codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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ALINORM 01/33

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-fourth Session
Geneva, 2 – 7 July 2001

REPORT OF THE FIFTEENTH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES

Paris, France, 10-14 April 2000

Note: This document incorporates Circular Letter CL 2000/12-GP

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CX 4/10 **CL 2000/12-GP**
April 2000

TO: - Codex Contact Points
- Interested International Organizations

FROM: - Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100 Rome, Italy

SUBJECT: **Distribution of the Report of the 15th Session of the Codex Committee on General Principles (ALINORM 01/33)**

A. MATTERS FOR ADOPTION BY THE 24th SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Amendments to the Rules of Procedure

1. Amendment to Rule VI.2 to clarify that the roll-call vote is subject to Rule X.2 referring to the adoption of standards by consensus (para. 73, Appendix II)

Governments and international organizations wishing to submit comments on the above amendment should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 30 March 2001**.

B. REQUEST FOR COMMENTS AND INFORMATION

Proposed Draft Principles at Step 3

2. Proposed Draft Working Principles for Risk Analysis (para. 73, Appendix III)

Governments and international organizations are invited to provide comments and proposals on the Working Principles as follows:
1) the application of precaution in risk management (paras. 34 and 35); and
2) the other Working Principles

Governments and international organizations wishing to submit comments on the above document should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, with a copy to the Codex Contact Point for France, SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot 75703 Paris Cedex 12, Fax. 33 (0)1 4487 16 04, Email: sgci-codex-fr@sgci.finances.gouv.fr **for point 1) before 1 July 2000 and for point 2) before 15 January 2001 .**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 15th Session of the Codex Committee on General Principles are as follows:

Matters for consideration by the Commission:

The Committee:

- recommended an amendment of Rule VI.2 of the Rules of Procedure to clarify that the request for a roll-call vote was subject to Rule X.2 that refers to the adoption of standards by consensus (para. 73, Appendix II)

Other matters of interest to the Commission

The Committee:

- agreed to return to Step 3 for further comments the Working Principles for Risk Analysis (para. 73, Appendix III)
- Agreed to return to Step 3 for further comments the Proposed Draft Revised Code of Ethics for International Trade in Foods (para. 108)
- agreed on Measurable Objectives to Assess Consumer Participation in Codex work (para. 110)
- proposed practical measures to facilitate consensus (paras. 68-69)
- agreed to consider further the composition of the Executive Committee and related matters, including an alternative proposal to hold the Commission on an annual basis (para. 84)
- agreed to consider further the role of "other legitimate factors" in relation to risk analysis at its next session (para. 95)
- agreed that the concept of "food safety objectives" could be developed further by other relevant committees and that it was premature to generalize it with a specific definition at this stage (paras. 65-66)

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INTRODUCTION

1. The Fifteenth Session of the Codex Committee on General Principles was held from 10-14 April 2000 in Paris at the kind invitation of the Government of the French Republic. The session was chaired by M. Pierre Gabrié, Head of Service, Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes. It was attended by 247 delegates and representatives of 54 Member countries and 29 international governmental and non-governmental organizations. A complete list of participants at the Session, including the Secretariat, is given in Appendix I.

2. The Session was opened by M. François Huwart, Secretary of State responsible for Foreign Trade at the Ministry of Economy, Finance and Industry.

3. Mr. Huwart underlined the interest of the French government in the work of Codex Alimentarius particularly in relation to the new perspectives that applied to world trade. He clearly expressed the opinion that the precautionary principle should be regarded as an appropriate tool of risk management provided that it was not used as an excuse to establish unwarranted and arbitrary trade barriers. He also emphasized that legitimate factors other than strictly scientific data could not be ignored by governments and that the development of world trade could not take place without having regard to the legitimate rights of consumers. Finally, Mr. Huwart welcomed the revision of the Code of Ethics for International Trade in Food and noted that its observance was crucial to ensure the protection of all consumers and the use of fair trade practices. He stressed the necessity of ensuring that products that are exported to developing countries in particular should comply with international requirements of food quality and safety.

ADOPTION OF THE AGENDA (Agenda Item 1)

4. The Committee adopted the Provisional Agenda[1] as the Agenda for its session. At the request of the Delegation of Switzerland, it agreed to discuss under Other Business the question of the relationship between Codex General Subject Committees and Codex Commodity Committees with special reference to food additives and contaminants.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)[2]

5. The Committee noted the decisions of the Commission concerning the work of the Committee. It noted in particular that the amendments to the Rules of Procedure proposed at the Committee's last session had been adopted by the Commission and had now been confirmed by the Directors-General.

6. The Committee noted that several of the matters referred by the Commission had been included on the present Agenda for discussion, notably risk analysis (Agenda Item 3) and the composition of the Executive Committee (Agenda Item 5). This latter point had also been the subject of matters arising from the Regional Coordinating Committee for Asia.

7. It was further noted that several Committees had responded to this Committee's request to provide information on the legitimate factors other than science used in their decision-making process. An addendum to CX/GP 00/2 with recent contributions was prepared for the Committee's consideration under Item 6.

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1 CX/GP 00/1.

2 CX/GP 00/2

RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS[3] (Agenda Item 3)

8. The Committee recalled that the last session had discussed the Working Principles for Risk Analysis and had agreed on several amendments to the sections on risk analysis and risk assessment; there had been no consensus on the inclusion of a reference what some Members referred to as the 'Precautionary principle' in the section on risk management.

9. The Committee had agreed to return the proposed Draft Working Principles to Step 3 for further comments, including specific proposals on the precautionary principle or approach and asked the Secretariat to prepare a revised draft and an analysis of the questions related to the precautionary principle or approach, in the light of the comments received[4].

10. The Committee considered the revised Working Principles section by section and made the following amendments

SCOPE

11. The Delegation of Malaysia proposed to include a reference to fair trade practices in the purpose of risk analysis, in addition to the protection of consumers' health, in order to reflect the general objectives of Codex (para. 2). Some delegations pointed out that the application of risk analysis should not result in disguised barriers to trade and that this should be reflected in the text. Other delegations expressed the view that the general objectives of risk analysis were a subset of the overall objectives of Codex, and that the primary purpose of risk analysis was health protection. The Committee recognized that the primary consideration should remain health protection but that fair trade aspects should be taken into account in the process. The text was therefore amended to reflect that the purpose of risk analysis was to protect the health of consumers 'while ensuring fair practices in food trade'.

