

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 01/33A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fourth Session
Geneva, 2 – 7 July 2001

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

Paris, France, 23-27 April 2001

Note: This document incorporates Circular Letter CL 2001/17-GP

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CX 4/10

**CL 2001/17-GP
May 2001**

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 16th Session of the Codex Committee on General Principles (ALINORM 01/33A)**

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

Amendments to the Procedural Manual

1. Amendment to the Terms of Reference of the Committee on Food Hygiene (para. 8, Appendix II)
2. Amendments to the *Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts: Principles for the Establishment of Methods of Analysis and Relations between Commodity Committees and General Committees: Methods of Analysis and Sampling* (para. 10, Appendix II)
3. *Statements of Principles on the Role of Science in the Codex Decision Making Process and the Extent to which Other Factors Are Taken into Account: Proposed Criteria for the Consideration of Other Factors* (para.102, Appendix III)

Governments and international organizations wishing to submit comments on the above amendments should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy **before 10 June 2001.**

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 16th Session of the Codex Committee on General Principles are as follows:

Matters for adoption by the Commission:

The Committee

- Endorsed the amendment to the Terms of Reference of the Committee on Food Hygiene proposed by the CCFH with editorial changes (para. 8, Appendix II) and the amendments to *the Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts* and to the *Relations between Commodity Committees and General Committees* as proposed by the Committee on Methods of Analysis and Sampling (para. 10, Appendix II);
- Recommended that the Commission adopt Proposed Criteria for the Consideration of Other Factors as an explanation of *the Statements of Principles on the Role of Science in the Codex Decision Making Process and the Extent to which Other Factors are Taken into Account*, and asked the advice of the Commission on the two sections remaining in square brackets (para. 102, Appendix III).

Matters for consideration by the Commission:

The Committee

- agreed to ask the advice of the Commission on the Scope of the Working Principles for Risk Analysis and on the application of precaution in risk management in Codex (paras. 71-72, Appendix V);
- agreed to inform the Commission of its discussions on the membership of regional economic integration organizations and attached the relevant Proposed Amendments to the Rules of Procedures (para. 135, Appendix IV);
- Could not come to a consensus on the proposals to revise the Rules of Procedure concerning the Executive Committee and/or to hold annual meetings of the Commission (para. 113).

Other matters of interest to the Commission

The Committee

- agreed to return the Proposed Draft Revised Code of Ethics for International Trade in Foods for redrafting and further comments (para. 124);
- did not endorse the new Guidelines and Working Instructions proposed by the Committee on Methods of Analysis and Sampling for inclusion in the Principles for the Establishment of Codex Methods of Analysis (para. 11).

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INTRODUCTION

1. The Sixteenth Session of the Codex Committee on General Principles was held from 23-27 April 2001 in Paris at the kind invitation of the French Republic. The Session was chaired by Mrs. Catherine Geslain-Laneelle, Director-General, Direction Générale de l'Alimentation. It was attended by 248 delegates and observers representing 60 Members Countries and 30 international organizations. A complete list of participants is attached as Appendix I.
2. The Session was opened by Mr Jean Glavany, Minister of Agriculture and Fisheries, who highlighted the importance of Codex Alimentarius work to ensure fair practices in international trade. He recalled the importance of the precautionary principle in Europe and the need to establish a clear and transparent framework for its application at the national and international level, and noted that this was a major issue for consideration by the present session. The Minister also pointed out that risk management should take into account other legitimate factors in addition to health protection such as environmental aspects, animal welfare and consumer concerns.
3. Mr. Glavany stressed the need to improve the participation of developing countries in Codex work and expressed the support of the French government for the creation of a trust fund managed by FAO and invited other member governments to contribute as France intended to do with a contribution of 150,000 Euros.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

4. The Committee adopted the Provisional Agenda and its Addendum as the Agenda for the session. As proposed by the Delegation of India, it agreed to discuss the following questions under Other Business: the participation of developing countries in Codex and the impact of international standards on trade facilitation.

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

COMMITTEE ON FOOD HYGIENE

5. The Committee considered the proposal put forward by the Committee on Food Hygiene (CCFH) for an amendment to its Terms of Reference, in order to reflect its work in the area of microbiological risk assessment and risk management.
6. The Committee agreed with the proposal of the Delegation of Sweden, speaking on behalf of the EC, to refer to “microbiological” risk assessment and risk management for clarification purposes. The Committee had an exchange of views on the need for other amendments and agreed to retain the current text.
7. The Delegation of India stated that in view of the separation between risk assessment and risk management and for consistency with other Codex Committees, the “questions to be addressed to risk assessors” should not be included in the text. The Representative of WHO indicated that such questions from CCFH were essential to orient the work of the FAO/WHO expert consultations and to ensure effective risk communication. The Committee also noted that this corresponded to current practice between Codex Committees and expert committees or consultations.
8. The Committee agreed to forward the proposed amendment to the terms of reference of the Committee on Food Hygiene to the Commission for adoption and inclusion in the Procedural Manual (see Appendix II).

COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

9. The Committee recalled that the last session of the CCMAS had agreed to apply the criteria approach to Type III methods and had proposed specific amendments to the Procedural Manual to reflect this new approach in the framework of Codex. The Committee also noted that the CCMAS had agreed to develop

¹ CX/GP 01/1; CX/GP 01/1-Add.1

² CX/GP 01/2; CRD 3 (comments of Sweden)

Guidelines for general application by governments concerning the selection of methods of analysis through the criteria approach.

10. The Committee agreed to endorse the addition of a new section in the *Principles for the Establishment of Codex Methods of Analysis* concerning “General Criteria for the Selection of Methods of analysis using the Criteria Approach”. It was further agreed to include an additional section addressing the endorsement of methods of analysis through the criteria approach in *the Relations between Commodity Committees and General Committees – Methods of Analysis and Sampling*.

11. The Committee noted that the CCMAS had also proposed the inclusion of new Guidelines and Working Instructions to facilitate the criteria approach, for inclusion in the Principles for the Establishment of Codex Methods of Analysis. The Delegation of Sweden referred to its written comments proposing several editorial and presentation amendments in order to simplify the text and to improve the format of the document. In particular, some explanatory and technical text had been removed, to ensure that it would be appropriate for inclusion in the Procedural Manual, while retaining the recommendations concerning procedure. The Committee did not consider the text in detail due to time constraints and did not reach a conclusion on this question, and recommended that the CCMAS should reconsider the text at its next session. The Committee also noted that the CCMAS had forwarded this text for adoption by the Commission.

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (CCFICS): Traceability

12. The Committee was informed that the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) had discussed this issue, and that it had noted in particular that several Codex Committees and Task Forces were dealing with traceability. The CCFICS had agreed that within its Terms of Reference it had a responsibility to consider work in this area. However, the CCFICS had recommended that in view of the system-wide interest in this issue, a paper should be prepared by the Secretariat in order to obtain the Commission’s guidance in this matter.

13. All Delegations that spoke highlighted the importance of the issue and the importance of a uniform approach to the concept and application of traceability. They welcomed the recommendation that such a paper be prepared for the Commission’s consideration. Most Delegations noted the fact that the issue was being dealt with or discussed in a number of Committees or Task Forces.

14. Some Delegations proposed that the Committee on General Principles should have a leading role in the preparation of general guidelines or principles on traceability, with other Codex Committee providing specific guidance on its application. Other Delegations were of the opinion that it would be premature to decide what role the Committee should have before consideration of the matter by the Commission. Individual issues that Delegations and observers believed to be important in the development of the topic included:

- The place of traceability in risk management;
- The use of traceability for product integrity, authenticity and identification;
- The use of equivalent measures;
- Practicability of traceability, and in particular the feasibility of its application in developing countries;
- Consumer confidence and information concerning the nature and origin of products;
- The possibility of using traceability for liability and redress.

