

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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HEALTH
ORGANIZATION



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ALINORM 03/33

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fifth Session
Rome, 30 June - 5 July 2003

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

Paris, France, 15-19 April 2002

Note: This document incorporates Circular Letter CL 2002/13-GP

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CX 4/10

CL 2002/13-GP
April 2002

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 17th Session of the Codex Committee on General Principles (ALINORM 03/33)**

MATTERS FOR ADOPTION BY THE 25TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Amendments to the Procedural Manual

Amendment to the Title and Terms of Reference of the Committee on Meat and Poultry Hygiene (para. 14).

Governments and international organizations wishing to submit comments on the above amendment should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 30 March 2003**.

MATTERS FOR ADOPTION BY THE 50TH SESSION OF THE EXECUTIVE COMMITTEE

Proposed Draft Principles at Step 5 of the Procedure

Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius at Step 5 of the Procedure, for inclusion in the Procedural Manual (para. 63 , Appendix II).

Governments wishing to submit comments on the implications which the Proposed Draft Working Principles may have for their economic interests should do so in writing in conformity with the Procedure for the Elaboration of World-wide Standards at Step 5 to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 30 May 2002**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 17th Session of the Codex Committee on General Principles are as follows:

Matters for adoption by the Commission:

The Committee

- Endorsed the amendments to the Title and Terms of Reference of the Committee on Meat and Poultry Hygiene, as proposed by that Committee (para. 14);

Matters for adoption by the 50th Session of the Executive Committee:

The Committee

- Agreed to advance to Step 5 the Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius (para. 63, Appendix II);
- Agreed to undertake new work on the elaboration of Proposed Draft Working Principles for Risk Analysis intended for governments (para. 72).

Other matters of interest to the Commission and the Executive Committee:

The Committee

- agreed to ask discuss further at its next session the amendments to the Rules of Procedure concerning the membership of regional economic integration organizations in the light of the advice provided by the FAO Committee on Constitutional and Legal Matters (para. 120, Appendix III);
- agreed to return the Proposed Draft Revised Code of Ethics for International Trade in Foods to Step 3 for redrafting and further comments (para. 91);
- agreed to consider further at its next session the cooperation between the Codex Alimentarius Commission and international organizations in the elaboration of Codex standards and related texts (para. 104);
- agreed to discuss questions related to traceability or product tracing at its next session on the basis of a paper prepared by the Codex Secretariat (para. 12).

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INTRODUCTION

1. The Codex Committee on General Principles held its Seventeenth Session in Paris from 15 to 19 April 2002 at the kind invitation of the government of the French Republic. The Session was chaired by Mrs. Catherine Geslain-Laneelle, Director General, Direction Générale de l'Alimentation, Ministère de l'Agriculture et de la Pêche. The Session was attended by 232 delegates from 49 member countries, 4 international intergovernmental organisations and 21 international non-governmental organisations. A complete list of participants is attached as Appendix I.

2. The Session was opened by Mr Jérôme Gallot, Director General, Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, on behalf of the Minister in charge of Trade and Consumer Affairs. Mr Gallot recalled the significance and the symbolism of the fact that the Codex Alimentarius Commission is attached to both the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO). He stressed that the confidence of consumers in food safety and quality was necessary to facilitate the liberalisation of international trade. Thus, governments and all interested parties should foster their involvement in establishing Codex standards that ensure both health protection and fair trade practices.

ADOPTION OF THE AGENDA¹

3. On the proposal of the Delegation of India, the Committee agreed to discuss Items 3(a) and 3(b), both concerning Risk Analysis, together. The Committee also agreed to discuss Item 6 (Membership in the Codex Alimentarius Commission of Regional Economic Integration Organizations) before Item 5 (Cooperation between the Codex Alimentarius Commission and Other International Intergovernmental Organizations). At the proposal of the Delegation of Canada, the Committee agreed that a report would be made by the Representatives of FAO and WHO under Agenda Item 7 (Other Business) on the status of the independent Review/Evaluation of the Codex Alimentarius and other FAO/WHO Work on Food Standards. With these changes, the Committee adopted the Provisional Agenda as the Agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES INCLUDING TRACEABILITY²

GENERAL ISSUES

4. The Delegation of the United States stressed the importance of the consideration of the Medium-Term Plan 2003-2007 and the need for member countries to provide comments. The Secretariat informed the Committee that the revised draft of the Medium-Term Plan, including the comments submitted by member countries, had been prepared and would be considered by the 50th Session of the Executive Committee.

TRACEABILITY

5. The Committee recalled the recommendations of the 49th Session of the Executive Committee concerning the consideration of traceability in Codex and noted the conclusions reached by the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology and the work undertaken by the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) and other Committees in this area. The Committee took note of the comments of Uruguay concerning the need to distinguish clearly the use of traceability in risk management and other applications.

¹ CX/GP 02/1.

² CX/GP 02/2; CX/GP 02/2-Add.1 (Comments of Uruguay); CRD.5 (Comments of the 49th Parallel Consortium).

6. The Delegation of France, referring to its written comments (CRD 4) proposed that the Committee should develop a definition for the purposes of Codex as well as working principles to address this question in concerned Committees, either in a separate document or as part of other documents such as the Working Principles for Risk Analysis. The Delegation recalled that the role of the Committee was to provide guidance to Codex Committees on general issues and proposed to convene a working group, chaired by a developing country, to develop a document for this purpose.

7. Several delegations supported this proposal and pointed out that the work undertaken by CCFICS concerning traceability was focused on modalities of implementation in inspection and certification systems; other committees were also working on provisions concerning traceability in their respective areas of competence but the Committee on General Principles should address this question from a general perspective in order to ensure consistency throughout Codex.

8. The Delegation of Brazil proposed to await the outcome of the work initiated by the CCFICS in order to avoid duplication; this would be consistent with the coordinating role of the Committee and with the recommendations of the Executive Committee that relevant Committees should undertake work as they deemed appropriate. Several delegations supported this position and stressed that the growing number of working groups established by different Codex Committees posed practical difficulties for governments, especially developing countries, and would not necessarily solve such complex issues. Some delegations also pointed out that traceability was only one of the measures applied in risk management and that it should not be addressed separately in specific guidelines or recommendations, but integrated in the work on risk analysis.

9. The Delegations of the United States, supported by other delegations, expressed the view that product tracing should be considered in the framework of risk management as a matter of priority, as recommended by the CCEXEC and taking into account the conclusions reached by the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (CTFBT) concerning risk analysis.

10. Other delegations and observers stressed the importance of traceability to ensure the authenticity of consumer information and proposed that the work of the Committee should not be limited to food safety aspects but should address all relevant applications of traceability.

11. Several delegations stated that these questions should also be examined in the light of the obligations of Members of WTO under the SPS and TBT Agreements, including consideration of alternative procedures.

12. The Committee could not reach a consensus on the need to create a working group but agreed to undertake work on this matter and agreed that the Secretariat should prepare a discussion paper considering how the Committee could best contribute to consideration of this issue in Codex, taking into account the work of other relevant committees, well in advance of the next session in order to allow for comments. The Secretariat was also asked to provide a draft definition for Codex use.

13. In reply to a question on the role of Regional Coordinating Committees, the Secretariat recalled that these Committees might wish to contribute to the debate, as agreed by the Executive Committee, and they would therefore be invited to discuss this question. The results of these discussions would be integrated into the document prepared for the Committee.