12. The Committee agreed to delete the reference to 'consistency' and to a 'thorough' risk analysis in paragraph 3[5] since these terms did not provide any further clarification; it was agreed that Codex standards and related texts intended to protect the health of consumers were 'based on risk analysis'.

13. During the debate, the Committee noted that since the draft principles were intended for application in the Codex framework and also by governments where applicable, some confusion arose with the interpretation of specific articles. It nevertheless decided to retain the dual scope of application.

RISK ANALYSIS – GENERAL ASPECTS

14. The Delegation of the United States proposed to specify that in para.1 it should be made clear that risk analysis should be science-based, and the Committee had an extensive exchange of views on this question. Some delegations expressed the view that science should not be mentioned in relation to risk analysis as a whole since risk management decisions were policy decisions, as reflected in the current definition of Risk Management in the Procedural Manual; in addition the question of 'other legitimate factors' was still under consideration and no conclusion had yet been reached on this question. Other delegations pointed out that risk analysis was based on science since the risk assessment process was based on scientific data. They referred to the first Statement of Principle, whereby Codex texts should be based on scientific analysis and recalled that other factors were mentioned in the second Statement of Principle and they were taken into account in the risk management process as appropriate, however it should be clear that the scientific basis was an essential element of the decision process.

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[3] CL 1999/16-GP; CX/GP 00/3; CX/GP 00/3-Add.1 (comments of Australia, Brazil, Canada, New Zealand, Norway, Republic of Korea, European Community, Consumers International, IACFO, CRN, EFLA); Add. 2 (EC); Add. 3 (IASDA); Add. 4 (CIAA); Add. 5 (United States); CRD 1 and 3 (CI); CRD 2 (IACFO), CRD 3 (United States), CRD 7 (ALA), CRD 9 (Peru), CRD 10 (Malaysia), CRD 11 (COMISA), CRD 14 (Thailand) , CRD 15 (India), Unnumbered CRDs (ICGMA and EFLA)

[4] ALINORM 99/33A, paras 16-37

[5] References to paragraph numbers are to those in the Proposed Draft text, Annex to CX/GP 00/3 and to Appendix III when the numbers are different.

15. The Committee could not come to a definite conclusion and agreed that the words 'soundly based on science' required further consideration and should be included in paragraph 1 in square brackets. The Committee noted that this matter was linked to the wording in the second paragraph of the section on Risk Management (para. 27, now para. 25 - see para. 33 of the report)

16. In the section on documentation (para. 2), the Committee considered a proposal concerning accessibility of documentation to consumers, in addition to the current text referring to 'interested parties'. In order to clarify the text and to make it more general, it was agreed to refer to 'all interested parties'. This was also added to paragraph 3 on communication and consultation.

17. In the section concerning uncertainty and precaution (para. 5), the Committee recognized that precaution was an essential element of risk analysis and agreed to include a statement to this effect at the beginning of the section, as proposed by the Delegation of the United States on the basis of the FAO Conference on International Food Trade beyond 2000 (Melbourne, 1999). It was agreed that this was particularly important when scientific evidence was insufficient and negative effects on health were difficult to evaluate.

18. The Committee considered the section on developing countries (para. 6) and agreed that in addition to their needs, the situation prevailing in these countries should be taken into account. This was especially important in order to obtain relevant data, such as exposure assessment from all regions of the world. The Delegations of Zimbabwe and Morocco expressed the view that this section should clarify the responsibilities for addressing the needs of developing countries, whether this applied to developed countries or international organizations. The Committee noted that all recommendations in the text were worded in a general manner, since they were intended to apply to FAO, WHO, Codex Committees, Expert Groups responsible for risk assessment, and to governments at the national level. The Committee included a general reference to 'the responsible bodies' in the text, as proposed by the Representative of WHO.

19. The Delegation of Chile referred to the recommendation of the Commission that Codex Committees should appoint a co-author from a developing country for position papers, where the main author was from a developed country. The Committee noted that this recommendation of the Commission was not in the nature of a principle for risk analysis and should not be included in the present text; however it should be followed by relevant Committees when considering matters related to risk analysis.

20. The Committee noted that the various language versions of the text required harmonization, in particular with reference to the use of the words 'should', 'shall' and 'must'.

RISK ASSESSMENT

21. The Committee agreed that the text of the first *Statement of Principle Relating to the Role of Food Safety Risk Assessment* should be used to define the purpose of risk assessment (para. 8, now para. 7), as proposed by the Delegation of Portugal and in order to achieve consistency.

22. The Committee agreed to rearrange and reword the paragraphs concerning the four steps of risk assessment, the identification of uncertainties and the need for documentation (paras. 11 to 13, now paras. 10 to 12) for clarification purposes, as proposed by the Delegation of Malaysia. The Committee agreed that the constraints affecting the quality of the risk estimate should be identified, and that expression of uncertainty or variability should be clearly documented, and the corresponding text was retained.

23. The Committee agreed with the proposal of the Delegation of India to use the text of the recommendation made by the Commission on global data for exposure assessment (para. 16, now para. 15). The Delegation of the United States questioned the use of the term 'global data' since it was not clearly defined. The Committee noted that when food safety risk analysis was initially developed, it tended to be more focused on chemical contamination but the concepts were somewhat different where microbiological hazards were concerned. The Committee agreed to refer to 'exposure assessment data from different parts of the world', as proposed by the Delegation of Sweden.

24. The Committee had an exchange of views on the need to provide further detail on the different stages of the food chain taken into account in risk assessment (para. 17, now para. 16). The Committee agreed to include a general reference to 'production and handling processes' since this covered all aspects of the food chain from the primary producer to the consumer, and to include a specific reference to traditional practices.

25. As regards the records of risk assessment, (para. 19, now para. 18), the Committee agreed to include a reference to minority opinions, and noted that the rules for the conduct of expert groups specifically required such a record.

RISK ASSESSMENT POLICY

26. The Delegation of Norway recalled that a definition of risk assessment policy had been discussed at the last session and proposed to include this definition, although it had not been finalized, in the text for clarification purposes. The Committee agreed that a description of the process based on the earlier definition should be included as a separate section (new para. 20) and that the sections on the establishment of risk assessment policy and on communication (paras. 21 and 22, now para. 21) should be combined since they both referred to the same process. The text was amended in order to clarify that risk assessment policy should be established by risk managers in consultation with risk assessors and all interested parties, and that the proposals of interested parties should be analyzed as necessary.