15. The Committee looked forward to receiving the advice of the Commission on this matter and drew attention to its role of ensuring a consistency of approach of such matters throughout the Codex system. It looked forward to contributing positively to the future development of this topic.

RISK ANALYSIS (Agenda Item 3)³

PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS (ITEM 3.A)

16. The Committee recalled that the elaboration of the Working Principles had been undertaken following the recommendations of the 22nd Session of the Commission concerning the use of risk analysis in Codex. The Committee recalled that its 15th session had returned the Proposed Draft Principles to Step 3 for further comments and consideration by the 16th Session, with the exception of the section on “precaution in risk management” (see paras. 49 to 69, below).

General aspects

17. The Delegation of New Zealand pointed out that the Principles should take into account the evolution in risk analysis concepts and the progress made in specific areas, especially microbiological risk assessment and management. In particular, the document should make it clear that the elements of risk analysis were not applied separately but within an overarching risk management framework; the use of terminology should also be reviewed to ensure consistency throughout Codex.

18. Several delegations expressed the view that the recommendations made in the framework of Codex in relation to risk analysis should not affect the rights and obligations of Member countries under WTO and especially the SPS Agreement.

19. The Delegation of Canada proposed to indicate that the principles were not intended as international standards, guidelines or recommendations as described in the SPS Agreement nor as a standard as defined under the TBT Agreement. The Representative of WTO recalled that the SPS Agreement did not establish any distinction between different types of Codex texts directed to governments, and referred to the reply from the SPS Committee to the question from the Commission on the status of Codex texts in 1998, in which it was indicated that “how a text would be applied depended on its substantive content”⁴. Any statement in a Codex text regarding the intended use of that text would be taken into consideration in the case of a WTO dispute.

20. The Committee agreed that to facilitate a better comprehension of the text, a Glossary of the terms used should be annexed to the document.

Scope

21. The Committee had an extensive discussion on the Scope of the document to determine whether the principles should apply only within Codex or to member governments.

22. The Delegation of the United States expressed the view that the scope of the Principles should be limited to Codex, as this was the original mandate given to the Committee by the Commission. As the current scope referred both to Codex and to governments, this created considerable confusion throughout the text and the interpretation of several sections was not clear, including those addressing precaution. The Delegation indicated that the development of risk analysis principles for application by governments could be considered at a later date but the development of principles for application in Codex was the highest priority. This position was supported by several delegations.

23. Several other delegations expressed the view that the current scope should be retained, and that the last session had achieved significant progress on recommendations directed both to Codex committees and to governments. These delegations also pointed out that it was the role of Codex to provide advice to governments on risk analysis, as recognized by the Commission.

24. Several delegations stressed the need to clarify the scope of the document before proceeding with a detailed discussion of the text, as this lack of clarity would cause difficulties with several sections. Other delegations proposed to discuss the text in detail in order to identify the sections where further clarification was required. The Committee, recognizing that there was no consensus on the scope at this stage, agreed that

³ ALINORM 01/33, Appendix III; CX/GP 01/3-Add.2 (comments of Australia, Canada, Malaysia, Thailand, United States, CI, EC, IACFO); CX/GP 01/3-Add. 4 (comments of New Zealand); CRD 1 (comments of Thailand); CRD 6b (India)

⁴ ALINORM 99/33, paras. 50-52

the first paragraph should be retained in square brackets, and that other references to the application of the principles would be subject to further discussion. The Committee agreed to ask the Commission whether it should develop principles for application within Codex only, or principles that would be applicable both within Codex and to governments, with the necessary clarification where necessary (see also para. 71, below).

25. Some delegations pointed out that the section should describe only the scope of the document and therefore proposed to delete paragraphs 2 and 3 as they referred to the objectives of Codex. The Committee did not come to a conclusion on this proposal. The Committee noted a proposal to refer to “food safety aspects” of Codex standards to establish a distinction with other health related issues, especially in the area of nutrition. The Delegation of Australia, supported by the Delegation of Brazil proposed to indicate in paragraph 2 that the purpose of the text was “providing an objective basis for measures to protect the health of consumers”.

26. As regards paragraph 4 on risk analysis in Codex, the Secretariat noted that while the Commission and its subsidiary bodies might consider some elements of risk assessment, they were mainly responsible for providing advice on risk management and that normally risk assessment was the responsibility of FAO/WHO expert committees and consultations. The text was therefore amended to reflect that Codex was providing advice rather than undertaking risk management itself.

Risk Analysis - General Aspects

27. The Delegation of Malaysia, supported by several delegations and observers, proposed to delete the reference to risk analysis being “soundly based on science” as the risk management and risk communication components took into account other aspects (paragraph 1). Other delegations supported the reference to science since the risk analysis process as a whole was based on scientific risk assessment.

28. The Committee had an exchange of views on this question and agreed that risk analysis “should be consistent with the *Statements of Principles Concerning the Role of Science and the Extent to which Other Factors are Taken into Account*”, rather than “soundly based on science”, as this covered both the need for a scientific basis and the consideration of other legitimate factors where appropriate. The recommendations in the paragraph were amended accordingly and rearranged for clarification purposes.

29. The Committee discussed a proposal to clarify that only “publicly available” documentation should be made accessible to all interested parties, as proprietary information was confidential. The Secretariat indicated that the CCFICS had addressed this issue in the *Principles for Food Import and Export Inspection and Certification*, where both confidentiality and the need for scrutiny by consumers and their representative organizations and other interested parties were covered in the section on Transparency (para. 14), and the Committee agreed to use a similar wording.

30. The Committee agreed to indicate at the beginning of paragraph 4 that “the three components of risk analysis should be applied in an overarching framework of strategies and policies to manage risk”, in order to reflect the integrated approach to risk analysis.

31. The Committee recognized that the separation between risk assessment and risk management was also intended to avoid confusion about the functions to be performed by risk assessors and risk managers, in addition to the need to avoid conflicts of interest, and amended the text of paragraph 4 accordingly.

32. The Delegation of Australia proposed an amendment to paragraph 5 to provide further clarification on the use of precaution in risk assessment and its importance in the selection of risk management options. The Delegation proposed to delete the second sentence and to add a new sentence as follows: “Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information”. The Committee agreed to retain the second sentence and to add the new sentence proposed by Australia. Some delegations expressed their reservation on the use of the term “precaution” and the Committee agreed to place the entire paragraph in square brackets.

33. The Delegation of Australia also proposed to add further explanations concerning the relationship between the degree of uncertainty in risk assessment and risk management options, and noted that clarification at this stage might facilitate the debate concerning precaution in risk management (paras. 34-35), although this was a separate issue. It was suggested that the additional paragraph should be transferred

to the section on precaution in risk management (paras. 34-35) but the Committee agreed to retain it for the time being under General Aspects as paragraph 5b.

34. Some delegations expressed their concern with this addition. Other delegations proposed to discuss it further and to consider how it might relate to the discussion on precaution in risk management and in particular the use of precaution in routine and exceptional circumstances. The Committee could not discuss this proposal in detail and agreed that it would require further consideration at the next session. The proposals for the revised text of paras. 5 and 5b are included in Appendix V.

35. The Committee had an exchange of views on the need to amend paragraph 6 on the needs and situation of developing countries.. The Delegation of Morocco expressed the view that clarification was needed on the reference to “responsible bodies” and that explicit reference should be made to the specific bodies concerned at the international and government level. The Delegation of Sweden, speaking on behalf of the EC, proposed to add at the end of the paragraph that “however, that should not compromise the level of consumer protection”. However, the Delegation of India, supported by other delegations, opposed the inclusion of this linkage. The Delegation of Bolivia stated that the level of consumer protection was already covered in paragraph 2 of the Scope. The Committee therefore agreed to retain the original text as agreed at the last session.