NAME AND TERMS OF REFERENCE OF THE COMMITTEE ON MEAT AND POULTRY HYGIENE

14. The Committee endorsed the proposal of the Committee on Meat and Poultry Hygiene to amend its name into “Committee on Meat Hygiene”, and to amend its Terms of Reference as follows: “To elaborate world-wide standards and/or codes of practice as appropriate for meat hygiene”.

RISK ANALYSIS (AGENDA ITEM 3)***PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS (AGENDA ITEM 3A)***³***THE APPLICATION OF RISK ANALYSIS IN THE APPLICATION OF CODEX STANDARDS (AGENDA ITEM 3B)***⁴

15. As agreed during the Adoption of the Agenda (see para. 3 above), the Committee discussed these two sub-items together. The Committee expressed its appreciation to the Delegation of India for the thoughtfulness of the paper prepared under Agenda Item 3(b) and also the Delegation's proposal to discuss the issues raised in the context of the Proposed Draft Working Principles.

16. The Committee recalled that at its previous session it had considered the Proposed Draft Working Principles for Risk Analysis and had agreed on several amendments to the text; however, it had been unable to arrive at a consensus on the Scope of the document or on the sections dealing with precaution in risk analysis, especially in risk management. The Committee had therefore requested the Commission for guidance on these matters (ALINORM 01/33A, paras 16-75, in particular 70-72). The Commission had confirmed its initial mandate to the Committee to complete the principles for risk analysis within Codex as a high priority, with a view to their adoption in 2003. It had also agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work. It also made a decision on how Codex should proceed when scientific data were insufficient or incomplete. The Commission had recommended that the host government convene a Working Group to facilitate discussions on the Proposed Draft Principles at the present session of the Committee (ALINORM 01/41, paras. 75-83).

17. On the basis of the Commission's clarification and the discussions at the Committee's previous session, the Secretariat revised the Proposed Draft Working Principles and circulated them for comment (CL 2001/24-GP). A Working Group was convened under the Chairmanship of Professor Chevassus-au-Louis (France) in December 2001 at which the replies to the Circular Letter were considered and which prepared a revised text of the Proposed Draft Working Principles. The revised text (including the text of all of the comments received) was again circulated for comment (CX/GP 02/3).

18. At the invitation of the Chairperson, Professor Bernard Chevassus-au-Louis, Chairman of the Museum National d'Histoire Naturelle, introduced the text prepared by the Working Group established and circulated for comments. Professor Chevassus-au-Louis indicated the participation of 22 Member countries and 11 international organisations in the Working group. The Committee noted the main changes that had been made in the text, in particular the removal of square brackets and rephrasing the relevant paragraphs where appropriate. Important progress had been realized on five issues, namely: that these principles addressed Codex Alimentarius (Commission) matters only; reference had been included to the Codex mandate of ensuring fair practices in the food trade; treatment of uncertainty in risk assessment and risk management had been clarified; concerns of developing countries were specifically taken into account; and the risk communication section completed. The Committee considered the text paragraph by paragraph.⁵

TITLE AND SCOPE

19. The Committee agreed that the text applied to the application of risk analysis within the framework of the *Codex Alimentarius* (i.e., the collection of Codex standards and related texts) and amended the Title and

³ Documents considered under Item 3(a): CL 2001/24-GP; CX/GP 02/3; CX/GP 02/3-Add.1 (Comments of Colombia, Cuba, Guatemala, Malaysia, Consumers International, Council for Responsible Nutrition; International Alliance of Dietary/Food Supplement Associations; International Council of Grocery Manufacturers' Associations); CX/GP 02/3-Add.2 (Comments of Canada, Argentina, Morocco, New Zealand, International Federation of Animal Health; Biotechnology Industry Organization); CX/GP 02/3-Add.3 (Comments of United States, Uruguay, European Community); CRD 2 (Comments of India); CRD 3 (Comments of Japan).

⁴ Documents considered under Item 3(b): CX/GP 02/4 (Document prepared by India); CX/GP 02/4-Add.1 (Reformulated version of the proposed recommendations – India); CX/GP 02/4-Add.2 (Comments of Canada).

⁵ Throughout the text, references are made first to the paragraph numbering of the working document followed by the new paragraph number in the revised document, as presented in Appendix II

paragraph 3 (2) of the text accordingly. It noted that in most of the remainder of the text reference should be made to the Codex Alimentarius Commission.

20. In the second paragraph of the proposed draft text presented by the Working Group and dealing with the objectives of the Working Principles, the Committee considered the proposed inclusion of a reference to the “promotion of fair trade practices” in association with the primary purpose of risk analysis, namely protection of consumers’ health. In response to a question, the Secretariat noted that the Codex Alimentarius Commission has not defined “fair trade practices” for the purpose of the Codex Alimentarius, however in previous decisions of the Commission, the following issues *not directed exclusively to the protection of consumers’ health* were identified, for example: Prevention of adulteration⁶; Prevention of false, deceptive or misleading labelling⁷; and Accurate product description⁸. Some delegations suggested that the concept of fair trading practices had evolved, especially since the establishment of the WTO, to cover risk management considerations as outlined in paragraph 37 of the document (now para. 35). Several delegations recommended the deletion of the reference, since, in their view the extent of “fair trade practices” was not precise and in any case had no bearing on risk analysis, or else was covered by the consideration of the “other legitimate factors” that would need to be taken into account in the course of establishing an appropriate standard.

21. The Representative of the WTO noted that the notion of “fair practices in the food trade” was a Codex concept, contained in its Statutes. He indicated that a possible reflection of the notion in the SPS Agreement was contained in Article 5.6 which stated that “... [WTO] Members shall ensure that ... measures are not more trade restrictive than required to achieve their appropriate level of protection taking into account technical and economic feasibility ...”. He also noted that according to Article 2.2 of the TBT Agreement “... technical regulations shall not be more trade restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objective are *inter alia*: ... the prevention of deceptive practices...”. He stressed that, including for WTO purposes, it would be helpful if the Committee could provide a definition of “fair practice in the food trade” as applied by Codex.

22. Other delegations were of the opinion that fair trade practices needed to be taken into account in the context of risk management, and were indeed referred to in the adopted definition of *Risk Management*.

23. Following the discussion of a proposed compromise text (also in association with a proposal to amend paragraph 32 (old)), the Committee came to the conclusion that all of the issues contained in the proposed paragraph were treated more precisely in other paragraphs and sections of the document, and therefore agreed to delete the paragraph in its entirety.

24. The Committee agreed to clarify paragraph 4 (3) of the text by indicating that for the purpose of these Working Principles, the Commission and its subsidiary bodies had the role of “risk managers”, while the FAO/WHO expert bodies and consultations took the role of “risk assessors”.

RISK ANALYSIS – GENERAL ASPECTS

25. In relation to the matter of “confidentiality”, the delegation of Argentina noted that there was international agreement on a definition of confidentiality in Article 39.3 of the TRIPS Agreement, and that a separate definition should not be necessary in the Working Principles. The Committee also agreed to modify the footnote describing the “other interested parties” for the purpose of clarity.

26. In paragraph 8 (7), the Committee agreed that the food-related risks referred to in the Working Principles were those defined by the Codex Alimentarius Commission in the Definitions of Risk Analysis Terms Related to Food Safety in the Procedural Manual⁹ and agreed to include a footnote to this effect.

⁶ For example *Code of Ethics for International Trade in Foods*, Section 4.2

⁷ For example *Code of Ethics for International Trade in Foods* (CAC/RCP 20-1979, Rev. 1-1985), Section 4.2

⁸ For example *Principles for Food Import and Export Certification and Inspection* (CAC/GL 20-1995), Section 3.

⁹ Procedural Manual, 12th Ed., pp. 43-44.