27. The Committee agreed to delete the requirements concerning the scope and purpose of risk assessment, as well as the selection of the assessors (para. 23) since they were already covered in the sections on risk assessment.

28. The Committee had an exchange of views on the section addressing the mandate given to the assessors (para. 24, now para. 22). It was proposed to delete this section since its provisions were already addressed in the section on risk assessment. The Representative of WHO stressed the importance of interaction between risk assessors and risk managers, which might result in a need to redefine the mandate given to risk assessors, especially where microbiological hazards were involved. The Committee agreed that the relevance of this section as regards risk analysis policy would need further discussion and it was retained in square brackets.

29. The Committee agreed that risk managers could ask risk assessors to evaluate the potential risk reduction resulting from different risk management options (para. 25, now para. 23). The Committee noted that this was not currently covered elsewhere in the document and agreed to retain the current text.

RISK MANAGEMENT

30. The Committee had an exchange of view on the need for a section referring to the structured approach of risk management and describing its components (para. 27, now para. 25). The Delegation of Portugal, speaking on behalf of the Members of the European Union present at the Session, supported by other delegations, expressed the view that the components of risk management introduced new concepts which were not defined and that they should not be included in the text. The Delegation of Singapore expressed the view that the approach to be followed in risk management should not be prescriptive and should be left to the responsibility of governments at the national level.

31. The Delegation of New Zealand, supported by other delegations, recalled that the need for a structured approach was generally recognized and was currently being applied in the Committee on Food Hygiene, and that the components of risk management had been defined by the FAO/WHO Expert Consultation on Risk Management and Food Safety (1997). Some delegations proposed to include definitions in the text or to reference them in a footnote for clarification purposes.

32. The Committee discussed these proposals and recognized that the structured approach described the steps in the process: evaluation of risk, assessment of risk management options, implementation, monitoring and review. These were not actually new concepts and they should not be presented as titles or concepts in the text. Some delegations pointed out that the term 'risk evaluation' still needed some clarification, especially to avoid confusion with risk assessment, and to address translation difficulties. The Committee agreed to retain the current text and to put 'risk evaluation' in square brackets for further consideration.

33. The Committee discussed the proposal of the Delegation of the United States to specify that risk management should be 'grounded on science-based risk assessment'. Several delegations objected to this proposal since risk management took into account other factors than science, as appeared from the recently revised definition of Risk Management. Some of these delegations proposed to add a reference to other factors if the reference to science was introduced, in order to reflect the difference between risk assessment and risk management. Some delegations also pointed out that since risk analysis terms were already defined in the Procedural Manual, additional explanations might not be necessary in the current text.

34. The Committee considered an amended text indicating that risk management was 'grounded on science-based risk assessment' and took into account 'other legitimate factors as appropriate', and agreed to retain it in square brackets for further discussion, since consensus could not be reached at this stage.

35. The Delegation of Portugal, supported by several delegations, expressed the view that risk management should be focused on agreed outcomes as well as on processes (para. 28, now para. 26). Other delegations and the Representative of WHO stressed that the current concept of outcome-based risk management was essential, and noted that the following sentence made it clear that all relevant processes were taken into account throughout the food chain. The Committee agreed to the proposal of the Delegation of New Zealand that 'in achieving agreed outcomes' risk management should take into account relevant processes throughout the food chain, and amended the text accordingly.

36. The Committee agreed to delete the reference to 'repeatability' in paragraph 29 (now para. 27).

37. The Committee agreed that risk management options should be evaluated in terms of the overall reduction of risk, to replace the current text referring to hazards (para. 30, now para. 28), and deleted the sentence referring to the risk management framework as it was already covered in paragraph 27 (now para. 25) (structured approach).

38. As regards the outcome of the process (para. 31, now para. 29), reference was made to the 'assessment of available risk management options' (rather than their 'evaluation') and in the second sentence, it was clarified that the 'risk management decision' was addressed, and that 'other legitimate factors' were considered as appropriate.

39. In the section on other legitimate factors (para. 32, now para. 30), the sentence on economic analysis was deleted since the current text adequately covered all relevant factors taken into account in the process. The Committee noted that this question would be specifically considered under Agenda Item 6.

40. The reference to communication was deleted (para. 33) since this aspect was covered more generally under Risk Communication. The provisions on consistency were amended to clarify that trade barriers should be avoided and that the section applied to the consideration of other legitimate factors (para. 34, now para. 31).

41. The Committee agreed that paragraph 36 (now para. 32) would include the text of the recommendation made by the Commission concerning the consequences of risk management options for developing countries, as proposed by the Delegation of India.

RISK COMMUNICATION

42. The Committee agreed that information and opinion should be 'exchanged between interested parties' in order to reflect the need for interactive communication (second paragraph). The rest of the section was left unchanged.

THE APPLICATION OF PRECAUTION: PRECAUTIONARY PRINCIPLE OR APPROACH

43. The Committee considered an amended text prepared by the Delegations of the United States, the member countries of the European Union, the European Community and several other delegations and describing the use of precaution, with a footnote indicating that this was referred to as the 'Precautionary Principle' in certain member countries (para. 38, now para. 34).

44. The Delegation of Australia expressed the view that the content of the proposed footnote could be adequately covered in the report of the meeting together with the alternative views of other countries.

45. The Delegation of Malaysia, referring to its written comments, proposed that when precaution was exercised as an interim measure, additional information should be sought and the measures should be reviewed within a reasonable time frame in order to achieve consistency with Article 5.7 of the SPS Agreement. Several delegations supported this proposal and pointed out that the reference to a limited time frame was essential in order to prevent the establishment of unjustified barriers to trade, and was in conformity with the obligations of member countries under the SPS Agreement.

46. The two proposals referred to above are presented as alternative texts in paragraph 34 of Appendix III, the proposal from Malaysia appearing first as the other proposal should be read in conjunction with para. 35.

47. Some delegations and observers pointed out that the concept of a precautionary principle, which originated in discussions related to the environment, was not generally recognized or defined in relation to food safety, and that precaution was inherent to the risk analysis process, as recognized in the current Working Principles (para. 5 of the revised text). In this perspective, the definition of an additional concept was not necessary.

