or not, are intended to protect the consumers' health and should be evaluated in relation to the overall reduction of the health hazard, but the specific aspects of non-quantitative measures should be further considered, and the revised text in para. 32 was included as a basis for discussion.

31. Since the Consultation recognized the need for an evaluation of risk management options in conjunction with the result of the risk evaluation process, this recommendation was introduced in order to clarify the decision process (para. 35) and to introduce the reference to "other factors considered as appropriate". Since the following paragraph also refers to these factors, the Committee may consider whether both references are necessary, and whether a specific mention of economic analyses is also required.

32. The paragraph on general issues was deleted as it was too vague and tended to create confusion; "issues of a general nature" can be any type of issues, addressed by general subject committees in Codex, and not necessarily related to risk analysis. The requirement to apply risk analysis to food safety matters is set out in the *Statement of Principles on Food Safety Risk Analysis*, already included at the beginning of the Risk Assessment section and there is no need to repeat it further here. Issues of a general nature in Codex should be addressed by the relevant general subject Committee as set out in the Procedural Manual and according to the terms of reference of those committees.

33. The need for interactive communication with consumers and other interested parties was specified in view of its importance in the context of risk management (para. 37), and the consistency of the decision process was reasserted and clarified on the basis of the comments received (para. 37). The regular updating of risk management decisions in the light of new scientific knowledge and other relevant information is reflected in the last paragraph, as proposed in the comments.

RISK COMMUNICATION

34. The first sentence was simplified as risk communication is defined in Codex and it is not necessary to repeat a part of the definition here. This section was revised to clarify the purpose of risk communication, but the specific recommendations made at each step of the process need not be repeated.

35. The respective role of risk assessors and risk managers in communication was specified, as communication should not be the responsibility of risk managers only. The last sentence was also amended in view of the recommendations of the Joint Expert Consultation on Risk Management and Food Safety on the communication of uncertainty.

DOCUMENTATION

36. The current text on Documentation includes recommendations on risk assessment and risk management which should preferably be included in the relevant sections. Since provisions concerning documentation have already been included in the relevant sections, a separate section on this aspect would create unnecessary duplication. Moreover, since the title of the document refers to the principles for risk analysis it would preferable to retain only the sections referring to the actual components of risk analysis. The section was therefore deleted as proposed in some comments.

PRECAUTIONARY PRINCIPLE/APPROACH IN RISK MANAGEMENT

37. The last session of the Committee recognized that precaution had consistently been an element of the decision process in Codex for the purposes of health protection. This applies to the whole risk analysis process and since there is consensus on this principle, it might be useful to make it explicit in the Working Principles. A proposal reflecting this aspect of "precaution" was put forward in the section on Risk Analysis for consideration by the Committee.

38. However, there was no consensus on the proposal to include a reference to a "precautionary principle" in the section on risk management, which would apply in cases when uncertainty exists, or the risk assessment cannot be completed, but risk management measures should be taken in order to protect consumers' health.

39. In previous discussions some confusion may have appeared on the applicability of "precaution" in risk management at the national level and its applicability within the Codex framework. In practice governments have to apply measures to protect the health of their consumers from serious hazards even when there is not enough scientific evidence, for example, emergency measures in crisis situations. This is the case for example of several emerging pathogens, due to the difficulties inherent to microbiological risk assessment. These decisions have to be taken at the level of governments, which cannot wait for a complete risk assessment to take urgent action.

40. At the international level, this issue has been taken into account in international agreements. Article 5.7 of the SPS Agreement does recognize the right of countries to take provisional measures in situations where scientific evidence is insufficient, but there is a concomitant obligation to seek additional information necessary for a more objective risk assessment and to review any measures taken within a reasonable period of time. Furthermore these provisions should not be considered in isolation from the other obligations of the SPS Agreement.

41. The recently concluded Protocol on Biosafety recognizes that:

> "*Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risk to human health, shall not prevent that party from taking a decision, as appropriate, with regard to the import of*

that living organism intended for direct use as food or feed, or for processing in order to avoid or minimize such potential adverse effects."

42. The right of countries to take protection measures is therefore recognized, provided that there is a justification in terms of health and under certain conditions ensuring that it is not used as barrier to trade. This is a critical problem which governments have to address on a regular basis, and in this perspective, it might be useful to provide them with guidance in this area. The Committee needs to decide whether this principle should be integrated in Risk Management principles, as directed to governments. In this context, it might be possible to describe the situation where scientific evidence is not complete but governments may take risk management measures to protect consumers' health. A similar debate is ongoing in the Committee on Food Hygiene, in the development of the Principles and Guidelines for the Conduct of Microbiological Risk Management.