27. In relation to paragraph 11 (10), the Delegation of the United Kingdom stated that the decision of the Commission should be reconsidered in view of way in which it was adopted at the 24th Session of the Commission and because of its inappropriateness and internal inconsistencies. The Delegation of Bolivia pointed out that the decision of the Commission was the most important element of the document on risk analysis. The Committee, however, decided not to re-open debate on this matter.

28. The Committee discussed proposals to amend the paragraph dealing with *precaution* (paragraph 12, now 11), in particular to delete the introductory sentence (Argentina) and to provide more detailed clarification on the nature of the risk and its potential public health consequences (USA). Noting however that considerable effort had been made in achieving a consensus on this issue and that the opening sentence was a statement of fact, the Committee agreed to retain the text as drafted.

RISK ASSESSMENT POLICY

29. The Committee agree to review the definition of Risk Assessment Policy currently presented in para. 15 when considering the Definitions (see para.60). The Committee agreed that risk assessment should be “unbiased”, in addition to the current requirements, and amended paragraph 16 accordingly.

30. In paragraph 18 (16), the Delegation of New Zealand proposed that risk assessors should evaluate the “potential changes in risk” rather than “risk reduction” resulting from different risk management options, as it would be more inclusive and cover all possible outcomes. In some cases, risk assessors might come to the conclusion that a particular option did not result in a reduction of the risk considered or might increase another risk, and the text should reflect the scientific nature of the evaluation process.

31. The Representative of WHO stressed that risk reduction was the overall objective of risk analysis, and it was important to retain this essential concept in the Working Principles. The Committee recognized that the purpose of risk analysis was to reduce health risks, as indicated in the Scope, but agreed with the amendment proposed as it clarified a specific aspect of risk assessment policy and did not detract from the overall purpose of the Working Principles.

32. The Committee also noted a proposal of the Delegation of India concerning the feasibility of the risk management options but recognized that this was the responsibility of risk managers and was addressed in the relevant section (para. 38, now 35).

RISK ASSESSMENT

33. The Committee agreed to delete the introductory paragraph to this section as it was already covered in the section on Risk Management and repeated the first paragraph of the *Statements of Principles Relating to the Role of Food Safety Risk Assessment* (old para. 19).

34. In paragraph 21 (18) on the selection of experts, the Committee agreed that the participation of experts from different parts of the world, including developing countries was a general principle applied by FAO and WHO and amended the sentence accordingly (deleting “where possible”), as proposed by the Delegation of India.

35. The Observer from Consumers International proposed that observers representing consumer interests should be admitted in expert bodies. The Representative of FAO recalled that experts were selected in their personal capacity on the basis of their competence through an open and transparent process and although they might belong to consumers organizations or to any other relevant organization, they did not represent these organizations nor their views. In the same vein, no observers representing specific interests could participate in expert committees or consultations in order to avoid conflict of interest. The current text was therefore retained.

36. The Committee discussed whether the qualitative information mentioned in para. 23 (20) should be described as “scientific”, in order to ensure that only useful information was provided to risk assessors. It was noted that this was covered more generally in para. 24 indicating that “risk assessment should take into account all available scientific data” and the current text was retained. The reference to the presentation of the risk assessment results was deleted for clarification purposes as it was addressed specifically in para. 29 (25).

37. The Committee also reorganized paragraphs 23 and 24 (20 and 21) in order to consider separately the use of scientific data and the other elements to be taken into account in risk assessment, as proposed by the Delegation of Malaysia.

38. In para. 25 (22), the Delegation of India proposed to include additional recommendations to address the need for data originating from developing countries and the action to be taken by FAO/WHO. The Committee recognized that this was not within the mandate of Codex, but that the Commission could make recommendations to FAO and WHO in this respect. Some delegations expressed concerns that the elaboration of Codex standards might be unduly delayed pending the collection of relevant data. After an exchange of views, the Committee agreed on a text proposed by Canada, Brazil and India to the effect that the Commission should request FAO/WHO to initiate time-bound studies when relevant data were not available from developing countries. The conduct of risk assessment should not be delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data were available.

39. The Committee agreed to delete para. 26 and to refer to explicit consideration of the sources of uncertainty at each step of the risk assessment process in para. 27 (23), with some amendments to the current text for clarification purposes.

40. The Committee amended paragraphs 29 and 30 (25 and 26) for clarification purposes and to address separately 1) the presentation of risk estimates to risk managers, other risk assessors and interested parties; and 2) the impact of uncertainties on risk assessment and risk management. It was also agreed that on the basis of the definition of Risk Characterization, "Risk Estimate" should be defined as follows: "quantitative estimation of the risk resulting from risk characterization", and that it should be included in the Definitions (see also para. 62).

RISK MANAGEMENT

41. The Delegation of the United States expressed the view that risk management options selected for similar risks might be quite different due to the nature of the hazard considered (e.g. in dealing with intentionally added substances versus naturally occurring substances) and proposed to delete the reference to "different situations". Other delegations supported the current text in order to promote consistency in risk management decisions. The Committee considered that the concerns of the United States could be addressed by the reference to "unjustified" differences and retained the current text (para. 31, new para. 28).

42. The Committee had an extensive debate on the need to include a reference to the promotion of fair trade practices, in conjunction with the discussion of the Scope (see para. 20). The Committee agreed on a compromise text for the first sentence proposed by the Delegation of Brazil in cooperation with other delegations in order to recognize "the dual purposes of the Codex Alimentarius to protect the health of consumers and ensuring fair practices in the food trade" while retaining the notion that the primary objective of risk management was the protection of consumer health. The last sentence of the current paragraph was left unchanged, except for the addition of the word "health" to "consumer protection". This expression was modified accordingly in the remainder of the text.

43. In para. 32 (28), the Committee agreed that the decisions should be based on risk assessment in general and that the reference to "as appropriate to the circumstances" should be deleted, as proposed by the Delegation of Brazil, although some delegations recalled that this was mentioned in the *Statement of Principle Concerning the Role of Food Safety Risk Assessment*.

44. The Delegation of India stressed the importance of uniformity in the application of risk analysis in Codex and proposed to include a new paragraph indicating that the risk assessment should be completed before any final decision was taken on risk management options, especially standards and maximum limits. Some delegations pointed out that risk assessment could never be "complete" and the Committee agreed that the "conclusions of the risk assessment" should be presented before the final decision was made, as proposed by the Delegation of Canada. It was also agreed that the guidance provided in para. 11(10) concerning the elaboration of standards and related texts in relation to risk assessment should be taken into account. The Committee agreed to add a new paragraph on this basis (new para. 29).

45. In para. 33 (30), the Committee agreed to add a statement to the effect that the “feasibility of enforcement and compliance” should also be taken into account in risk management process.

46. In para 36 (33), the Committee agreed to remove a redundant reference to “other legitimate factors” as this was already covered in previous paragraphs. The footnote referring to the FAO/WHO Expert Consultation was also deleted as it was not needed in the final text.

47. The Committee discussed para. 37 (34), that had been included following earlier discussions on how to address trade implications in standard setting. The Delegation of Brazil proposed to include part of the text of Article 5.6 of the SPS Agreement to clarify that risk management options should not be more trade restrictive than necessary. Some delegations pointed out that this was not the role of the Commission as the level of protection was determined by member countries and national measures were subject to the provisions of the SPS Agreement. Some delegations and observers also expressed the view that this would unduly burden and delay the work of the Commission.