Risk Assessment

36. Some delegations pointed out that the references to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* throughout the text were not always consistent with the exact wording of the *Statements*, and a footnote referring to the *Statements* was added to the heading of this section.

37. In order to clarify paragraph 9 on the selection of experts, the Committee agreed with the proposal of the Delegation of Sweden to add a reference to their “experience and expertise”, in addition to the current text.

38. The Committee agreed to delete paragraph 11 and to replace it with the following: “Explicit consideration should be given to variability and other sources of uncertainty at each step in the risk assessment process”. The paragraphs concerning the data used in risk assessment were grouped and reordered to follow a more logical sequence (10,13, 16 and 15). Paragraph 13 was amended to reflect more precisely the use of quantitative and qualitative information in risk assessment.

39. The Committee noted some proposals to amend paragraph 15 (developing countries and the use of global data) but left the text unchanged because, as pointed out by the Delegation of India, it repeated a specific recommendation of the Commission. The Delegation of the United States pointed out that the use of global data did not apply to national governments, and a reference to Codex was added accordingly. A reference to “storage” was added in paragraph 16 (food chain) to make it consistent with para. 26 in the Risk Management section, as agreed at the last session.

Risk Assessment Policy

40. The Committee recognized that the establishment of risk assessment policy affected the risk analysis process as a whole and agreed to transfer paragraphs 19 to 23 to the end of the section on General Aspects.

41. The Committee noted that paragraph 20 provided a definition of Risk Assessment Policy and the Committee agreed that it could be used in the Glossary of Terms (see para. 20 above). In paragraph 21, the Committee agreed that risk assessment policy should be established “preferably” in advance of risk assessment and amended the text accordingly.

42. The Committee recognized that it was not always possible to determine in advance whether the mandate given to risk assessors was “achievable” and agreed that it should be “as clear as possible”. The square brackets in paragraph 22 were therefore deleted.

43. The Delegation of the United States proposed to consider paragraph 23 (risk management option) in conjunction with paragraph 28 (risk reduction) under Risk Management. Following the discussion on paragraph 28 (see para. 45, below) the Committee agreed to retain paragraph 23 in the current section as it addressed a different issue.

Risk Management

44. The Committee agreed to use the wording of the *Statement of Principles* to describe “other legitimate factors” in paragraph 25, and to delete the square brackets. The Committee recalled that the description of the components of risk management reflected the recommendations of the Joint FAO/WHO Expert Consultation on Risk Management and Food Safety concerning the structured approach and agreed to retain the current text. The Committee agreed that the description of “risk evaluation” proposed by the Consultation should be included in the Glossary of terms mentioned above, in order to prevent confusion on that term; it was also noted that translation difficulties would need to be addressed.

45. An alternative wording was added in paragraph 28 indicating that risk management options should be “assessed” or “evaluated”. The Committee had an exchange of views on the notion of risk reduction, as some delegations felt it that it was too narrow and that risk management options should be considered in relation to the level of consumer protection. The Committee agreed to replace “risk reduction” with a reference to “the scope and purpose of risk analysis and the ability to achieve the required level of consumer protection”, and to include an assessment of the option of “doing nothing” in the risk management options.

46. The Committee agreed to simplify paragraph 31 by deleting the superfluous reference to legitimate factors. The Delegation of Canada proposed to amend this paragraph to stress the need for consistency in the decisions taken under similar circumstances, in addition to the current recommendations on transparency. The Committee did not discuss this question in detail and could not come to a conclusion at this stage.

47. The Committee amended paragraph 33 to reflect that standards and related texts should be updated as necessary to reflect new scientific knowledge.

Risk Communication

48. The Committee noted some proposals for amendments to that section, as mentioned in the written comments of the EC and CI. However it was not possible to consider this section in detail due to time constraints and the current text was retained, with the understanding that there would be an opportunity to examine it in more detail later.

PRECAUTION IN RISK MANAGEMENT (PARAS. 34-35)⁵

Background

49. At the 15th Session of the Committee it was agreed that a drafting group co-ordinated by the French Secretariat would work by electronic mail in order to propose a revised draft text of these paragraphs. Comments were also requested from Member governments and interested international organizations by means of Circular Letter CL 2000/12-GP. In the light of comments received the French Secretariat prepared a revised text (CX/GP 01/3) which was distributed for further comments. A Working Group was then convened immediately preceding the present Session to discuss this proposal in the light of the comments received. Professor Chevassus-au-Louis, Chairman of the Working Group, presented the following report to the Committee⁶:

Report of the Working Group

50. “The Working Group had considered the proposed wording of paragraphs 34 and 35 of the Proposed Draft Working Principles for Risk Analysis in document CX/GP 01/3. The main changes introduced to document CX/GP 01/3 were the following:

51. The Working Group agreed to delete footnote 1 (“It is recognized that hazard identification is a crucial step in this process”) and to replace it by the following phrase “from a preliminary risk assessment” coming after “reasonable evidence”. It was recalled that hazard identification is defined in the Procedural Manual.

⁵ CX/GP 01/3 ; CX/GP 01/3-Add.1 (Comments of Australia, Malaysia, Thailand, United States, Uruguay, CI, CRN, CIAA, EFLA/AEDA, GCPF, IASDA, IACFO, ICGMA) ; CX/GP 01/3-Add.3 (Argentina, Costa Rica, Malaysia, Norway, Uruguay, United States, CI, COMISA, EC, GCPF, IAFCO) ; CX/GP 01/3-Add.3 (New Zealand, ALA); CRD5 and 7 (CRN) ; CRD 6 bis (India) ; CRD 11 (Australia – compromise text).

⁶ Unnumbered CRD: “Report of the Working Group – 21 April 2001. The Application of Precaution in Risk Management”

On the other hand, the working group wished to recall that the application of precaution should be exercised following a preliminary risk assessment.

52. The Working Group discussed at length the scope for the application of precaution. It wondered whether precaution had to be applied by governments, by Codex or by both. It concluded that the situation described was the same but that precautionary measures could take different forms according to whether they are taken within the Codex framework or by governments. Consequently it suggested a text comprising:

- A general paragraph intended for risk managers and describing the situation.
- Two specific paragraphs, one intended for Codex and the other for governments, which define the action likely to be undertaken.

53. The Working Group agreed that there was a link between paragraph 34 and elements of paragraph 35, in particular on the issue of proportionality but it did not have time for a full discussion to determine which elements applied to Codex and which applied to governments.

54. The Working Group had no time to consider footnote 2 (“Some members refer to this concept as the “precautionary principle”). This discussion would have to take place during the plenary session.

55. Finally the Working Group agreed on the appended wording which it proposed to submit to the plenary session of the CCGP (see Appendix V).

56. The following reservations were expressed in relation to this wording (in the Working Group):

- Although recognizing that clarifications had been made, the Delegation of the United States expressed a general reservation on the whole text.
- The Delegation of Brazil stated that the paragraph intended for governments should be put in square brackets.
- Some delegations, including Japan and the European Union wished to discuss further the wording of the last sub-paragraph of paragraph 34 by comparison with the wording initially proposed.”

Discussion of the Working Group’s “Compromise Text”

57. Following the presentation of the Working Group report, there was a general debate in the Committee.

58. Several delegations including Argentina, Bolivia, Paraguay and Uruguay asked for the deletion of paras. 35-35 as in their view there was a question of the legitimacy of referring to precaution as a principle of international law. The Delegation of Uruguay expressed the view that paragraphs 34 and 35 in the Working Principles should be deleted since the confusion created by these paragraphs as regards terminology and legal aspects could result in measures that would adversely affect the protection of consumers’ health and fair trade practices.