48. Several other delegations, observers and the Representative of WHO stressed that it was essential to address the uncertainties in risk assessment; in some cases, there were inherent difficulties to establish an adequate scientific basis due to the nature of the health hazard; risk assessment might take a long time to complete, or might still contain a wide range of uncertainty after it was carried out. In such cases, risk managers had to take action to protect consumers' health on the basis of precaution. The Delegation of Egypt expressed the view that when there was a doubt concerning scientific evidence it was the duty of risk managers to protect consumers; this was demonstrated clearly by such examples as the use of pesticides which were eventually prohibited, and the case of BSE.

49. The Delegation of the United Kingdom, supported by several delegations and observers, expressed the view that the reference to a principle was important and should be retained, at least in a footnote and that a definition of the 'Precautionary Principle' as used for risk assessment in Codex was essential, since this term was used in several countries in order to enhance consumer confidence in sanitary measures at the national level. These delegations however noted that in order to facilitate consensus, the reference to 'precaution' in the revised text would be acceptable.

50. In reply to a question, the Delegation of the United States clarified that the reference to 'robustly' assessing risk corresponded to the terminology used in statistics when data were adequate, but other terms like 'objectively and fully' could be used. The Delegation pointed out that the use of the precautionary principle was not generally recognized or defined and that further discussion on this issue was necessary to clarify how precaution was applied.

51. The Delegation of Uruguay pointed out the precautionary approach, as described in the text proposed by several delegations (see para. 46 above), could apply to risk management decisions taken by governments but was not pertinent in the framework of Codex, where a scientific basis was essential to establish international recommendations. Other delegations expressed the view that this was primarily an area for national governments rather than Codex and stressed the need for clarification of this important issue.

52. Several delegations stressed that the recommendations on precaution in risk management should be applicable both to governments and in the framework of Codex. The Delegation of Sweden indicated that precaution was reflected in the development of Codex codes of practices when the risk assessment of certain contaminants was not completed, but it was necessary to address public health problems through preventive action

53. The Delegation of New Zealand indicated that the text did not adequately address all aspects of uncertainty in risk assessment. The Delegation further noted that while interim measures applied by national governments were provided for under the SPS Agreement, they were very unlikely to be used in elaborating Codex standards when risk assessment was not available.

54. The Delegation of Morocco indicated that the responsibility for identifying uncertainty would need to be clarified, since it was not specified in the amended text, although the original text (para. 38) had indicated that risk assessors would identify such uncertainty.

55. Some delegations indicated that the criteria proposed in the current text (para. 39, now para. 35) could be used as a starting point for further discussion. The Delegation of the Philippines proposed that the need for a time frame to review provisional measures should be included in this section. Some delegations proposed that the criteria should be discussed first in order to clarify the conditions for the application of precaution, while other delegations stressed the need to describe the nature of the principle or approach before selecting the criteria. The Committee did not discuss the criteria in detail and recognized that both parts of the section would require further consideration at the next session.

56. The Representative of WTO, recalling the provisions of SPS Article 5.7, indicated that guidelines on the application of precaution could facilitate common understanding of risk analysis but should not contradict the rights and obligations of member countries under the SPS Agreement.

57. The Committee recognized that no consensus existed at this stage on the different proposals put forward on the application of precaution, and discussed how to proceed further. The Chairperson proposed to establish a drafting group, which would work by electronic mail, and prepare revised proposals for consideration by the next session. A Working Group could also be held prior to the next session if necessary in order to facilitate discussion. Some delegations objected to such a discussion in a Working Group since issues of principle should be addressed in the plenary session of the Committee.

58. Some delegations proposed that FAO and WHO should convene a workshop to consider matters related to precaution, uncertainty and the interaction between risk management and risk assessment, in order to facilitate a common understanding of these issues. The Representatives of FAO and WHO indicated that they would consider the possibility of holding such a workshop, if this was the wish of member countries and the participation of Members from developing countries should be as large as possible. The Delegation of Chile asked FAO and WHO to consider convening a similar workshop at the level of the Regional Coordinating Committees.

59. Some delegations emphasized the responsibility of the Committee to address the issue of the application of precaution, as agreed in the FAO Conference on International Food Trade beyond 2000, and stated that this responsibility could not adequately be addressed in another meeting like an expert consultation or a workshop. It was also pointed out that a drafting group would need a clear mandate and an initial text as a basis for discussion.

60. The Committee agreed that the two proposals referred to as alternative texts (see para 46 and Appendix III, para. 34) would be circulated for comments, as part of the Proposed Draft Working Principles at Step 3, and agreed that a drafting group, coordinated by the French Secretariat, would work by electronic mail in order to prepare a revised text for consideration by the next session. All member countries and international organizations were invited to participate in this electronic drafting group. The Committee noted that the French Secretariat would ensure prompt distribution of material to all members and observers, including replies to the Circular Letter sent at Step 3. The Committee agreed that a Working Group could be held to finalize a revised proposed text on the day preceding the Plenary Session, if required.

61. The Committee noted that significant progress had been made on most sections of the Working Principles; however, the application of precaution in risk management still needed additional discussion, and it was preferable to retain the text at Step 3 for further consideration

STATUS OF THE PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS

62. The Committee agreed to return the Proposed Draft, as amended at the current session, to Step 3 for further comments and consideration by the next session (see Appendix III).

RISK ANALYSIS : FOOD SAFETY OBJECTIVES (Agenda Item 3.2)[6]

63. The Committee noted that it had agreed at its last session[7] to consider the general aspects of the development and application of "food safety objectives" following discussions at the 7th Session of the Codex Committee on Food Import Export Inspection and Certification Systems (CCFICS) and the 45th Session of the Executive Committee.

64. The Committee discussed whether there was a need to define "food safety objectives" and how it would proceed to consider the concept in relation to risk analysis specifically. The Committee noted that the 32nd Session of the Codex Committee on Food Hygiene (CCFH) had discussed the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management that included a section on food safety objectives. It also noted that the 8th Session of the Codex Committee on Food Import Export Inspection and Certification Systems decided to develop the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems pending approval as new work by the 47th Session of the Executive Committee.

65. The Committee was of the opinion that the application of "food safety objectives" concept was of a technical nature and it was premature to generalize the concept with a specific definition.

66. The Committee agreed that the concept of "food safety objectives" could be further developed by other relevant Committees in order to identify how it could be applied to specific food safety issues, and that the Committee should continue to oversee the consistency in the definition and application of the concept.