48. The Representative of WTO questioned whether the Commission should systematically consider trade implications and suggested that this sentence be deleted, especially as the text under discussion was intended for application within Codex, but that it could be reconsidered when developing recommendations to member countries. The Secretariat recalled that the need to consider the implications of draft standards for the economic interests of member countries was explicitly mentioned in the Elaboration Procedure (at Steps 5 and 6).

49. After some debate on the consideration that should be given to trade aspects in the development of Codex texts, the Committee agreed that the Commission should “seek and take into consideration the potential impact of such measures on trade between member countries”, as proposed by the Delegation of Canada.

50. In para. 38 (35), some delegations questioned the need for “flexibility” in the establishment of the standards and asked for clarification on the purpose of the second sentence. The Committee recalled that the current recommendation did not refer to flexibility in the implementation of standards, that was outside the mandate of Codex, but to the consideration of different risk management options that could achieve the same level of health protection. The Committee agreed to replace “flexibility” with “alternative options” for clarification purposes.

51. The Committee deleted the reference to developing countries in the first sentence as feasibility of risk management options and economic consequences should be taken into account in all cases. A new sentence was added at the end of the paragraph to reflect the need to consider the circumstances of developing countries.

RISK COMMUNICATION

52. The Committee agreed that the paragraphs of this section should be re-ordered into a more logical sequence and that throughout the section statements of fact or intent should be re-worded as principles. It was also agreed that throughout the section, when reference was made to “interested parties”, a linkage would be made to the footnote describing these parties (Footnote 4).

53. A new introductory paragraph outlining the goals of risk communication was inserted using the wording of the second part of the former paragraph 44 (new para. 37).

54. The Committee agreed that risk communication should be identified as a “reciprocal” exercise and amended the paragraph accordingly. The paragraph was also amended to indicate that the expert bodies and consultations referred to were the joint bodies of FAO/WHO (para. 40, now 38).

55. The Committee discussed combining paragraphs 41 and 42 (39 and 40), but decided to retain separate paragraphs defining the functions and the requirements of risk communication respectively. The paragraph describing the requirements of risk communication was amended for clarification (old para. 42, now 40).

56. The Committee agreed to amend paragraph 44 (42), firstly by removing the second part of it to the beginning of the Section on Risk Communication (see para. 53, above), and secondly by simplifying the reference to “other interested parties” (see also para. 52, above).

57. The Committee agreed to delete requirement for the Codex Commission and its subsidiary bodies to establish proactive communication strategies and communications plans, noting that activities had been foreseen in the Strategic Framework 2003-2007 and formed part of the Draft Medium-Term Plan 2003-2007. It was also noted that to request Codex Committees to develop communication plans could have a serious impact on their capacity to elaborate standards and related texts for consumer health protection (old para. 45).

DEFINITIONS

58. The Committee agreed that the definitions previously adopted by the Commission and included in the Procedural Manual should be left unchanged.

Risk Assessment Policy

59. The Delegation of Brazil suggested that the text as drafted in English and Spanish was tautological due to the reference to “policy choices” and that the French version of the definition that used the expression “choir d’orientation” was preferred. The definition was therefore aligned with the French version.

60. Noting its earlier discussion concerning paragraph 15 of the draft document that had contained the identical text as the proposed definition, the Committee agreed to delete this paragraph.

Risk Evaluation and Risk Profile

61. The Committee agreed to the definitions proposed by the Working Group and based on the work of the Joint FAO/WHO Expert Consultations.

Risk Estimate

62. See paragraph 40 above.

STATUS OF THE PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS AND THE RELATED DEFINITIONS

63. The Committee agreed to advance the text of the Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius to Step 5 of the Procedure for consideration by the 50th Session of the Executive Committee. It noted that, when finalized, this text would be included in the Procedural Manual as general guidance to the Commission and its subsidiary bodies.

64. The Committee also agreed to advance the above Definitions to Step 5, on the understanding that, when finalized, they would be included in the list of Definitions for the Purpose of the Codex Alimentarius that was published in the Procedural Manual.

65. The revised Proposed Draft Working Principles are contained in Appendix II to the present report and the proposed draft Definitions in the Annex to this Appendix.

66. Concerning the status of the Working Principles when finally adopted by the Commission, the Delegation of Denmark raised some questions about the practical implementation of the principles in Codex work. To illustrate the issue the Delegation indicated that the following questions needed to be addressed: who had the formal competence to establish risk assessment policies; which procedures should be followed; and how the policies so established would be addressed to the independent risk assessment bodies. The Delegation encouraged the Committee to consider such issues in the elaboration process leading to the final adoption of the text by the Commission.

CONSIDERATION OF THE DEVELOPMENT OF WORKING PRINCIPLES FOR RISK ANALYSIS TO BE APPLIED BY GOVERNMENTS (AGENDA ITEM 3C)¹⁰

67. The Commission had confirmed its initial mandate to the Committee to complete the principles for risk analysis within Codex as a high priority, with a view to their adoption in 2003. At the same time, it had also agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work.

68. The Secretariat noted that if the Committee decided to proceed with the elaboration of such principles, the following elements could be taken into account: the sections of the earlier draft of the Working Principles that could apply to governments; the recommendations originating from the FAO/WHO expert consultations on risk analysis issues; and the recommendations of Codex Committees currently working on risk analysis in specific areas, especially food hygiene and foods derived from biotechnology.

69. The Delegation of France indicated that significant progress had been made on risk analysis principles for Codex purposes at the current session and that it was appropriate to initiate work on risk analysis principles intended for governments. Referring to the proposals presented in CRD 1, the Delegation suggested that the Committee convene a Working Group to elaborate a proposed draft for consideration by the next session, as this could facilitate further discussion.

70. Several delegations expressed the view that a Working Group could be useful at a later stage, especially to consider comments, but proposed that an initial draft should first be developed by the Secretariat and circulated in order to allow all member countries and international organizations to provide their comments.

71. Some delegations, while recognizing the importance of developing risk analysis principles for governments, pointed out that the highest priority of the Committee was to finalize the risk analysis principles for application within Codex.

72. The Committee agreed to initiate new work on Proposed Draft Working Principles for Risk Analysis directed to governments, subject to the approval of the 50th Session of the Executive Committee. The Proposed Draft would be prepared by the Codex Secretariat for comments at Step 3 and consideration by the 18th Session of the Committee. It was also agreed that France, as host country, might convene a Working Group at an appropriate time to facilitate further discussions and that a decision would be taken in the light of the comments received.

PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS (AGENDA ITEM 4)¹¹

73. The Committee recalled that the last session had discussed the general aspects of the text and identified several issues that would require further consideration. The text had not been discussed in detail and it had been agreed that the Secretariat would revise the text in view of the comments and the discussion held at the session.

74. The Committee noted that only limited changes had been introduced to the document as several important issues remained to be addressed, as indicated in the introductory section. The Committee agreed to discuss the relevance of the Code under WTO and its applicability to governments and commercial operators before proceeding with detailed consideration of the text.

75. The Representative of WTO noted that the matter had been raised at the previous meeting of the Committee and that the advice of the SPS Committee could be sought if the Committee so wished. However, he emphasized that standard setting organizations were independent and it was their responsibility to establish recommendations in the framework of their specific objectives. The Committee also recalled the earlier advice from the SPS Committee to the Commission concerning the status of Codex standards, guidelines and

¹⁰ CRD 1

¹¹ CX/GP 02/5, CX/GP 02/5-Add.1 (comments of Canada, Colombia, Cuba, Malaysia, Moldova, Thailand, Turkey, United States, EC, ENCA, IBFAN) , CRD 2 (comments of India), CRD 8 (comments of Brazil)

recommendations in relation to the SPS Agreement, and in particular that “how a text would be applied depended on its substantive content rather than on the category of the text” (ALINORM 99/33, paras. 50-51).