59. The Committee expressed its appreciation to the Working Group and its Chairman for their efforts to find a solution to the problems raised in relation to paragraphs 34-35. In particular, delegations stated that some progress had been made towards a clearer definition of the means by which Codex on one hand, and Member governments on the other hand, applied precaution in their respective areas of competence. Nevertheless, several delegations stated that without a clarification of the Scope of the Working Principles as a whole, the situation would remain confused. At different points in the discussion, Delegations made reference to differences in the perceived mandate of the Committee as set down by the Commission. One Delegation drew attention to the goals in reference to risk analysis set out by the Commission in 1999 in its Medium-Term Plan 1998-2003.⁷ Reference was also made to the initial mandate of the Commission in 1997 to draft “integrated principles for risk management and assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual”.⁸ However, attention was also drawn to the Commission’s statement that “governments should be encouraged to integrate risk analysis in their legislation”.⁹

⁷ ALINORM 99/37, Appendix II, para.3.

⁸ ALINORM 97/37, Paragraph 164 (ii).

⁹ ALINORM 99/37, Paragraph 49.

60. There was general agreement that governments had the right to take interim measures to protect the health of consumers as set out in Article 5.7 of the SPS Agreement. However, agreement could not be reached about the actions that Codex should take in situations where there was uncertainty and/or lack of scientific information including adverse effects on human health, as some delegations were of the opinion that Codex should not develop international standards, guidelines or recommendations under such conditions. Other delegations stated that Codex did, and should, prepare guidance, as appropriate, under such circumstances.

61. Some delegations requested the removal of any explicit reference to “precaution”, claiming that all necessary measures to protect consumers’ health when scientific evidence was insufficient were covered by the SPS Agreement and that any additional reference could foster the use of precaution for the purpose of trade protection, and that reference to a “precautionary principle” could allow governments to deviate from the disciplines of the SPS Agreement. The Delegation of Argentina, referring to its written comments, stated that it did not recognize any legal status for a so-called “precautionary principle” and therefore requested to delete any reference to such a principle. Other delegations stated that for the purpose of understanding and the fostering of consumer confidence in the risk analysis process, a reference to “precaution” was essential, and stated that this could be a reference to a “precautionary principle” as well as to a “precautionary approach”. In the opinion of these delegations the use of either expression would indicate to consumers that a high level of protection was being sought, and that precaution was not being used only in acute situations.

62. Several delegations, referring to the International FAO Conference on International Food Trade beyond 2000 (Melbourne 11-15 October 1999), expressed the view that precaution was an essential element of risk analysis. There was a difference of opinion as to whether Codex should be encouraged to develop standards, guidelines or recommendations exclusively on this basis, without comprehensive scientific information and evidence.

63. On the basis of this debate and several explicit proposals for amendment to the Working Group’s compromise text, the Chairperson of the Committee tabled a revised text for the consideration of the Committee. The Delegation of Australia also circulated a revised text for consideration.

Consideration of the Chairperson’s Text

64. The Committee expressed its appreciation to the Chairperson for her efforts in drawing together many of the diverse opinions expressed during the discussion of the Working Group draft.

65. The Representative of WHO stated that the issue of food safety had been recognized as one of high significance by the World Health Assembly. He reported that the Director-General of WHO had recently referred to the use of risk analysis as the “third wave” of strategies that were being used to improve the food safety status of countries around the world, the first and second “waves” being the use of Good Manufacturing Practices and the application of HACCP. However, risk analysis gave developing countries the opportunity to make even more significant advances than the developed countries in food safety. The Representative stated that risk analysis had to be considered as a health issue with trade implications and not as a trade issue with health implications, and that the debate on precaution should be viewed in this light.

66. Some Delegations stated that explicit reference to the use of precaution in Codex decision-making would reinforce the view that protecting consumers’ health was the primary purpose of risk analysis over and above any trade concerns. The Observer from Consumers International expressed concern with the trend, within Codex and at the present meeting, to emphasize trade concerns over and above those of protecting the health of consumers. This view was supported by the Delegations of the United Kingdom and Norway. The Delegation of Argentina referred to the objectives of Codex of protecting consumers’ health and ensuring fair practices in food trade.

67. Several Delegations stated that there was a need for a single document for use within Codex that described the application of precaution and also guidance for governments on how to apply precaution. These Delegations stated that they could accept most of the Chairperson’s text, including the footnote which made explicit reference to “precautionary principle/precautionary approach”. In the opinion of most of these Delegations, reference to the application of precaution was essential to maintain consumer confidence in the ability of food control authorities to ensure the safety of the food supply.

68. Several other Delegations expressed their preference for a complete deletion of paragraphs 34 and 35 as they should not apply to the work of Codex. Some of these delegations proposed however that, if the Chairperson's text was to be retained, reference to "precaution" should be deleted along with reference to actions to be undertaken by governments. Several delegations were also of the opinion that the footnote that referred explicitly to "precautionary principle/precautionary approach" should be deleted. The Delegation of Bolivia supported deleting the note because the precautionary principle could be used as a justification for trade protectionism. Some delegations also expressed their concern about the proposal to equate "precautionary principle" with "precautionary approach". The Delegation of Uruguay stated that the measures referred to in paras. 34 and 35 should only be applied by governments, in accordance with the WTO Agreements.

69. A number of Delegations expressed their preference for the draft text tabled by the Delegation of Australia, stating that the Chairperson's text still retained elements of ambiguity as to the work of Codex and the work of Member governments. These Delegations stated that it was inappropriate to suggest that Codex should develop standards, guidelines or recommendations by recourse to the "precautionary principle" when data were inadequate, even though it was recognized that precaution was an essential element in the Codex normal decision-making process. These Delegations also noted the linkages with the general statement on the application of precaution in risk analysis as contained in the Section on General Aspects (paragraph 5) of the draft document (see also paras. 32-34, above).

STATUS OF THE PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS

70. The Committee noted that it had reviewed the complete text of the Working Principles now for the second time, and that progress had been made on a number of points although it had not been possible to achieve consensus on all of the text, in particular on the paragraphs dealing with Scope (paragraph 1) and precaution (paragraphs 5, 34 and 35). In relation to paragraph 34, the Committee agreed that all of the current alternative proposals, as presented in Appendix V of the present report, would be included in any revised text in square brackets.

71. The Committee agreed to request the Commission for a clarification of the intended scope and application of the document; i.e., whether it was a text exclusively for application within the Codex framework, or by Member governments, or both (bearing in mind that some paragraphs then might need to be singled out as being for specific application either by Codex or by Member governments).

72. The Committee also agreed to request the advice of the Commission on how Codex should react when scientific data were insufficient or incomplete and evidence of a risk to human health existed, in particular whether it should proceed to elaborate a standard or related text or whether it should refrain from such action.

73. In order to assist in the interpretation of the manner in which precaution was being used by Codex, the Committee invited the Chairpersons of relevant Codex Committees as well as governments and interested international organizations, to forward examples to the Secretariat in time to be available for discussion of this matter by the Commission (see para. 60, above).

74. On the basis of the Commission's advice, the Committee noted that it should be possible to proceed with the development of a text that would incorporate the decisions made at the present session. It requested the Secretariat to prepare such a revised text for circulation at Step 3 and consideration at the Committee's next session. It also requested the Secretariat to review the editorial presentation of the text, to remove duplication or repetition where possible while ensuring that the consensus decisions of the Committee remained as they had been agreed.

75. The Delegation of Australia stressed the importance of an effective mechanism to ensure progress between the sessions and offered to lead a small working group to redraft the Working Principles for Risk Analysis. Several delegations supported this proposal. The Committee agreed that there was a need for the Host Country to convene an open-ended working group (open to all members and observer organizations) between sessions to review the document and the comments received so as to facilitate the discussion of the text at the Committee's next session. The Delegation of Bolivia expressed the view that this working group should be open to developing countries and be provided with interpretation. The Chairperson confirmed that, as had been the case before the present session, the Working Group would be open to all countries and provided with interpretation into French and Spanish.