IMPROVEMENT OF PROCEDURES FOR THE ADOPTION OF CODEX STANDARDS AND MEASURES TO FACILITATE CONSENSUS (Agenda Item 4)[8]

67. The Committee reviewed the document "Improvement of procedures for the adoption of Codex standards and measures to facilitate consensus". The Committee noted the amendments made to Rule X.2 of the Rules of Procedure by the Commission at its 23rd Session and the on-going efforts of the Chairpersons of Codex Committees to exchange information and experience in this matter. The Committee focussed on a number of practical measures for achieving consensus and on specific amendments to the Rules of Procedure concerning voting in cases where consensus could not be achieved.

68. The Committee noted that much of the responsibility for facilitating the achievement of consensus lay in the hands of the Chairpersons and members of Codex Committees. In addition and more generally, it noted possible additional practical measures that might facilitate consensus-building that could be used as a reference by the Chairpersons of concerned committees, Codex members and the secretariat as appropriate. These included the following:

- Refraining from submitting proposals in the step process where the scientific basis is not well established on current data and, where necessary, carry out further studies in order to clarify controversial issues;
- Providing for thorough discussions and documentation of the issues at meetings of the committees concerned;
- Organizing informal meetings of the parties concerned where disagreements arise, provided that the objectives of any such meetings are clearly defined by the Committee concerned and that participation is open to all interest delegations and observers in order to preserve transparency;

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6 CX/GP 00/4; CRD 7 (Comments of ALA).

7 ALINORM 99/33A, paras 7-9.

8 CX/GP 00/5; CRD 4 (Comments of IACFO); CRD 10 (Comments of Malaysia); CRD 14 (Comments of Thailand).

- Redefining, where possible, the scope of the subject matter being considered for the elaboration of standards in order to cut out issues on which consensus could not be reached;
- Providing that matters are not progressed from step to step until all relevant concerns are taken into account and adequate compromises worked out;
- Emphasizing to Committees and their Chairpersons that matters should not be passed on to the Commission until such time as consensus has been achieved at the technical level;
- Facilitating the increased involvement and participation of developing countries.

69. It was suggested that these proposals be drawn to the attention of the Commission.

70. The Delegation of Australia proposed that there should be greater use of the Executive Committee and the informal meeting of the Chairpersons of Codex Committees in order to facilitate consensus.

Rule VI.2

71. The Committee noted that Rule VI.2 could be interpreted as implying that any Member of the Commission had the right to call for a vote to be taken on any matter at any time. It was noted that such an interpretation was contrary to the decision of the Commission when it adopted Rule X.2 to enhance consensus building.

72. The Delegation of Chile proposed to specify that Rule VI. 2 (majority) applied "in cases where it is necessary to vote, because it has not been possible to reach consensus on a standard" and that Rule VI.4 (roll-call vote) applied "in the event that it is decided to proceed to a vote", for clarification purposes.

73. The Committee agreed to propose an amendment to Rule VI.2 to clarify this situation. In response to a question of the Delegation of Malaysia, it was stated that the proposed amendment did not abridge the right of a Member to call for a roll-call vote in the cases where the Commission proceeded to a vote on matters such as the adoption and amendment of standards. The proposed draft amendment is presented in full in Appendix II to this report.

Rule X.2

74. The Committee also had before it two proposals to amend the Rules of Procedure to provide for a qualified majority to be used in the case where voting was required. These proposals were for (i) a two/thirds majority, or (ii) a majority of two/thirds on two consecutive sessions of the Commission with a simple majority at the following third session, if required.

75. Most of the Delegations that expressed a preference for one or other of these options expressed a preference for the first option. The Delegation of India also supported this option but stated that it would be useful to examine other means of ensuring the participation of the full Membership of the Commission where decisions had to be taken but consensus could not be reached. It suggested that this might be done through postal balloting or by requiring that a majority of the Members in each Region were in agreement.

76. Several delegations stressed the importance of Codex working by consensus and were of the opinion that the proposals to amend Rule X.2 were premature, and that the effect of the application of the new Rule X.2 and the additional practical measures intended to facilitate consensus needed to be examined before further changes were introduced.

77. The Committee noted that there was no consensus for proposing amendments to the current Rule X.2 and therefore decided not to take further action until further experience was gained in this matter.

COMPOSITION OF THE EXECUTIVE COMMITTEE AND RELATED MATTERS[9]
(Agenda Item 5)

78. The Codex Commission at its Twenty-third session in 1999 discussed a number of issues relating to the composition of the Executive Committee and participation of observers in its work. These issues were: the possibility of participation in meetings of the Executive Committee of a limited number of representatives of INGOs as observers, the possibility of enlarging the membership of the Executive Committee to include additional Members from the different Regions along the lines of the FAO Council; and clarification of the rights of Member countries to participate as observers in sessions of the Executive Committee.[10] The paper before the Committee addressed each of these issues and also proposed that consideration be given to the participation of a limited number of developing member countries as observers as a means of improving the participation of these countries and allowing such countries to gain a wider experience in the functioning of Codex bodies.

79. Many delegations and observer organizations supported the proposals to provide for the participation of representatives of INGOs as observers in the Executive Committee along the lines proposed in the paper, namely on the basis of such participation in the World Food Summit. One observer organization expressed a contrary view. The delegations and observer organizations that favored the proposals quoted the need for transparency as the basis for such participation. Several delegations expressed concern at the fairness of allowing the participation of INGOs as observers in the Executive Committee when Member countries themselves did not have the same right.

80. Several delegations also supported the proposals to enlarge the Membership of the Executive Committee, including the designation of the Regional Coordinators as Members. However, there was a difference of opinion between delegations on the proposal to enlarge the Membership of the Executive Committee so that representation would be proportional to the membership of the regions. It was stated that each Region had its own characteristics and problems and as such Regions should be equally represented. Several delegations were also of the opinion that the experience with the role of advisors to the Members (Regional Representatives) had been positive and that they should therefore not be excluded from the meeting of the Executive Committee. It was suggested that the efforts should be made to strengthen the relationship between the Regional Representatives and the Regional Coordinators. Several delegations gave their strong support to the proposal for the participation of developing country members with financial support at meetings of the Executive Committee.

81. Some delegations and the Observer from ICGMA expressed concern that the enlargement of the Executive Committee as proposed would impinge upon its efficiency and that the Executive Committee would become, in effect, a “mini-Commission” closed to a large part of the Membership of the Commission itself. It was generally recognized that the increased importance of the Executive Committee was due to the responsibilities that it exercised on behalf of the Commission in the years in which the Commission did not meet, especially in relation to the approval and allocation of work (Step 1) and advancing draft texts at Step 5.