76. Some delegations expressed the view that there was no need to ask the advice of WTO and that the Committee should concentrate on revising the contents of the Code, as the role of Codex was to provide recommendations that could then be used as a reference in the framework of WTO. The Committee agreed to proceed accordingly.

77. Many delegations stressed that the Code should be intended for governments because Codex was an intergovernmental organization and its recommendations were directed to governments. National authorities should implement the provisions of the code and make them applicable to commercial operators and all those engaged in food trade. The Delegation of Spain, speaking on behalf of the Member States of the European Union and expressing the EC position, indicated that the Code was intended for governments and for commercial operators, with the understanding that governments were responsible for applying regulations to operators. The Committee agreed to consider the recommendations to governments as a matter of priority and to discuss later how it could apply to commercial operators, if required.

78. Following the general discussion, the Committee considered the text section by section.

PREAMBLE

Para (b)

79. The Committee agreed that food safety should be mentioned in addition to food quality to reflect the essential importance of food safety in the context of the Code.

Para (c)

80. The Delegation of Spain expressed its objections to the current text as the right to food safety applied equally to all consumers and no specific reference should be made in this respect to low-income consumers. The Delegation of Chile proposed to delete the reference to low income consumers because the Code should guarantee the quality and safety of food for all consumers. Other delegations supported the current text as the specific difficulties of vulnerable groups should be taken into account. The Committee decided to retain the current text, and noted that consistency between the three versions (English, French and Spanish) should also be ensured.

Para (d)

81. The Delegation of Canada proposed to amend the text concerning food safety and other concerns to reflect that there had been significant improvement in food quality and safety. The Committee however noted that this was not consistent with the surveys conducted by WHO concerning the incidence of foodborne diseases. The Secretariat suggested to retain the current text but to indicate that effective food control systems could lead to improvements in this situation, as it would emphasize the measures to be taken, and the Committee agreed with this proposal.

Para (f)

82. Several delegations noted that Members had rights and obligations beyond those specified in the WTO Agreements and agreed to refer to "certain" rights and obligations.

Para (g)

83. The Delegation of Argentina proposed to delete all references to specific products, such as was the case with the International Code of Marketing of Breast-Milk Substitutes, because if one specific product was mentioned all products should be mentioned. Many delegations and observers were opposed to this deletion and

wished to retain the current text, especially supporting the World Health Resolutions on the Code. It was agreed to retain the current text of paragraph (g).

Para (h)

84. The Delegation of Bolivia expressed the view that serious consideration should be given to the purpose of the Code in terms of ethics, and should not be limited to fair practices in food trade; many related issues affected the ethical aspects of food trade, especially the lack of access to food for populations suffering from hunger and malnutrition, the depletion of genetic resources and the resulting distortions in trade. It was therefore necessary to decide whether the Code should address only trade related issues or basic ethical values, and whether the title should be amended. The Delegation of Chile proposed to refer to the Plan of Action of the World Food Summit in addition to the Rome Declaration as it concerned all issues related to access to food and the Committee agreed that the text should be amended accordingly. The Delegation of Brazil noted that further consideration should be given to such basic issues while revising the Code.

85. The Secretariat recalled that the Scope of the Code covering food trade was determined by the overall mandate of Codex to protect the health of consumers and to ensure fair practices in food trade; other aspects such as genetic resources were addressed by other international bodies and were beyond the competence of the Committee and the Commission.

86. The Delegation of the United Kingdom indicated that although the specific mandate and competence of Codex should be respected, the context in which food trade was conducted also needed to be taken into account.

87. The Committee noted the proposal of the Observer from 49P to add a new paragraph indicating that “other international agreements, currently in effect, may also impact international trade in food directly or indirectly.” Several delegations opposed a general reference to agreements that were not binding on all member countries and were not specifically related to the objectives of the Code. The Committee recalled that in application of Objective 3 of the Strategic Framework Codex should promote linkages with other international standard setting and regulatory organizations. However, it did not come to a conclusion on the addition of references to specific organizations or agreements at this stage.

88. The Committee noted the proposal from the Observer from IBFAN to address the questions of other agreements under paragraph (a) and to include a reference to the International Covenant on Economic, Social and Cultural Rights.

Para (i)

89. The Delegation of Brazil proposed to amend the text to reflect the difficulties of member countries to comply with the regulations of importing countries from a general point of view, and to delete the current description of the situation in developing countries as it reflected a negative judgement on the ability of developing countries to develop and apply their own regulations. Although some delegations supported the current text, the Committee agreed with this proposal, as presented in the comments of Brazil (CRD 8).

90. The Committee could not proceed with the consideration of the text section by section due to time constraints. Some delegations expressed their concern that the consideration of the Code would again be delayed, especially as little progress had been achieved so far.

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

91. The Committee agreed that the Proposed Draft Code should be returned to Step 3 and redrafted by the Secretariat to incorporate the amendments made to the text, the written comments submitted for the session and the discussions held at the current session, for circulation and consideration at the next session as an early high priority item on the Agenda.

GUIDELINES FOR COOPERATION WITH INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (AGENDA ITEM 5)¹²

92. The Secretariat introduced the working paper that had been prepared subsequent to the decisions taken by the Codex Alimentarius Commission at its 24th Session, on the cooperation between the Codex Alimentarius Commission and other international intergovernmental organizations when elaborating Codex Standards and Related Texts¹³. It noted that the Secretariat had proposed amendments to the Uniform Elaboration Procedures contained in Procedural Manual, rather than separate guidelines for this purpose since the matter being considered dealt with the procedures for the elaboration of texts.

93. The Committee noted that in the matter of the cooperation between the Commission and other international bodies, no distinction was made in the Statutes between intergovernmental bodies and non-governmental bodies. Furthermore, the Commission was not able to enter into formal agreements with other international intergovernmental organizations as relations between the Commission and other international organizations were handled under the applicable regulations of FAO and WHO by the respective Directors-General, as appropriate¹⁴. The Committee also noted that nevertheless, the Commission had the authority under its Statutes to allocate work to other international bodies for the development of standards and related texts.

94. The delegation of Malaysia, referring to its written comments in CRD 6, expressed its disagreement with several points raised in the working document and questioned whether the working paper was consistent with the mandate given by the Commission. The Delegation also raised the issue that allowing the development of food standards by bodies other than Codex subsidiary bodies would result in an unnecessary burden for developing countries wishing to participate in the work, both in terms of human and financial resources, especially if it meant participating in meetings of other bodies. In relation to the interpretation of Article 1(b) of the Statutes of the Commission, the Delegation expressed the view that this might be construed to mean that the work undertaken by other bodies might be taken into account as references in the development of Codex standards. It should not be construed as allowing work to be undertaken by bodies other than Codex subsidiary bodies, not even at Step 2 of the Procedure. The Delegation drew attention to the conclusion of the Commission that it was the main body responsible for elaborating international food standards. Many other delegations supported these views and also drew attention to the importance of inclusiveness, openness and transparency in the process of elaboration of a proposed draft text and to the fact that the first drafting of a standard was of importance in terms of the source and manner of its preparation, its content and the orientation of further debates.

95. The delegation of India, supported by other delegations, highlighted the critical nature of the disadvantages, as compared to the advantages¹⁵ in delegating Codex work to other international bodies, in particular because of the burden put on developing countries in relation to very limited available resources. This would impede attendance of delegates from developing countries to meetings of international bodies other than the Commission's subsidiary bodies as well as increase the workload on technical agencies and Codex authorities at national level and the coordination required between them.