THE APPLICATION OF RISK ANALYSIS IN THE ELABORATION OF CODEX STANDARDS (Agenda Item 3.b)¹⁰

76. The Delegation of India presented the document and stated that it had been prepared in the light of a number of decisions taken in the recent past by Codex Committees which demonstrated that scientific information from only a limited number of countries had been used as a basis for the decision-making and that draft standards had been advanced in some cases before completion of the risk assessment. The Delegation particularly addressed the discussions concerning Aflatoxin M₁ in Milk and Lead (Pb) in various foods as examples where global data, in particular data from developing countries, had not been taken into account. The paper contained proposals for specific guidelines that might be used to ensure that Codex standards were indeed based on global data.

77. The Delegation proposed that in addition to the proposals contained in the working paper, consideration should be given by FAO and WHO to the identification of collaborating centres and/or sentinel sites that could develop the necessary epidemiological and exposure data in order that global information be used in the Codex Risk analysis process.

78. The Committee expressed its appreciation of the paper prepared by the Delegation of India and many delegations expressed the view that the paper identified issues requiring serious consideration.

79. The Delegation of the United States expressed its support for many of the recommendations contained in the proposals, but noted that some of them had already been included in the Draft Working Principles. The Delegation proposed that for the moment the elaboration of separate Guidelines appeared to be premature, and that the proposals be forwarded to the relevant Codex Committees for consideration. The view that many of the specific proposed Guidelines should be incorporated into the Working Principles was supported by other Delegations including Australia, Malaysia, Sweden and United Kingdom. The Delegation of Uganda also noted the problems of developing and verifying data used in risk analysis. The Delegation of Chile referred to the recommendation of the 23rd Session of the Commission on risk analysis and especially (para. 56 f)) that a co-author from a developing country should be appointed for position papers where the main author was from a developed country, and proposed that this should be taken into account if a drafting group was established for the Working Principles for Risk Analysis.

80. The Representative of FAO stated that there was a great need for capacity building for developing countries in developing the necessary data for risk analysis both at the national and global levels. FAO was giving consideration to the establishment of a Global Facility for Capacity Building in Food Safety and Quality that would address this issue among others, and welcomed the initiative announced by the French Minister of Agriculture in his opening address. The Representative also pointed out that capacity-building workshops on risk analysis had been held in most regions, including recently in the Near East and South-Asian regions. Workshops on exposure assessment had been held in association with Codex Regional Coordinating Committees in the past biennium.

81. The Chairperson of Committee on Pesticide Residues (Dr. van Eck, the Netherlands) noted that the lack of relevant data from developing countries had been recognised as a constraint in that Committee's work. The Committee had recommended to strengthen regional cooperation to develop data. Similarly, the Delegation of Denmark supported the objective of providing means to improve developing country participation in Codex work, but stated that emphasis should be placed on support to develop more complete food safety systems; the question was not only about participation in Codex meetings. The Delegations of Dominican Republic, Norway and Swaziland also drew attention to the need for addressing the issue of capacity building. The Observer from Consumers International stressed the need to use global data, particularly on epidemiological surveillance and exposure studies; and the need to develop capacity building, particularly in developing countries.

82. The Representative of WHO stated that new procedures for the identification of experts by FAO and WHO and for obtaining data, especially in the area of microbiological risk assessment and the risk assessment of foods derived from biotechnology, gave the opportunity for developing countries to use the Internet or the Codex-L distribution list to contribute to the early stages of the risk analysis process. The Representative noted that participants in expert meeting were selected in their personal capacities and not as

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representatives of their countries; nevertheless considerable efforts were made to ensure that the membership of expert committees and consultations reflected the global membership of the parent organizations.

83. The Committee thanked the Delegation of India for its thoughtful paper and agreed that the recommendations should be considered together with the Working Principles as appropriate. The Committee also agreed to send the paper to the relevant Codex Committees for their consideration of the specific issues raised. It also agreed to circulate the recommendations contained in the paper for government comments and to consider these recommendations in the light of comments at its next session.

REVIEW OF THE STATEMENTS OF PRINCIPLES ON THE ROLE OF SCIENCE AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO ACCOUNT: ROLE OF SCIENCE AND OTHER FACTORS IN RELATION TO RISK ANALYSIS (Agenda Item 4)¹¹

84. The Committee recalled that the last session had discussed a document on the role of other legitimate factors, taking into account the discussions held in several relevant Committees on this issue. The Committee had agreed that it should consider criteria providing general guidance on the use of such factors in the framework of Codex, and that the Secretariat would prepare a revised document for this purpose. The 47th Session of the Executive Committee had confirmed that the CCGP was responsible for the development of general guidance at the request of the Commission and that no further action was required at this stage from other committees.

85. The Committee considered the revised draft criteria and made the following amendments.

86. In the first indent, the Committee agreed that reference should be made to all Statements of Principle Concerning the Role of Science (instead of the first Statement only).

87. In the second indent, the Committee agreed that the development of standards and related texts should be mentioned to clarify the outcome of risk management options in the framework of Codex.

88. In the third indent, the Committee discussed the need for a specific reference to interaction between risk assessment and risk management. However, the Committee agreed to retain the current text as interaction was addressed in the 4th Statement of Principles Relating to the Role of Food Safety Risk Assessment.

89. The Committee discussed whether the distinction between justification of national measures under the SPS and TBT Agreement should be reflected in the text of the fourth indent. Some delegations expressed the view that it was superfluous and also proposed to delete the entire paragraph. Other delegations supported its inclusion as it was essential to clarify the difference between the factors that could be taken into account within Codex and at the national level. The Committee agreed with the suggestion of the Representative of WTO to put the first sentence in a footnote as it might be useful for clarification purposes, and retained the current text of the second sentence. The Delegation of Thailand requested the inclusion of an amendment to encourage the harmonization of food standards.

90. In the fifth indent, the Committee agreed that other factors could be accepted on a regional basis in the case of regional standards and related texts, and amended the text accordingly.

91. In the sixth indent, a minor change was made to clarify that specific consideration of other factors in the development of risk management recommendations should be clearly documented, whether such factors had an influence on the final decisions or not. The Committee also agreed that other factors should be considered in the decision process on a case by case basis.

92. The Committee considered in detail the 7th indent referring to health concerns related to the environment. The Delegation of Sweden, speaking on behalf of the EC, proposed to recommend that “concerns relating to the environment, animal and plant health and animal welfare” might be taken into account “if international requirements or recommendations of the competent international fora” existed. This proposal was supported by other delegations outside the European Union and the Observer from IACFO. The Delegation of the Netherlands pointed out that linkages with the work of other international organizations and consistency with international agreements was essential to ensure credibility of international harmonization.

¹¹ CX/GP01/5; CRD 1 (Comments of Thailand); CRD 12 (comments of Consumers International)

93. Several other delegations opposed this amendment as it was not consistent with the *Statements of Principle*, and the deletion of the reference to health would introduce considerations that were excluded from the mandate of Codex; these delegations expressed their concern that such amendments would not improve consumer health protection but would be likely to create additional barriers to trade. Other delegations supported the deletion of this paragraph as its lack of clarity created confusion.

94. The Committee could not come to a consensus on the specific factors that should be mentioned in the text and recognized that a general reference to international agreements might be more generally acceptable. The Committee also agreed with the proposal of the Delegation of Canada to clarify the nature of the international recommendations and organizations concerned.

95. After an exchange of views the Committee considered a compromise proposal to the effect that “certain factors may be taken into account if recommendations of relevant multilateral intergovernmental organizations exist”.

96. The Delegation of Argentina indicated that it could accept this text provided the factors were described as “relevant for the health protection of consumers and for the promotion of fair practices in food trade” as specified in the Statement of Principle. This proposal was supported by several delegations.