82. The Delegation of Malaysia with the support of many other delegations proposed that a review of the role of the Executive Committee should be undertaken with a view to its possible abolition; its functions being assumed by annual meetings of the Commission as provided for in Rule IV.1 of the Rules of Procedure. It was stated by these delegations that such a step would address all of the problems currently under consideration in relation to the composition of the Executive Committee and the transparency of its procedures.

83. The Delegation of Argentina pointed out that the aspects of the Executive Committee’s work which required increased transparency should be clearly identified and that specific and practical proposals should be put forward to improve its operation, if this was necessary.

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9 CX/GP 00/6; CRD 2 (Comments of IACFO); CRD 10 (Comments of Malaysia); CRD 14 (Comments of Thailand), Unnumbered CRD (Consumers International).

10 ALINORM 99/37, paras, 44-46

84. The Committee requested the Secretariat to provide a paper for consideration at its next Session on the role of the Executive Committee and the implications of abolishing it and replacing it with annual meetings of the Commission. It also asked that specific modalities for improving transparency, for the representative participation of INGOs and for additional participation of developing countries be developed for consideration, in case that the Executive Committee would not be abolished.

REVIEW OF THE STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT: ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK ANALYSIS (Agenda Item 6)[11]

85. The Committee recalled that its 14th Session had considered the role of other legitimate factors and had agreed to ask relevant Committees to identify and clarify the relevant factors taken into account in their work, in the framework of risk analysis, as this would facilitate the general debate in the CCGP[12]. The conclusions of the Committee on Food Hygiene were presented in the working document and the discussions and conclusions of other committees that had met later were presented in an unnumbered CRD.

86. The Delegation of the Netherlands, supported by other delegations, stressed the importance of considering other legitimate factors in order to restore consumer confidence in food safety regulations; for this purpose, the scope of this question should be expanded to address issues such as animal welfare, consumer concerns and consumer choices, and the question should also be forwarded to the new Task Forces.

87. The Observer from Consumers International expressed the view that the consideration of other factors should not be limited to risk management, that it should be forwarded for consideration by other Codex Committees, including Food Labelling and the new Task Forces, and suggested that two separate lists should be prepared to distinguish the legitimate factors that were considered at the national and international level.

88. The Delegation of the United States, supported by other delegations, recalled that legitimate factors were limited by the second Statement of Principle and that factors which were not relevant to the protection of consumers' health and the promotion of fair practices in food trade were not within the mandate of Codex. The Delegation pointed out that societal choices were the responsibility of national governments and did not constitute risk management measures.

89. Some delegations pointed out that some of the factors identified by the Committees or in the working document should not be considered as 'other factors' since they were based on scientific information, especially Good Manufacturing Practice, Good Agricultural Practice, Good Veterinary Practice, and methods of analysis and sampling. The Observer from ALA indicated that the scope and use of the factors listed by different Committees should be defined and the CCGP should determine whether they were legitimate on this basis.

90. Some delegations stressed the need for further clarification from the individual committees on how other factors were integrated into the risk management process, especially on the weight they were given in the decision process; the replies received so far from the Committees were not precise enough. In this regard, the Committee noted that the Committee on Pesticide Residues had not yet addressed this question and some delegations proposed that the CCNFSDU should also consider this question as its activities included certain aspects of risk analysis.

91. In considering the proposed criteria for the inclusion of other legitimate factors within the Codex context (para 34), the Committee agreed to the amendments proposed by the Delegation of Canada, as follows:

- In the 5th indent, the incidence of other factors should be documented 'including the rationale for their integration' as this allowed for further clarification of the process.

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[11] CX/GP 00/7, CDR 5 (IACFO), CRD 7 (comments of ALA), CRD 13 (CI), CRD 10 (Malaysia), Unnumbered CRD (ICGMA).

[12] ALINORM 99/33A, para. 76

- In the 7th indent on economic interests, reference was made to the practical feasibility of various risk management options, to make it more general.

- In the last indent on unjustified barriers to trade, it was specified that 'in doing so, particular attention should be given to the impact on developing countries of the inclusion of such other factors' to make this provision more explicit.

92. Several delegations sought clarification on the status of the examples presented as a list in para. 33 of the working document, and questioned whether the Committee should proceed further, proposing that further work should be deferred until all relevant committees had considered this question. Other delegations pointed out that the work of individual Committees was useful but that CCGP was responsible for providing general guidance on this issue. Some delegations pointed out that the assignment given to the Committees was not to develop exhaustive lists but to determine the legitimacy of such factors in the framework of Codex.

93. The Secretariat indicated that the Committee had a specific mandate following its decision at the 13th Session, and in accordance with the recommendation of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety, as endorsed by the 22nd Session of the Commission. The Medium-Term Plan for 1998-2002[13] approved by the Commission included the development of guidance on the identification, management, application and interpretation of other legitimate factors as defined in the second Statement of Principle. The examples described in the working document and summarized in the list (para.33) were intended to facilitate discussion of general recommendations and the input of other Committees had been sought for this purpose. In addition these Committees were in the process of clarifying this question since they were considering the integration of risk analysis in their work.

94. It was recalled that the responsibility of the CCGP was to develop general guidance, a first draft of which was presented at the end of the document (para. 34). It was noted that the ongoing debate in the Committees responsible for risk analysis could assist the general discussion but that the Committee should proceed within its own mandate to develop general guidance. It was also clarified that until now, the debate concerned the factors taken into account in past and present work of the Committees and the request of CCGP had not therefore been addressed to the new Task Forces, which reported to the Executive Committee and the Commission.

95. The Committee agreed that it should proceed with its consideration of this issue at its next session on the basis of the current text, taking into account the amendments made at the current session. The conclusions of the committees involved in risk management (including CCFH, CCFAC, CCRVDF and CCPR) would also be taken in account, with the understanding that these Committees might need to clarify further the integration of other factors in their work, as necessary. It was also agreed that the CCNFSDU should be invited to consider the integration of other legitimate factors in its activities involving risk analysis aspects. The Committee agreed that the Secretariat would develop draft general guidance based on paragraph 34 of the current document (CX/GP 00/7) and circulate the revised text for comments and consideration by the next session.

PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD (Agenda Item 7)[14]

96. The Committee recalled that its 13th Session had agreed to undertake the revision of the Code of Ethics in view of significant changes at the international level since its previous revision in 1985. Following approval of this new work by the 23rd Session of the Commission, the current text had been revised by the Secretariat in the light of the proposals received in reply to CL 1999/19-GP and circulated at Step 3 for comments. In view of time constraints, the Committee did not consider the Code section by section but had an exchange of views to identify the areas which needed further clarification.