96. Several delegations expressed the opinion that any proposed draft text prepared by external bodies should enter the Elaboration Procedure at Step 3 and not at later Steps.

97. The Delegation of Chile stressed the need to distinguish two types of relationships with either those organizations that may collaborate in the standard-setting process or those of a similar nature and with similar objectives, with which cooperation and coordination should be sought. The Delegation pointed out that the relationship with bodies such as the International Office of Epizootics (OIE) should be singled out and addressed separately because this was a matter of bilateral cooperation between two international standard-setting

¹² CX/GP 02/6 ; CRD 6 (comments of Malaysia)

¹³ ALINORM 01/41, para. 31.

¹⁴ Rules of Procedure of the Codex Alimentarius Commission: Rule VII.5.

¹⁵ See CX/GP 02/6, paras. 13 and 14.

organizations recognized by the WTO under the SPS Agreement. This recommendation was supported by other delegations.

98. Many delegations supported the importance for the Commission to explore potential benefits in strengthening a wider cooperation between the Codex Alimentarius Commission and other international intergovernmental bodies, in line with the Article 1.b) and 1.c) of its Statutes and in conformity to the Objective No. 3 of the Strategic Framework 2003-2007, adopted by the 24th session of the Codex Alimentarius Commission (July 2001) for *Promoting linkages between Codex and other multilateral regulatory instruments and conventions*. They highlighted the benefits of using the expertise of these organizations. Some delegations brought to the attention of the Committee that due to future challenges in the food safety area, there was a need to envisage more efficient ways for the Commission to elaborate and revise standards to respond to the needs of Member countries.

99. The Delegation of Spain referred to the previous standardization work carried out in joint UNECE/Codex Groups of Experts and stressed the need to take into account standards prepared by other bodies that were already widely used in trade and thereby reduce the amount of work for developing countries.

100. All of the delegations that spoke stressed the necessity for inclusiveness, openness and transparency to be an essential part of any cooperation with other bodies when considering the elaboration of standards or related texts. The Observer from Consumers International noted that Codex had demonstrated good principles of openness, transparency and inclusion of consumers and public interests and that other international organizations should also work in this way.

101. The Representative of OIE informed the Committee of informal consultations to reinforce the synergy and identify the overlaps between the respective mandates of the two organizations. He also noted that the OIE had entered into formal consultations with FAO and WHO to revise the existing out-of-date agreements with the two organizations. Several delegations supported the move to a closer cooperation between the OIE and the Codex Alimentarius Commission as it was considered to be the only way to apply a consistent and integrated approach to the management of risks to human health in food products of animal origin.

102. The Observer from OIV (Office International de la Vigne et du Vin), an intergovernmental body dealing with standards for wine and vine products, stated that the OIV had recently changed its statutes to allow for more open membership and improved procedures for cooperation with other bodies such as the Codex Alimentarius Commission. The Observer looked forward to cooperation with Codex on matters of mutual interest.

103. Some delegations noted the special arrangements that had been developed through the Committee on Methods of Analysis and Sampling, for the adoption by reference of testing methods and other texts prepared by IUPAC, ISO, AOAC and other organizations, and was of the opinion that these arrangements were generally satisfactory in meeting the Commission's need for specialized texts in this area of work. Reference was also made to the current working relationships with the International Dairy Federation (IDF) on the development of standards for milk and milk products.

104. On the basis of its overall above discussion, the Committee agreed that consideration of amendments to the Uniform Procedures for the Elaboration of Codex Standards and Related Texts was premature at this stage. It requested the Codex Secretariat to draft specific guidelines to define more precisely the modalities of cooperation between the Codex Alimentarius Commission and other international intergovernmental and non-governmental organizations when elaborating standards and related texts. These guidelines should in particular emphasize the leading role of the Codex Alimentarius Commission in establishing international food standards and the requirements of inclusiveness, openness and transparency. The guidelines should also specify that the decision to undertake such new cooperative work should be taken by the Codex Alimentarius Commission itself and recommendations should be made to consider whether texts prepared by external bodies should enter the Procedure at Step 3 or through other modalities to be considered. The guidelines should give orientation to the external bodies cooperating on the development of standards and related texts under the Codex procedures. It was suggested that the draft guidelines should examine more in detail the cooperation between the Commission and the IPPC and OIE as intergovernmental bodies mentioned in the WTO SPS Agreement, other intergovernmental bodies such as the OIV, and non-governmental bodies such as the IUPAC and the IDF.

MEMBERSHIP IN THE CODEX ALIMENTARIUS COMMISSION OF REGIONAL ECONOMIC INTEGRATION ORGANIZATIONS (AGENDA ITEM 6)¹⁶

105. In introducing this item, the Representative of the Legal Counsel of FAO recalled that this matter had been discussed on several occasions, most recently at the Committee's 16th Session in April 2001 and the Commission in June/July 2001¹⁷. The Representative of the Legal Counsel stated that the EC had been a Member of FAO since 1991 as a result of amendments to the FAO Constitution that allowed Regional Economic Integration Organizations to become Members on the basis of the alternative exercise of membership rights with their Member States in the areas of their respective competence. He further noted that up until now, the EC had participated in the Codex Alimentarius Commission as an Observer since it had been understood that the Membership of the EC in the Commission would require amendments to the Rules of Procedure and these had not yet been effected.

106. The Representative of the Legal Counsel of FAO stated that the proposed draft amendments to the Rules of Procedure reflected the FAO situation, but took into account the special technical nature of the Codex Alimentarius Commission and the need to maintain the diversity of views available to the Codex Alimentarius Commission on the various issues under discussion. Finally, the Representative of the FAO Legal Counsel noted that these proposals and the views of the Committee would be submitted to the FAO Committee on Constitutional and Legal Matters, a Committee of the FAO Council that also advised the FAO Director-General on such matters. Pursuant to its mandate, the Committee followed closely all matters concerning EC Membership in FAO and had asked to be kept informed of any proposed amendments to the Codex Rules of Procedure regarding Membership of Regional Economic Integration Organizations.

107. The Observer of the European Community, informed the Committee that the information note available to the Committee had been prepared to reply to many of the questions raised at the last session, in particular as to the nature of the EC and questions of competence between the EC and its Member States.

108. Several Delegations raised the question of voting rights, in particular the right of the Regional Economic Integration Organization to exercise the voting right of a Member that may have submitted credentials or had registered as a participant but that was not present at the time of the vote. Some delegations were of the opinion that if the voting right of a registered, but absent, participant could be exercised this practice would dilute the rights of other Members, especially those smaller countries with single person delegations. On the other hand, the Delegation of the United Kingdom was of the opinion that once competence had been transferred, the presence of the member no longer having competence ceased to be relevant. The Delegation of Australia commented that as this right applied not only to voting but to determining whether consensus existed, it was of fundamental importance to later decision-making.

109. The Representative of the Legal Counsel of FAO stated that in FAO, provided any necessary formalities had been complied with, it was not required that each of the Member States of the EC actually be present in the meeting room for the EC to be able to vote on matters within its competence.

110. The Committee agreed to propose an amendment to the proposed new Rule II.3 to indicate that a Member must be present at the time of voting in order for its voting right to be exercised by the Regional Economic Integration Organization of which it was a member, and requested the opinion of the FAO Committee on Constitutional and Legal Matters on the appropriateness of this amendment. The full text of the amended proposed Rule would read as follows:

II.3. A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings [and present at the time the vote is taken]. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely.

¹⁶ CX/GP 02/7; CX/GP 02/INF.1 (Information Note submitted by the European Community).