43. The new section intends to describe the situation where scientific evidence suggests that adverse effects exist but it is difficult to evaluate their extent, and risk managers need to take appropriate action to protect consumers' health. This problem may be described as the basis for the precautionary principle or approach, as proposed in some comments. It may also be addressed without referring to a separate principle, through the same recommendations, in order to avoid controversy based only on the terminology used.

44. For this purpose, the text included in the revised Working Principles was based on the proposals made in the comments as regards the "precautionary principle" or a "precautionary approach" and an alternative wording referring only to the possibility "to take measures intended to protect the health of the consumer", all of these in square brackets for further discussion.

45. The conditions proposed for the application of the precautionary principle/approach do not seem to warrant the development of detailed guidelines, which were mentioned in the discussion by the Committee, they are more in the nature of criteria or principles which would fit more logically into the text of the Working Principles. The section on risk management could be then read as a whole, without referring to another text, especially since the section to be added is relatively short.

46. The criteria proposed are based on the comments received, which identified the following essential requirements: proportionality to the risk identified; transparent explanation of the measures taken; consistency; the provisional nature of the decision, subject to review; the need to gather further information with a view to facilitating further risk assessment. It was also proposed to consider carefully all available risk management options before taking a decision.

47. If the recommendations are directed to governments, they reflect a situation which commonly occurs and it should be possible to arrive at a common understanding after thorough discussion. This appears from a similar debate on precaution and risk management in the Committee on Food Hygiene; the problem may be the expression of the risk management approach rather than an issue of principle.

48. The situation is different if this section is intended for application in Codex, where standards and related texts represent a reference in international trade, but risk management recommendations do not result in regulations and practical implementation. In this context, the role of Codex is to provide the advice to governments on the basis of available scientific evidence and it may be questioned whether risk management decisions resulting in standards should be taken when risk assessment has not been completed. The current proposals on the precautionary principle, if they are applied within Codex, may be understood as allowing Codex Committees (risk managers in this context) to take measures which do not rely on a thorough risk assessment, such as establishing a maximum limit for additives and contaminants which have not evaluated by JECFA.

49. In practice decisions of Codex to protect consumers' health have been consistently based on the risk assessment carried out by the expert committees and in the absence of expert committees, on the scientific evidence provided by expert consultations or within the Committees themselves.

50. In the area of food hygiene, risk management options are generally directed to the process and not to the product, especially with the development of codes of practice, which recommend control measures at all critical stages of the food chain. These provisions are often intended to address a number of hazards, and this approach is different from requirements on the end product for a specific chemical or microbiological contaminant.

51. There are very few microbiological limits in Codex because the scientific basis to establish such limits is not clearly established or sufficient. The precautionary principle, as currently proposed, would result in risk management measures which are not based on risk assessment; the current approach in Codex is based on the reverse inference that prescriptive risk management measures should not be taken when the risk assessment is not sufficient. In this respect there should be a clear distinction between its application at the national level and at the international level. If Codex were to put forward standards, and especially quantitative requirements which were not based on scientific evidence, this would not be consistent with its role as an international standardizing body under the WTO SPS Agreement.

52. It might therefore be necessary to establish a distinction between measures affecting the end-product and specific to a particular contaminant or health hazard (MRLs or maximum limits for contaminants and additives), and the measures affecting the whole process, which are by nature less prescriptive and allow for some flexibility. Risk management options which intend to protect consumers' health but do not relate to the end-products are especially important in the area of food hygiene, and they sometimes correspond to hazards which cannot be controlled through the application of quantitative requirements, due to a lack of conclusive evidence. However, the Committee will need to clarify if this type of measures are covered by the proposed reference to precaution, which did not seem to be the case in earlier discussions.

53. As regards quantitative requirements, the possibility to establish standards or MRLs when the risk assessment is not available or completed would represent a complete shift in the decision process followed so far by Codex Committees and would be likely to detract from its status under WTO. In addition it might be more difficult to reach consensus in such circumstances; the decision process in the case of the maximum limit for aflatoxins reflects the difficulty to arrive at a decision when the risk assessment has not been completed. Agreement was reached on a maximum limit only after the reevaluation was carried out, including an evaluation of the risk management options.

54. The Committee will need to discuss the applicability of the "precaution" section in risk management before discussing the actual text, in order to clarify its scope either for governments or in the framework of Codex, and in that framework for which type of recommendation.