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13 ALINORM 99/37, Appendix II

14 CL 1999/19-GP; CX/GP 00/8, CX/GP 00/8-Add.1 (comments of Australia, Brazil, Canada, Egypt, Guyana, United States, ENCA, IBFAN), CX/GP 00/2 (comments of Cuba, Uruguay, ENCA, IBFAN, CI, IACFO), CRD 8 (South Africa), CRD 10 (Malaysia), CRD 14 (Thailand)

97. Several delegations stressed the need to clarify the status of the Code in international trade, especially in relation to the SPS and TBT Agreements; in addition the consequences of non-compliance with the provisions of the Code should be addressed.

98. Some delegations pointed out that Codex standards and related texts were usually addressed to governments and that some clarification was needed as to the scope of the Code, especially whether it applied to governments or to producers. It was noted that the Code applied to all those engaged in international trade and that this would apply to all sectors involved in the production, transport and distribution of food, as reflected in Section 7.

99. The Delegation of Malaysia, referring to its written comments, made the following proposals: specific provisions should refer to the consideration of developing countries, including the Introduction; Article 6.1(b) should refer to the SPS and TBT Agreements; and the definition of food should be amended to include dietary supplements and functional foods. The Observer from ICGMA supported the proposals of the Delegation of Malaysia concerning the reference to the SPS Agreement, since consistency in the measures applied was an important concern for developing countries.

100. The Delegation of India proposed to take into account the needs of developing countries with additional text based on the provisions of Articles 9 and 10 of the SPS Agreement, and stressed that countries should not export food which did not correspond to their own standards, which should be reflected in Article 6.

101. The Delegation of Canada pointed out that the current text in Article 5 was too prescriptive and should rather recommend that national standards should 'take into account' Codex standards and related texts but that in the final analysis it was the national standards that applied. Some delegations expressed the view that national standards should be in accordance with Codex standards, as indicated in the current text.

102. The Delegation of Kenya proposed to add to the Preamble of the Code that "religious and cultural factors should, as far as practically possible, be respected in the promulgation of food standards".

103. The Representative of WTO recalled that the provisions of the TBT Agreement required member countries to base their technical regulations on international standards when they exist or their completion is imminent, and proposed that the text could refer to national standards based on Codex standards. The Representative also indicated that the code would be considered as relevant under the SPS Agreement to the extent its provisions applied to sanitary matters, and that the provisions on notification corresponded to the requirements of SPS and TBT.

104. The Delegation of Austria proposed to amend the title to a "Code of Ethics and General Principles", and to include consideration of other legitimate factors. The Committee noted some other proposals as follows: in order to simplify the text of Article 5, the references to specific classes of standards could be avoided; foods for infants and young children should be distinct from foods for special dietary uses; the order of the provisions in Article 7 should be reviewed. The Delegation of Brazil proposed some amendments to Articles 9 (exchange of information) and 11 (developing countries).

105. Some delegations supported the inclusion of a reference to the resolutions of the World Health Assembly as regards foods for infants and young children, while other delegations expressed the view that this was too vague and the Code should only mention specific texts. The Delegation of Switzerland pointed out that the Committee on Nutrition and Foods for Special Dietary Uses had not yet taken a decision on the inclusion of a reference to WHA Resolutions[15] and that consistency should be sought between all Codex texts in this regard.

106. The Observer from Consumers International proposed to include a reference to openness and transparency, defined as "good governance" and including the selection of experts for risk assessment.

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[15] ALINORM 99/26, para. 86 and Appendix V

107. Some delegations pointed out that all food should conform to the same standards, including under food aid programmes and exceptional circumstances, and that there should be no exceptions to the provisions of the code. The Secretariat recalled that this question was specifically addressed in Article 2.1 of the Scope, which covered food aid.

STATUS OF THE PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD

108. The Committee agreed to return the Proposed Draft Code to Step 3 for redrafting by the Secretariat in the light of the comments received and the above discussion, for consideration at the next session.

CONSUMER PARTICIPATION IN CODEX WORK AND RELATED MATTERS (Agenda Item 8)[16]

109. The Committee welcomed the progress made in addressing the question of increasing consumer participation in Codex work, both in the Commission and at the national and regional levels. It welcomed the proposed draft Guidance on Measurable Objectives to Assess Consumer Participation in Codex and focussed its attention of the proposals in Appendix A to the discussion paper.

110. The Committee agreed to modify these proposals by providing that the names be included of countries that have established a national Codex Committee or Contact Point or held open consultations with consumers when developing national positions for Codex meetings. It was also agreed to include information on the action of governments to support the establishment and activities of consumer NGOs. On that basis the Draft Guidance was endorsed by the Committee as being appropriate for the development of a baseline set of data and for consideration by the Regional Coordinating Committees when discussing the standing item on consumer participation in the countries of the various regions. The Committee called upon the Secretariat to begin the development of a set of baseline data as soon as possible. It was recommended that a report should be made to the Commission every two years.

111. In relation to a question concerning the membership of the individual consumer organizations participating in the Codex process, it was noted that the Secretariat was required under the provisions of *the Principles concerning INGO participation in Codex* to report on the status of all observer INGOs to the Commission and that this report would contain a list of addresses and contact details. Furthermore, it was noted that the Yearbook of International Organizations, published by the International Union of International Organizations, contained this information in detail.

112. The Committee also highlighted the Commission's recommendation for the development, by FAO and WHO, of guidelines or models for enhancing consumer participation in Codex and food standards work at the national and international levels and recalled prior FAO and FAO/WHO work in this area that could be of relevance.

OTHER BUSINESS, FUTURE WORK AND THE DATE AND PLACE OF NEXT SESSION (Agenda Item 9)

RELATIONS BETWEEN CODEX COMMODITY COMMITTEES AND CODEX GENERAL SUBJECT COMMITTEES

113. The Delegation of Switzerland requested that the Committee review the working relationships between the Codex Commodity Committees and the Codex General Subject Committees in order to avoid confusion between their roles when specific provisions were to be included in Codex commodity standards and general standards. The Secretariat recalled that the Section in the Procedural Manual dealing with the relationships between the general subject and commodity committees had recently been revised to take into account the Commission's priority of elaborating general standards that covered all foods wherever possible. The Section established clearly the working relations between these two groups of committees and the detailed arrangements to be followed.