¹⁷ ALINORM 01/33A, paras. 125-153 and ALINORM 01/41, para. 88, respectively.

111. The Observer of the EC stated that it could not agree with this amendment without further reflection on its meaning.

112. Several delegations also requested information on how the question of quorum would be handled. The Representative of the FAO Legal Counsel indicated that the matter of quorum was linked to voting rights and that the Members constituting a quorum would be those Members that had voting rights on the issue at hand for which it was necessary to determine a quorum.

113. The Secretariat also clarified that a Regional Economic Integration Organization could not be eligible for election or designation nor could it hold any office, and that therefore such organizations could not be designated as a “host government” of a Codex Committee or appointed as a Regional Coordinator.

114. On the question of participation in the Executive Committee, a point that was raised by several Delegations, including Japan, the Committee was informed that the same principle of alternative exercise of membership rights would apply when the Member of the Executive Committee elected by the Commission was a member state of a Regional Economic Integration Organization. In this case, the Regional Economic Integration Organization would exercise the membership rights of the elected Member when matters before the Executive Committee were those in which the Regional Economic Integration Organization had competence. When the elected Member was not a Member of a Regional Economic Integration Organization, the question of alternative exercise of membership rights did not arise.

115. The Codex Secretariat pointed out that although the seven Members elected to the Executive Committee were commonly referred to as “Regional Representatives”, they sat on that Committee as individual Members and did not formally represent the Region from which they were elected.

116. In relation to the alternative exercise of membership rights in other Codex subsidiary bodies (Codex Committees and Task Forces), the Representative of the Legal Counsel of FAO noted that the same general rules allowing for participation on an alternative basis would apply; in practice since these bodies normally worked by consensus the question of alternative exercise of voting rights would not normally arise.

117. The Committee also discussed the question of the role to be played by Regional Economic Integration Organizations in working and drafting groups established by subsidiary bodies. The Secretariat informed the Committee that these groups were “informal” and that the question of alternative exercise of membership rights should not arise.

118. In response to questions concerning the Membership of the EC in the Codex Alimentarius Commission as a joint body of FAO and WHO and the potential impact on WHO and other UN bodies of which the EC was not a member, the Representative of the FAO Legal Counsel stated that the rules governing the entry of the EC into FAO had been fully discussed with the Legal Counsel of the UN at the time, and that the question of membership in joint bodies had been a specific issue in these discussions. It had been agreed at that time that there were no legal implications for WHO or any other UN agency. The Observer of the EC stated that the changes that had been proposed to accommodate the special nature of the EC participation in the Codex Alimentarius Commission would have no implications for FAO or any other body.

119. In relation to the specific question of the potential membership of the European Community in the Codex Alimentarius Commission, Members that spoke accepted this development provided that the issues discussed above could be resolved successfully. The Delegation of Bolivia welcomed the possible membership of the European Community in the Codex Alimentarius Commission but pointed out that such membership should not affect the rights and obligations of other Members. The Delegation of India questioned the urgency with which this matter was being pursued and raised the issue of benefits that might accrue to members of such groups. The Delegation of the United States pointed out that there were several international bodies in which the EC was a member but where the EC exercised only one vote. It expressed concern at the prospect of “block voting”, especially as the membership of the EC was expected to enlarge in future years. The Representative of the FAO Legal Counsel pointed out that in the bodies referred to by the Delegation of the United States, the EC participated to the exclusion of its Member States.

STATUS OF THE PROPOSED DRAFT AMENDMENTS TO THE RULES OF PROCEDURE

120. The Committee agreed that it would be premature to submit the proposed draft amendments to the Commission for adoption and agreed to consider the matter at its next session in the light of the advice to be provided by the FAO Committee on Constitutional and Legal Matters. It also welcomed the offer of the Observer of the EC to provide a model agenda showing the relative competencies of the EC and its Member States at a typical Codex meeting, for example, the Committee on Food Hygiene.

121. The Proposed Draft Amendments to the Rules of Procedure are presented in Appendix III to this report for information.

OTHER BUSINESS FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION (AGENDA ITEM 7)**JOINT FAO/WHO EVALUATION OF THE CODEX ALIMENTARIUS**

122. As requested by the Committee, the Representative of FAO informed the Committee that FAO and WHO had called for an in-depth independent evaluation of the work of the Joint FAO/WHO Food Standards Programme, including the Codex Alimentarius Commission, in order to meet more effectively the needs of all concerned regarding health, safety and trade in food. The request for an evaluation had been approved by the FAO Programme Committee and the WHO Executive Board and its terms of reference had been defined by the evaluation units of FAO and WHO. These terms of reference would be considered by the 87th Session of the FAO Programme Committee. The evaluation, scheduled for completion in 2003, would be carried out by an independent Evaluation Team and an Expert Panel, and would include recommendations for consideration by the Governing Bodies of FAO and WHO, the Executive Committee and the Codex Alimentarius Commission.

123. A Press Release and "Information Note and Informal Public Call for Comments" had been recently distributed and were made available to delegates at the current session, as well as the document prepared for the FAO Programme Committee. It was also noted that a formal questionnaire would be sent shortly to member countries.

124. The Delegation of Chile stressed the importance of coordination at the national level in member countries of FAO, WHO and Codex to ensure effective participation in the process; in addition, the report of the evaluation should be considered in the governing bodies of FAO and WHO and in the Codex Alimentarius Commission in order to ensure that the decisions that might affect Codex work should be taken by member countries as a result of a transparent process.

125. The Delegation of the United States expressed the view that the evaluation should have been limited to management issues and that its terms of reference appeared to go beyond the initial mandate discussed by the Executive Committee.

126. The Representative of WHO recalled that the 49th Session of the Executive Committee had been informed about the decision to undertake a comprehensive evaluation and had welcomed this initiative (ALINORM 03/5, para. 42). It would be carried out in conformity with the terms of reference agreed upon by FAO and WHO and would cover not only Codex but the entire FAO/WHO Food Standards Programme, including the scientific advice provided by FAO/WHO expert bodies.

DATE AND PLACE OF THE NEXT SESSION

127. The Committee was informed that its 18th Session would be held in Paris from 7 to 11 April 2003, the final dates to be confirmed by the host country and Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 03/33
Proposed Amendments to the Procedural Manual: Title and Terms of Reference of CCMPH		Governmemnts 25 th CAC	para. 14
Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius	5	CCEXEC Governments 18 th CCGP	para. 63 Appendix II
Proposed Draft Revised Code of Ethics for International Trade in Foods	2/3	Secretariat Governments 18 th CCGP	para. 91
Membership of Regional Economic Integration Organizations		FAO (CCLM) 18 th CCGP	para. 120 Appendix III
Guidelines for Cooperation with International Organizations in the elaboration of Codex standards and related texts		Secretariat 18 th CCGP	para. 104
Proposed Draft Working Principles for Risk Analysis intended for governments	1/2/3	CCEXEC Secretariat/Governments 18 th CCGP	para. 72
Matters related to traceability/product tracing		Secretariat 18 th CCGP	para. 12

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**ALINORM 03/33
APPENDIX II****PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION
IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS¹**

(At Step 5 of the Procedure)

SCOPE

- 1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.
- 2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.
- 3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment normally lies with the joint FAO/WHO expert bodies and consultations (risk assessors).

RISK ANALYSIS - GENERAL ASPECTS

- 4) The risk analysis process used in Codex should be:
 - applied consistently
 - open, transparent and documented
 - conducted in accordance with both the *Statements of Principle Concerning the Role of Science and the Extent to Which Other Factors are Taken into Account* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*
- 5) The risk analysis process should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission², each component being integral to the overall risk analysis process.
- 6) The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality³, documentation should be accessible to all interested parties⁴.
- 7) Effective communication and consultation with all interested parties should be ensured throughout the risk analysis process.