55. Another issue needs to be addressed although it is not mentioned in connection with the precautionary principle, and is mentioned only as a general requirement in the Risk Analysis section (para. 8) : differences of views between risk managers and risk assessors. The current wording of the "precaution" section refers to uncertainty in the risk assessment. Preliminary risk assessment indicates that a health hazard exists but risk assessors have recognized the gaps or missing elements in the scientific basis, which prevents a complete risk assessment. For clarification purposes, it was specified that risk assessors identify the uncertainty and risk managers apply precaution in their decisions. However, the proposals put forward did not indicate how the uncertainty was identified and the Committee will need to clarify that aspect.

56. It may happen that risk managers do not agree with the results of the risk assessment, or consider that it did not correspond, partially or totally, to the mandate given. This would not be a situation in which to apply "precaution" as defined in the proposal, but a risk communication issue or some lack in the formulation of risk assessment policy, so these two issues should not be confused.

57. Conflict between risk managers and risk assessors should be avoided by clearly defining the risk assessment policy and improving risk communication. In practical terms, it means that risk managers should not refer to the precautionary principle/approach only because differences arise with risk assessors; that might result in risk management decisions which are in conflict with the results of risk assessment. When risk assessors have completed the assessment and risk managers have difficulties to take a decision on the basis of that assessment, further interaction may be necessary to identify the problem. This is not an issue of precaution, but of risk communication between risk managers and risk assessors, and this should be clear in order to prevent significant confusion in the debate.

PROPOSED DRAFT CODEX WORKING PRINCIPLES FOR RISK ANALYSIS

(At Step 3 of the Procedure)

SCOPE

1) The principles for risk analysis are intended for application in the framework of Codex and are also intended to provide advice to governments where applicable.

2) The primary purpose of risk analysis in Codex is the protecting the health of consumers.

3) The objective of the Working Principles is to ensure that Codex standards and related texts intended to protect the health of consumers are consistently based on a thorough risk analysis.

4) Within the framework of Codex, the responsibility for risk management lies with the Commission and its subsidiary bodies, while the responsibility for risk assessment normally lies with the Joint FAO/WHO Expert Committees and Consultations.

RISK ANALYSIS - GENERAL ASPECTS

1. The risk analysis process used in Codex should be consistent, open and transparent and follow a structured approach including three components of risk analysis (risk assessment, risk management and risk communication), each component being integral to the overall risk analysis process.

2. The three components of risk analysis should be documented fully and systematically in a transparent manner, with the documentation accessible to interested parties.

3. Effective communication and consultation with interested parties should be ensured throughout the risk analysis process as appropriate.

4. There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment and reduce any conflict of interest between risk assessment and risk management. However it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors are essential for practical application

5. The situations where scientific evidence is insufficient or negative effects are difficult to evaluate should be clearly identified, in order to ensure that adequate precaution is integrated in the risk analysis process.

6. The needs of developing countries should be specifically identified and addressed in the different stages of the risk analysis process.

~~7. The risk analysis procedures used by Codex and those used by other relevant international intergovernmental, expert and non-governmental bodies should be harmonized where appropriate.~~

RISK ASSESSMENT

8. Codex decisions and recommendations intended to protect the health of consumers should be based on a risk assessment, as appropriate to the circumstances.

9. 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

10. 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 and the procedures used to select these experts should be documented.

11. Risk assessment should be based soundly on science, should incorporate the four steps of the risk assessment process (i.e. hazard identification, hazard characterization, exposure assessment and risk characterization) and should be systematically documented in a transparent manner, indicating any constraints, uncertainties and assumptions and their impact on the risk assessment.

12. At the risk characterization step, the uncertainties involved in each step of the risk assessment process should be described. The constraints that are likely to influence the quality of the risk estimate should be identified

13. Risk assessment should take into account uncertainty in hazard identification and characterization and variability associated with estimates of exposure. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but in either case should be clearly documented.

14. Risk assessments should use available quantitative data to the greatest extent possible and may include non-measurable, qualitative data. Risk characterisations should be presented in a readily understandable and useful form.

15. 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.

16. Risk assessment for Codex purposes should be based on global data for exposure assessment, including data provided by developing countries.

17. Risk assessment should take into account all available scientific data and relevant production, storage and distribution processes throughout the food chain, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

18. The conclusions of the risk assessment should be conveyed to risk managers in a readily understandable form. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessor.