97. The Delegation of the United States expressed the view that Codex standards should avoid having a negative impact on the application on international agreements or recommendations. The Committee recognized that this important concept should be addressed, in view of the need for coordination between international organizations, and included an additional sentence to this effect in the paragraph.

98. The Delegation of Australia, supported by other delegations, stated that as there were clearly concerns about the application of this paragraph, it should be deleted in order for the remainder of the document to be advanced. The Delegation proposed that in view of the important issues covered in this paragraph, the relationship between Codex and other multilateral intergovernmental organizations should be considered as a separate issue. Several delegations, although they had no specific opposition to the revised paragraph, proposed to discuss it further at the next session. The Committee could not come to a consensus on the text of the seventh indent and agreed to put it in square brackets for consideration by the Commission together with the other criteria.

99. The Committee retained the eighth indent addressing the constraints of developing countries with slight editorial changes for clarification purposes.

100. In the ninth indent concerning barriers to trade, the Delegation of Argentina, supported by several delegations, proposed to include a reference to WTO principles and to the provisions of the SPS and TBT Agreements. Other delegations pointed out that such a reference was not necessary since the obligations of member countries were defined under WTO and should not be repeated in a Codex text. After some discussion it was agreed to put this proposal in square brackets also for further consideration.

101. Some delegations proposed to retain the current reference to generally accepted scientific evidence as a basis for decision in Codex, even when no specific international agreement existed. This question was not discussed and the current text was deleted.

102. The Committee agreed to forward the Proposed Criteria to the Commission and requested the Commission to resolve the issues mentioned in the two sections remaining in square brackets. The Committee recommended that the criteria be included in the Procedural Manual as an explanation of the *Statements of Principle* (see Appendix III).

THE EXECUTIVE COMMITTEE AND RELATED MATTERS (Agenda Item 5)¹²

103. The 23rd Session of the Codex Alimentarius Commission (1999) discussed a number of issues related to the composition of the Executive Committee and the participation of observers in its work¹³. These questions were referred to the Committee, which discussed them at its 15th Session on the basis of a paper provided by the Secretariat (CX/GP 00/6). In the course of the discussion, questions were raised about the role of the Executive Committee. It was proposed by some delegations that the role of the Executive

¹² CX/GP 01/5; CRD 2 (Consumers International); CRD 6 (Malaysia); CRD 8 (India).

¹³ ALINORM 99/37, paras. 44-46.

Committee be reviewed with a view to its possible abolition; its functions being assumed by the Commission which would meet annually as provided for in Rule IV.1 of the Rules of Procedure.

104. The Secretariat was requested to provide a paper on this matter for consideration of the Committee at its 16th Session and was also requested to provide for consideration specific modalities for improving transparency, for the representative participation of international non-governmental organizations, and for additional participation of developing countries in case that the Executive Committee would not be abolished.¹⁴

105. The paper before the Committee analysed the current status and work of the Executive Committee; examined the issues that needed to be addressed should the Executive Committee be abolished; examined alternatives to the Executive Committee including annual meetings of the Commission; examined a proposal to restructure the Executive Committee to provide for increased participation from developing countries; and set out proposals for the participation of INGO observers and the observer status of countries that were Members of the Commission, but not Members of the Executive Committee.

106. The Delegations of the United States, Sweden (on behalf of the EC), and Australia expressed the view that the process of considering the role and appropriate composition of the Executive Committee should be a step-wise one, with a decision first being made on annual meetings of the Commission. Should there be annual meetings, it was clear that the role of the Executive Committee would be diminished. In this case, it was suggested that the size of the Executive Committee could be reduced. The Delegations of the Czech Republic, Uganda, Japan also expressed a preference for holding annual meetings of the Commission while retaining the Executive Committee. The Delegation of Japan stressed that the Executive Committee should be made more open and transparent in the conduct of its work.

107. The Delegation of Chile stated that, independently from the decision concerning annual meetings of the Commission, in view of the Medium Term Plan, the Executive Committee performed important functions of strategic planning and monitoring that could not be carried out by the Commission itself. The Delegation expressed the view that the Executive Committee should be retained and strengthened.

108. The Delegation of India stated that annual meetings of the Commission would create a considerable burden for developing countries and also called for a restructuring of the Executive Committee by providing additional representation to countries of different regions and restricting its work to executive functions only.

109. The Observer from Consumers International stated that this organization could support the proposal for annual meetings of the Commission as well as keeping the Executive Committee, provided that in the latter case the issue of transparency and consumer representation was resolved. The Observer from IACFO drew attention to the proposal (also included in the Chairperson's Action Plan) to establish a more restricted advisory body and the problems that this would raise in relation to transparency. The Observer from the 49th Parallel Consortium drew attention to the problems of ensuring adequate civil society participation in Codex Committees and Task Forces in general.

110. The Delegation of Canada pointed out that any change must result in an enhancement of the Codex structures and procedures, and noted that the proposal to hold annual meetings of the Commission solved a number of outstanding problems pertaining to the Executive Committee such as transparency and representative membership. The Delegations of Malaysia and Singapore stated that the Executive Committee should be abolished and that there should be annual meetings of the Commission.

111. A number of Delegations (South Africa, India, Swaziland, Brazil, Kenya, Uganda, Tunisia) drew attention to the potential cost burden to developing countries of holding annual sessions of the Commission. The Delegation of Chile expressed its concern with possible annual meetings of the Commission, as the trust fund was still a project and in addition to the costs of participation it was indispensable to consider the costs and other aspects involved in the preparation of meetings at the national level, recognizing the great complexity of the process in which various public and private sectors participate. Although the Delegation of South Africa did not oppose annual meetings, it noted that there were already considerable resource problems for developing countries in view of the additional work of Codex in important areas such as animal feeding, foods derived from biotechnology and meat hygiene.

¹⁴ ALINORM 01/33, paras. 78-84.

112. In reply to a question from the Delegation of India, it was noted by the Secretariat that the proposal to hold annual meetings of the Commission did not imply that all Codex Committees (especially Regional Coordinating Committees) would also need to meet annually. The Representative of WHO stated that questions relating to the cost burden of annual meetings were closely linked to the proposals to establish a trust fund or other support facility.

113. The Committee noted that since a large number of Delegations had expressed themselves in favour of annual meetings of the Commission with or without the abolition of the Executive Committee, and others has expressed themselves in favour of Executive Committee's retention with or without restructuring, that there was no consensus in this matter and agreed to inform the Commission accordingly.

PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS (Agenda Item 6)¹⁵

114. The 13th Session of the Committee had proposed to revise the Code of Ethics with the following purpose: to take into account the texts on food import and export developed by the CCFICS and the entry into force of the SPS and TBT Agreements; to address the specific situation of developing countries; and to generally update its provisions to make them consistent with current Codex texts. Following approval as new work by the 22nd Session of the Commission, a first draft had been circulated at Step 3. The 15th Session of the Committee (2000) had agreed that the text would be redrafted for circulation at Step 3 and further consideration.

115. The Secretariat recalled that the last session of the Committee had not discussed the text in detail and that several issues put forward in the comments remained to be addressed: the relevance of the Code in the framework of WTO, the applicability of a Codex text to trade operators in addition to governments, and non-compliance with the provisions of the Code.

116. Many delegations supported the revision of the Code with its current scope and format to provide guidance both to governments and food traders, while pointing out that several important questions had not been addressed and required detailed consideration in the Committee; further amendments would also be required to simplify and update the text. Several delegations pointed out that time constraints had not allowed substantial discussion of the Code so far, and that it should be considered prior to or as a matter of priority at the next session.

117. Many delegations supported the simplification of section 5 and the alternative section 5.1 with a general reference to Codex standards. Some delegations and observers proposed to retain sections 5.10 and 5.11 on foods for infants, children and vulnerable groups in view of their importance to address these specific public health concerns. Reference was also made to the linkage between section 5.9 (foods derived from biotechnology) and the Cartagena Protocol.