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

² See *Definitions of Risk Analysis Terms Related to Food Safety*, page 43-44 12th Edition Codex Alimentarius Commission Procedural Manual.

³ A definition should be added at a later stage into the glossary in annex

⁴ For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”)

- 8) The three components of risk analysis should be applied within an overarching framework for management of food related risks⁵ to human health.
- 9) There should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.
- 10) When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.⁶
- 11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.
- 12) The needs and situations of developing countries should be specifically identified and taken into account by the responsible bodies in the different stages of the risk analysis process.

Risk Assessment Policy

- 13) Determination of risk assessment policy should be included as a specific component of risk management.
- 14) Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties, in order to ensure that the risk assessment process is systematic, complete, unbiased and transparent.
- 15) The mandate given by risk managers to risk assessors should be as clear as possible.
- 16) Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

RISK ASSESSMENT⁷

- 17) 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
- 18) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise and experience. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.
- 19) Risk assessment should be conducted in accordance with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment process, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

⁵ As defined in the Codex Alimentarius Commission Procedural Manual (in *Definition for the purpose of the Codex Alimentarius Commission*, 12th Edition, p. 44): “A function of probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.”

⁶ Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

⁷ Reference is made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*

- 20) Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.
- 21) Risk assessment 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.
- 22) Risk assessment should seek and incorporate data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.
- 23) Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment process and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
- 24) Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.
- 25) The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment, and minority opinions. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.
- 26) The conclusion of the risk assessment including a risk estimate if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

- 27) While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.
- 28) Risk management should follow a structured approach including risk evaluation, assessment of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles*⁸.
- 29) The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers, in the context of these Working Principles should ensure that the conclusion of the risk assessment is presented before making final proposals or decision on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind of the guidance given in paragraph 10.
- 30) 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, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

⁸ These criteria have been adopted by the 24th Session of the Commission (see Procedural Manual 12th Edition - Appendix, page 165)

- 31) The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.
- 32) Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.
- 33) 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.
- 34) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission should seek and take into consideration the potential impact of such measures on trade among its Member countries.
- 35) Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, risk managers should give particular attention to the circumstances of developing countries.
- 36) Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

37) Risk communication should :

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis process;
- ii) promote consistency and transparency in formulating risk management options/recommendations;
- iii) provide a sound basis for understanding the risk management decisions proposed;
- iv) improve the overall effectiveness and efficiency of the risk analysis process;
- v) strengthen the working relationships among participants;
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- vii) promote the appropriate involvement of all interested parties⁴; and
- viii) exchange information in relation to the concerns of interested parties⁴ about the risks associated with food.

38) Risk analysis should include clear, interactive and documented communication, amongst risk assessors (Joint FAO/WHO expert bodies and consultations) and risk managers (Codex Alimentarius Commission and its subsidiary bodies), and reciprocal communication with member countries and all interested parties⁴ in all aspects of the process.

39) Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion essential for effective risk management is incorporated into the decision making process. Ongoing reciprocal communication amongst all interested parties⁴ should be an integral part of the risk analysis process.

40) A requirement for risk communication should be to establish a process whereby information and opinion essential to effective risk assessment and risk management is exchanged amongst all interested parties⁴.

41) Risk communication involving interested parties⁴ should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis process, and minority opinions.

42) The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties⁴.

ANNEX 1

DEFINITIONS

Definitions included in the Procedural Manual

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

Risk Analysis: A process consisting of three components : risk assessment, risk management and risk communication.

Risk Assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Hazard Identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.

Dose-Response Assessment: The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

Exposure Assessment: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.

Risk Characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

Risk Management: The process, distinct from risk assessment of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Other Definitions

Risk Assessment policy :Elaboration of documented guidelines for the choice of options and associated judgements as well as for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk Evaluation

- identification of a food safety problem
- establishment of a risk profile
- ranking of the hazard for risk assessment and risk management priority
- establishment of risk assessment policy for conduct of risk assessment
- commissioning of risk assessment
- consideration of risk assessment result

Risk profile

The description of the food safety problem and its context

Risk estimate

The quantitative estimation of risk resulting from risk characterization.

**ALINORM 03/33
APPENDIX III****PROPOSED DRAFT AMENDMENTS TO THE RULES OF PROCEDURE*****Membership of Regional Economic Integration Organizations***

Note: These Proposed Draft Amendments are presented for information and should be read in conjunction with paragraphs 105 to 121 of the present report.

Add a new Rule I.3 to the Rules of Procedure, and re-number current Rule I.3 as Rule I.4:

"Membership shall also comprise regional economic integration organizations members of either FAO or WHO that notify the Director-General of FAO or WHO of their desire to be considered Members of the Commission".

Add a new Rule to the Rules of Procedure after Rule I to read as follows:

"Rule II - Member Organizations

1. A Member Organization shall exercise membership rights on an alternative basis with its Member States that are Members of the Commission in the areas of their respective competence.
2. A Member Organization shall have the right to participate in matters within its competence in any meetings of the Commission or its subsidiary bodies in which any of its Member States is entitled to participate*.
3. A Member Organization may exercise on matters within its competence, in any meetings of the Commission or any subsidiary body of the Commission in which it is entitled to participate in accordance with paragraph 2, a number of votes equal to the number of its Member States which are entitled to vote in such meetings [and present at the time the vote is taken]. Whenever a Member Organization exercises its right to vote, its Member States shall not exercise theirs, and conversely.
4. A Member Organization shall not be eligible for election or designation, nor to hold office in the Commission or any subsidiary body. A Member Organization shall not participate in voting for any elective places in the Commission and its subsidiary bodies.
5. Before any meeting of the Commission or a subsidiary body of the Commission in which a Member Organization is entitled to participate, the Member Organization or its Member States shall indicate in writing which, as between the Member Organization and its Member States, has competence in respect of any specific question to be considered in the meeting and which, as between the Member Organization and its Member States, shall exercise the right to vote in respect of each particular agenda item. Nothing in this paragraph shall prevent a Member Organization or its Member States from making a single declaration in the Commission and each subsidiary body in which a Member Organization is entitled to participate for the purposes of this paragraph, which declaration shall remain in force for questions and agenda items to be considered at all subsequent meetings, subject to such exceptions or modifications as may be indicated before any individual meeting.

* This is without prejudice to the possibility for the Member States to develop or support the position of the Member Organization in areas within its competence.

6. Any Member of the Commission may request a Member Organization or its Member States to provide information as to which, as between the Member Organization and its Member States, has competence in respect of any specific question. The Member Organization or the Member States concerned shall provide this information on such request.

7. In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matters which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the discussions. In such cases the meeting, in arriving at its decisions^{**}, shall take into account only the intervention of the party which has the right to vote^{***}.

8. For the purpose of determining a quorum, as specified in paragraph 6 of Rule IV, the delegation of a Member Organization shall be counted for a number equal to the number of its Member States which are entitled to participate in the meeting, to the extent that it is entitled to vote under the agenda item in respect of which the quorum is sought."

Renumber the subsequent Rules accordingly.

^{**} The word 'decisions' should be understood to mean both voting and situations where a decision is taken by consensus.

^{***} The above is without prejudice to the question of whether or not the views of the party not having the right to vote shall be reflected in the report of the meeting. Where the views of the party not having the right to vote are reflected in the report, the fact that they are the views of the party not having the right to vote shall also be reflected in the report.