19. 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. They should indicate any constraints, uncertainties and assumptions and their impact on the risk assessment.

RISK ASSESSMENT POLICY

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

21. Risk assessment policy should be established in advance of risk assessment, in collaboration between risk managers and risk assessors.

22. Risk managers should ensure communication with interested parties in the establishment of risk assessment policy to ensure that the risk assessment process is systematic, complete and transparent.

23. When a risk assessment is commissioned by the risk managers, the scope and purpose of that risk assessment should be clearly defined. Risk assessors should be selected according to their capacity and expertise to fulfil the mandate given by risk managers.

24. The mandate given by risk managers to risk assessors should be achievable, taking into account available scientific evidence and any constraints affecting the risk assessment process.

~~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~~.

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

25. Where necessary, risk managers may ask risk assessors to evaluate the potential risk reduction resulting from different risk management options.

RISK MANAGEMENT

26. Risk management decisions should have as their primary objective the protecting the health of consumers. Decisions on acceptable levels of risk should be determined primarily by human health considerations, and unjustified differences in the level of acceptable risk should be avoided.[1]

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[1] Joint FAO/WHO Expert Consultation on Risk Management and Food Safety

27. Risk management should follow a structured approach. The risk management framework includes the following elements: Risk Evaluation, Risk Management Option Assessment, Implementation of Management Decision, and Monitoring and Review[2].

28. Risk management should be focused on agreed outcomes rather than on processes. Risk management should take into account relevant production, storage and distribution processes throughout the food chain, methods of analysis, sampling and inspection and the prevalence of specific adverse health affects.

29. The risk management process should be transparent, consistent, repeatable and fully documented. Risk management decisions 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.

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

30. Risk management options should be evaluated in terms of the overall reduction of the health hazard considered. Risk management options which result in non-quantitative requirements and may not require a formal risk assessment should be evaluated according to a relevant risk management framework.

31. The outcome of the risk evaluation process should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk. In arriving at this decision, protection of consumers' health should be the primary consideration, with other factors being considered as appropriate.[1]

32. Guidelines should be defined for the integration in the risk management process of "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade". If economic analyses are used in support of risk management decisions, risk managers should ensure the transparency and consistency of the decision process, in order to avoid unjustified trade barriers.

33. Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.

34. Risk managers should ensure consistency in the decision process. Under similar circumstances, including the nature of the risk and the results of risk assessment, the decisions taken should be consistent.

~~35. 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.~~

36. Risk management decisions should take into account conditions prevailing in all countries where possible, especially the feasibility of risk management options in developing countries, without affecting the agreed outcome in terms of consumers' health protection.

37. 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 must be consistent with new scientific knowledge and other information relevant to risk analysis.

38. When risk assessors identify situations 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, it should be possible for risk managers to apply [a precautionary approach/the precautionary principle] to protect the health of the consumer

Alternative wording

42) [In such situations it is possible to take measures intended to protect the health of the consumer without awaiting additional scientific data and a full risk assessment]

39. [In such situations the following criteria should be taken into account to ensure the consistency and transparency of the decision process:

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2 Joint FAO/WHO Expert Consultation on Risk Management and Food Safety. In the framework of Codex, the Implementation "component" is not relevant.

- Following preliminary risk assessment, a specific risk is identified, or there is evidence to suggest that a risk exists, but the cause or extent of any negative effects are unknown due to gaps or uncertainty in the available scientific data
- the decisions taken are proportional to the extent of the health risk and based on the available scientific data
- there should be a transparent explanation of the need for the measures and the procedures followed to establish them
- the decisions taken are consistent with those taken in similar circumstances and are the least trade restrictive necessary to achieve protection of the health of consumers
- the decisions are provisional and are subject to an on-going, transparent review process involving interested stakeholders
- information should continue to be gathered to strengthen the scientific evidence and decisions taken should be reviewed and modified, strengthened or rescinded as appropriate in the light of such information
- examination of the full range of management options should be undertaken. This should include an assessment of the potential advantages and disadvantages of various measures, including cost/effectiveness considerations]

RISK COMMUNICATION

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

5) A major function of risk communication is establishing a process whereby information and opinion essential to effective risk management is made available.

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

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

43. An assessment of uncertainty in risk estimates should be included in the communication process with the public and other interested parties.

~~**DOCUMENTATION**~~

~~Risk assessment and risk management should be fully and systematically documented in a transparent manner. Risk management should be transparent, flexible, objective and repeatable and this requires full documentation~~.