118. Some delegations proposed to recommend that national standards should be harmonized with Codex standards in view of the provisions of the WTO SPS and TBT Agreements. Other delegations expressed the view that Codex standards should be taken into account but that governments had the right to establish national standards that might differ from international standards, provided they complied with their obligations under WTO.

119. The Delegation of Sweden, speaking on behalf of the EC and referring to its written comments, presented the EC proposal to amend the scope and purpose of the code in order to focus on certain broader ethical considerations in relation to practices in the food trade. Several delegations expressed concern about some elements of the EC proposal and supported the use of the Secretariat's current draft as the basis for further revision.

120. The Delegation of India, supported by other delegations and observers proposed to consider the problems caused by export to developing countries of food with a short remaining shelf life. The Delegation also supported a strengthening of Article 11 concerning developing countries in the light of specific provisions in the SPS Agreement. The Delegation of Morocco expressed the wish that developed countries should implement programmes to strengthen the capacity of developing countries to produce, import and export safe food well before the Code was finalized, as its completion should take a certain time.

¹⁵ CX/ 01/7; CX/GP 01/7-Add.1 (comments of Costa Rica, Malaysia, CI, ENCA IDF); CX/GP 01/7-Add.2 (comments of EC, IBFAN); CRD 1 (comments of Thailand); CRD 9 (comments of India)

121. The Delegation of Uganda, supported by other delegations and observers, stressed the problems caused by the export to developing countries of foods rejected at the import stage in other countries, especially in the case of foods for infants and children. The Committee agreed that the provisions of the Code should include clear recommendations to address such situations. The Observer from IBFAN proposed to retain the reference to a regular review mentioned in Article 10 of the present Code.

122. The Committee noted that the following points would require further consideration: export of food which did not meet the requirements of the exporting countries; the export of food that requires further processing in the importing country; the requirements to be applied to food in transit; and the need for food aid transactions to comply with the Code even in emergency cases. The Observers of CI and IACFO proposed to include a reference to transparency in the selection of experts. The Secretariat indicated that the Code addressed import/export issues and was directed to those engaged in international trade, while transparency in risk analysis was currently under consideration in the Working Principles for Risk Analysis.

123. In reply to some questions on the status of the Code, the Representative of WTO indicated that the code could be considered relevant under the SPS Agreement to the extent its provisions applied to sanitary measures, but it appeared unlikely that the Code would be a decisive factor in a dispute situation. The Chairperson suggested that further clarification from the WTO regarding the status of the Code under the SPS and TBT Agreements would be helpful.

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

124. The Committee agreed that the Proposed Draft Code would be redrafted by the Secretariat in the light of the comments received and the discussion at the present session, for circulation at Step 3 and consideration at the next session early in the Agenda.

MEMBERSHIP IN THE CODEX ALIMENTARIUS COMMISSION OF REGIONAL ECONOMIC INTEGRATION ORGANIZATIONS (Supplementary Agenda Item 7.a)¹⁶

125. The Secretariat introduced the working document, noting that the item had been included on the Provisional Agenda of the Committee pursuant to a request under Rule V.5 of the Commission's Rules of Procedure from Sweden, the State currently holding the Presidency of the European Union. The Secretariat stated that Article 2 of the Statutes of the Codex Alimentarius Commission provided that "membership of the Commission is open to all Member Nations and Associate Members of FAO and WHO which are interested in international food standards. Membership shall comprise such of these nations as have notified the Director-General of FAO or of WHO of their desire to be considered as members".

126. Under Article II.3 of the FAO Constitution, regional economic integration organizations may be admitted to membership of FAO. Member Organizations have the right to participate in matters within their competence in any meeting of a body of FAO in which any of its Member States is entitled to participate, unless otherwise provided in rules adopted by the FAO Conference. The FAO Constitution provides further that any references to Member Nations thereunder include Member Organizations, except as otherwise expressly provided. Member Organizations of FAO are also eligible for Membership in joint bodies of FAO such as the Codex Alimentarius Commission. The European Community is a Member Organization of FAO, but not of WHO.

127. The Secretariat noted that the proposal before the Committee was to establish clear Rules of Procedure for the membership of regional economic integration organizations in the work of Codex, including the membership of the European Community. Without such Rules, recourse would have to be made to the General Rules of FAO should a regional economic integration organization exercise its right to membership of the Commission.

128. The Delegation of Sweden, speaking on behalf of the EC, introduced Conference Room Document No. 4 that contained three changes to the proposed amendments to the Rules, and noted that these amendments (Annex 1 to CX/GP 01/8) were the result of discussions between the legal representatives of FAO, WHO and the European Commission. The Delegation requested that the Secretariat proposals and the proposals in CRD 4 be forwarded to the Commission.

¹⁶ CX/GP 01/8; CRD 2 (Consumers International); CRD 4 (European Community)

129. The Delegation of the United States expressed its concern at the use of Rule V.5 to include the current item on the Committee's Agenda, stating that no urgency (as required by Rule V.5) had been demonstrated in this matter. It also drew attention to the opinion of the Legal Counsel of the United Nations in 1991, that the membership of regional economic integration organizations in any United Nations body should not infringe the principle of "one nation, one vote", and that the admission of regional economic integration organizations into FAO should not be seen as a precedent for other UN bodies. The Delegation stated that the changes to the Rules would allow the Member States of such organizations to enjoy privileges not available to other Members. Moreover, the Delegation was of the view that over the years Codex had been enriched by the diversity of views expressed by all Member countries, and that any loss of such diversity would be a loss to Codex.

130. The Delegation of Argentina, supported by Paraguay, stated that the membership of regional economic integration organizations was an appealing concept, which other regional organizations could eventually avail themselves of in the future. However, it objected to the sense of urgency impressed on this issue. The Delegation requested that a comprehensive legal report on the competence of the European Community on Codex matters be compiled by the FAO and WHO Legal Services, in order to evaluate whether membership was justified on a competence basis, and no further action should be taken on this issue until that report had been circulated among members.

131. The Delegations of Canada and Australia, while recognizing the right of the regional economic integration organizations to become members of the Commission, also reiterated the views of the United States concerning the need for continued diversity of Member countries' opinions in the Commission's debates and the importance of ensuring fair and equitable treatment of all member countries in Codex and in particular voting rights. These views were supported by the Delegations of Malaysia and Singapore.

132. The Observer from Consumers International stated that the proposals did not address possible negative effects such as issues of consultation, openness and transparency and the ability of consumers' organizations to interact with regional economic integration organizations, and asked that this should be adequately addressed. The Delegation of Bolivia questioned the participation of Observers to the debate on membership of regional economic integration organizations. The Secretariat recalled that Observers could participate in the debate on the issues considered by Codex Committees, in conformity with the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*¹⁷.

133. In response to a question from the Delegation of India, the Representative of the Legal Counsel of FAO stated that discussions on this matter had been undertaken as part of the normal consultations between the FAO Secretariat and a Member of FAO on matters of interest to that Member, and that in this case, due to the joint nature of Codex, the Office of the Legal Counsel of WHO had been invited to join these discussions. He also noted that at the time of the entry of the EC into FAO in 1991, there had been an explicit agreed reference to the possibility of the Membership of the EC in the Codex Alimentarius Commission.

134. The Delegation of Sweden stated that in practical terms, there would be little if any impact on the nature of debate within the Commission or in Codex Committees, should the proposals be adopted. It was further noted that the EC membership in the Codex Alimentarius Commission would not lead to extra voting rights.

135. The Committee agreed to report the current exchange of views to the Commission and to attach the text of the two proposals to the present report (see Appendix IV). It noted that consultations between the Legal Counsels of FAO, WHO and the EC would continue.