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[16] CX/GP 00/9; CX/GP 00/9-Add.1 (Comments of Consumers International); CRD 6 (IAFCO); CRD 14 (Thailand).

114. It was noted that a special case might exist in the case of food additives and contaminants, where the provisions of individual standards following endorsement by the Codex Committee on Food Additives and Contaminants, were to be incorporated into the corresponding general standards. Until recently however, the General Standards for Food Additives had been in the formative phase and as a result there had been incomplete or overlapping information in relation to the Codex-approved use of additives. It was proposed by the Secretariat that a paper be prepared for consideration the Codex Committee on Food Additives and Contaminants that would lead to complete integration at the earliest possible opportunity of all food additives provisions in Codex standards into the general standard. Depending on the outcome of this exercise, there may or may not be a need to review the corresponding Section of the Procedural Manual.

APPLICATION OF RISK ANALYSIS IN THE ELABORATION OF CODEX STANDARDS AND CODES BY DIFFERENT COMMITTEES

115. The Delegation of India recalled that the Commission at its 23rd Session had confirmed that the elaboration of Codex standards and related texts should be based on risk analysis. It requested the Committee to consider how the principles of risk analysis should be applied at various stages of the elaboration process. In particular, the Delegation drew attention to the development of certain Codes of Hygienic Practice under consideration by the Codex Committee on Food Hygiene at Step 3. The Delegation also drew attention to the consideration of Aflatoxin M_1 in milk and the provisions for Lead (Pb) in various foods by the Codex Committee on Food Additives and Contaminants where, in the opinion of the Delegation, the measures proposed were not consistent with the current JECFA risk assessments and yet advanced to the further step. The Delegation proposed that the Committee in future should consider how risk assessment would be applied to proposals for standards or related texts that were currently being considered by Committees or submitted to the Commission for adoption.

DATE AND PLACE OF NEXT SESSION

116. The Committee was informed that the 16th Session of the Committee would be held in Paris in April 2001. In view of the proposal to convene a Working Group if necessary for drafting the section dealing with precaution in the Proposed Draft Principles of Risk Analysis, the precise dates would be confirmed at a later time.

SUMMARY STATUS OF WORK

Subject Matter	**Step**	**Action by**	**Reference in ALINORM 01/33**
Proposed Amendment of Rule VI.2		Governments 24th CAC	para. 73 Appendix II
Working Principles for Risk Analysis	3	Governments 16th CCGP	para. 62 Appendix III
Proposed Draft Revised Code of Ethics for International Trade in Foods	3	Governments 16th CCGP	para. 108
Consumer participation		Secretariat Coordinating Committees - 24th CAC	para. 110
Practical measures to facilitate consensus		24th CAC	paras. 68-69
Composition of the Executive Committee and related matters		Secretariat 16th CCGP	para. 84
Role of science and other factors in relation to risk analysis		Secretariat 16th CCGP	para. 95
Relationship between commodity committees and CCFAC		Secretariat 33rd CCFAC	para. 115

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PROPOSED AMENDMENT TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION

CLARIFICATION OF RULE VI.4 (VOTING AND PROCEDURES)

Amend Rule VI.4 as follows (inclusion underlined):

Subject to the provisions of paragraph 5 of this Rule and paragraph 2 of Rule X, any Member of the Commission may request a roll-call vote, in which case the vote of each Member shall be recorded.

PROPOSED DRAFT CODEX WORKING PRINCIPLES FOR RISK ANALYSIS

(Returned to Step 3 of the Procedure)

SCOPE

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

2) The primary purpose of risk analysis by the Codex Alimentarius Commission is protecting the health of consumers while at the same time ensuring fair practices in the food trade.

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

4) Within the framework of Codex Alimentarius Commission and its procedures, 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 [soundly based on science,] consistent, open and transparent and follow a structured approach comprising the 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 all interested parties.

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

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. Precaution is an essential element of risk analysis. This is particularly important where scientific evidence is insufficient and negative effects on health are difficult to evaluate.

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

RISK ASSESSMENT

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

8. 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

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 and the procedures used to select these experts should be documented including a public declaration of any potential conflict of interest.

10. Risk assessment should be based soundly on science and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

11. Risk assessment should take into account uncertainties at each step in the risk assessment process and variability in risk estimates.

12. Any constraints, uncertainties and assumptions and their impact on the risk assessment should be documented in a transparent manner, including constraints that are likely to influence the quality of the risk estimate. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative.

13. 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.

14. 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.

15. Recognizing that primary production in developing countries is largely through small and medium enterprises, risk assessment should be based on data from different parts of the world, including that from developing countries. This data should particularly include epidemiological surveillance data and exposure studies.

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

17. 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.

18. 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. It should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions.

RISK ASSESSMENT POLICY

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

20. Risk assessment policy consists of documented guidelines for scientific judgement and policy choices to be applied at appropriate decision points during risk assessment.

21. To ensure that the risk assessment process is systematic, complete and transparent, risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties.

22. [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.]

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

RISK MANAGEMENT

24. 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

25. Risk management should follow a structured approach [be grounded on science-based risk assessment and take into account other legitimate factors as appropriate]. The risk management framework includes [risk evaluation][2], assessment of risk management options, implementation of management decisions, and monitoring and review[3].

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

27. The risk management process should be transparent, consistent 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.

28. Risk management options should be evaluated in terms of the overall risk reduction.

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

30. Guidelines should be defined for the integration in the risk management process of legitimate factors other than science relevant for the health protection of consumers and for the promotion of fair practices in food trade.

31. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases including where legitimate factors other than science are applied.

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

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. Food standards and related texts must be consistent with new scientific knowledge and other information relevant to risk analysis.

The two following paragraphs are alternative proposals:

34. [Where relevant scientific evidence is insufficient, precaution can be exercised as an interim measure to protect the health of consumers. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly within a reasonable timeframe.]

34. [When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food[4], and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment, in accordance with the following criteria[5]:]

35. [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 The Committee is of the opinion that this term requires clarification or could be re-worded to avoid confusion with "risk assessment".

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

4 [It is recognized that hazard identification is a crucial step in this process.]

5 [Some Members refer to this concept as the "precautionary principle".]

- 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 potential 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

36. Risk analysis should include clear, interactive and documented communication, between risk assessors and risk managers, and communication with consumers and other interested parties in all aspects of the process.

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

38. 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.

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

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