¹⁷ Procedural Manual, 11th Edition, page 62

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF THE NEXT SESSION (Agenda Item 7.b)***OTHER BUSINESS¹⁸***

136. The Committee did not have time to discuss in detail the items proposed by the Delegation of India under “Other Business”. Nevertheless, the Delegation of India noted that many aspects of its proposal to discuss the question of participation of developing member countries had been raised during the course of the various debates, especially in relation to the establishment of a trust fund or other facility that would enhance capacity building and participation. Professor S. Slorach (Sweden) speaking as one of the Vice-Chairpersons of the Commission, stated that this matter had also been taken up in the Chairperson’s Action Plan.

137. In relation to the proposals to study the impact of international standards on trade facilitation, the Secretariat reported that FAO’s Committee on Commodity Problems was undertaking studies covering agricultural commodities to assess the impact of the SPS and TBT Agreements on the foreign exchange earnings of developing countries, including the development and application of international standards.

DATE AND PLACE OF NEXT SESSION

138. The Committee was informed that its 17th Session would be held in Paris in April 2002, the exact dates to be determined by the French and Codex Secretariats.

¹⁸ CRD 10 (document prepared by India)

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 01/33A
Proposed Amendments to the Procedural Manual <ul style="list-style-type: none"> – Terms of Reference of the CCFH – Provisions concerning methods of analysis 		Governments 24th CAC	paras. 8 and 10 Appendix II
Review of the Statements of Principle: Proposed Criteria for the Consideration of Other Factors		Governments 24th CAC	para. 102 Appendix III
Proposed Draft Working Principles for Risk Analysis	2/3	CAC – Secretariat Governments 17 th CCGP	paras. 71-74 Appendix V
Proposed Draft Revised Code of Ethics for International Trade in Foods	2/3	Secretariat Governments 17 th CCGP	para. 124
Executive Committee and Related Matters		24 th CAC	para. 113
Membership of Regional Economic Integration Organizations		24 th CAC	para. 135 Appendix IV
Application of Risk Analysis in the Elaboration of Codex Standards		Governments 17 th CCGP	para. 83

LIST OF PARTICIPANTS/LISTE DES PARTICIPANTS
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PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

**SECTION III OF THE PROCEDURAL MANUAL
SUBSIDIARY BODIES UNDER RULE IX.1 (B) (I)**

Terms of Reference of the Codex Committee on Food Hygiene

Add the following provisions:

- ◆ To suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors
- ◆ To consider microbiological risk management matters in relation to food hygiene and in relation to the microbiological risk assessment activities of FAO and WHO

**GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS
AND RELATED TEXTS**

PRINCIPLES FOR THE ESTABLISHMENT OF CODEX METHODS OF ANALYSIS¹

Addition of a new subsection at the end of *General Criteria for the Selection of Methods of Analysis* as follows:

General Criteria for the Selection of Methods of Analysis using the Criteria Approach

In the case of Codex Type III methods, method criteria may be identified and values quantified for incorporation into the appropriate Codex commodity standard. Method criteria which are developed will include the criteria in section Methods of Analysis, paragraph (c) above together with other appropriate criteria, e.g., recovery factors.”

**RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL COMMITTEES
METHODS OF ANALYSIS AND SAMPLING²**

Addition of new paragraphs at the end of “*Normal Practice*” section as follows:

“The Codex Committee on Methods of Analysis and Sampling will assess the actual analytical performance of the method which has been determined in its validation. This will take account of the appropriate precision characteristics obtained in collaborative trials which may have been carried out on the method together with results from other development work carried out during the course of the method development. The set of criteria that are developed will form part of the report of the endorsement by the Codex Committee on Methods of Analysis and Sampling and will be inserted in the appropriate Codex Commodity Standard.

In addition, the Codex Committee on Methods of Analysis and Sampling will identify numeric values for the criteria for which it would wish such methods to comply.”

¹ Procedural Manual, 11th Edition, pages 72-73

² Procedural Manual, 11th Edition, page 96

**STATEMENTS OF PRINCIPLE ON THE ROLE OF SCIENCE IN THE CODEX DECISION-
MAKING PROCESS AND THE EXTENT TO WHICH OTHER FACTORS ARE TAKEN INTO
ACCOUNT**

PROPOSED CRITERIA FOR THE CONSIDERATION OF OTHER FACTORS

- ◆ when health and safety matters are concerned, the *Statements of Principle Concerning the Role of Science* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* should be followed;
- ◆ other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- ◆ consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- ◆ it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide;³
- ◆ only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;
- ◆ the consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- ◆ [albeit not within the mandate of Codex, certain factors may be taken into account, if recommendations of relevant multilateral intergovernmental organizations exist. Codex standards should avoid having a negative impact on the application of such internationally agreed recommendations];
- ◆ the feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
- ◆ the integration of other legitimate factors in risk management should not create unjustified barriers to trade, [according to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

³ Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level

**PROPOSED AMENDMENTS TO THE RULES OF PROCEDURE CONCERNING THE
MEMBERSHIP OF REGIONAL ECONOMIC INTEGRATION ORGANIZATIONS**

1. Proposal of the Secretariat:

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. 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.
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.

2. Amendments Proposed by the European Community:

Paragraph 1, line 1 (of the proposed new Rule II)

Add the word "voting" after Membership

Paragraph 6, line 3

Replace the word "competence" by the expression "voting rights"

Paragraph 7

Delete the second sentence

**PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS: PROPOSALS
CONCERNING PRECAUTION IN RISK ANALYSIS**

The Appendix contains the various proposals put forward in relation to paragraphs 5 and 34-35 of the Proposed Draft Working Principles for Risk Analysis (see para. 70 of the Report)

PARAGRAPH 5

[5. Precaution is an essential element of risk analysis. This is particularly important where the scientific evidence is insufficient and negative effects on health difficult to evaluate. Precaution should be exercised through the use of appropriate assumptions in the risk assessment and the choice of risk management options that reflect the confidence in the available scientific information.]

Additional Australian Proposal

[5 bis. Many sources of uncertainty exist in the process of risk assessment of food borne hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis process. As the degree of scientific uncertainty increases, the assumptions used for the risk assessment and the risk management options selected should become more cautious and conservative.]

PARAGRAPH 34***ORIGINAL TEXT (CX/GP 01/3)***

"When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food ^[1], and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for [risk managers/members governments] to apply precaution ^[2] through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment.

However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly [within a reasonable time frame/until a more complete risk assessment is performed]."

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

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

WORKING GROUP COMPROMISE TEXT

[34. When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply precaution ^[1] through actions adapted to circumstances, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment.

34bis. In the case of Codex, such precautionary actions could comprise the development of guidelines, recommendations or, where possible, standards. [In circumstances in which there is insufficient confidence in available information, Codex should not take any action.]

34ter. In addition, in the case of member governments, precaution may be applied through interim measures.

34qua. In both cases, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]

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

AUSTRALIAN TEXT

[33bis. In deciding whether to elaborate a standard, guideline or recommendation relating to a particular hazard in food, Codex should consider the adequacy of current scientific knowledge, the level and extent of the risk to human health. Where there is evidence of a risk to human health but scientific knowledge is insufficient to provide a sound basis for a standard (such as maximum limit for a contaminant) Codex may consider other risk management options (such as Codes of Practice to minimise contamination of food) while awaiting further developments in scientific knowledge.

34. When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for governments to apply precaution^[1] through interim measures, in order to protect the health of consumers without awaiting additional scientific data and a full risk assessment.

However, additional information should be sought, a more complete risk assessment should be performed, and the measures taken reviewed, all in a reasonable time frame.]

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

PARAGRAPH 35

ORIGINAL TEXT (CX/GP 01/3)

[35. In such situations the following considerations should be taken into account :

- a) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.
- b) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
- c) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.
- d) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.
- e) The measures taken are the least trade restrictive to achieve protection of the health of consumers.
- f) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.
- g) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.]