JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Twenty-sixth Session
Rome, 30 June - 7 July 2003

REPORT OF THE EIGHTEENTH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES
Paris, France, 7-11 April 2003

Note: This document incorporates Circular Letter CL 2003/16-GP
TO: - Codex Contact Points
    - Interested International Organizations

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

SUBJECT: Distribution of the Report of the 18th Session of the Codex Committee on General Principles (ALINORM 03/33A)

MATTERS FOR ADOPTION BY THE 26TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

 Proposed Amendments to the Procedural Manual

1. Proposed Amendment to the General Criteria for the Selection of Methods of Analysis Using the Criteria Approach, and to the Principles for the Establishment of Codex Methods of Analysis (inclusion of a new section on Working Instructions for the Implementation of the Criteria Approach in Codex) (para. 6, Appendix II)

2. Proposed Amendments to the Rules of Procedure concerning the Membership of Regional Economic Integration Organizations (para. 84, Appendix III)

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

Draft Principles at Step 8 of the Procedure


Governments wishing to propose amendments or comments on the Draft Working Principles should do so in writing in conformity with the Guide to the Consideration of Standards at Step 8 (see Procedural Manual of the Codex Alimentarius Commission) to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, c/-FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy before 30 May 2003.
SUMMARY AND CONCLUSIONS

The summary and conclusions of the 18th Session of the Codex Committee on General Principles are as follows:

Matters for adoption by the Commission:

The Committee

- Endorsed the amendments to the General Criteria for the Selection of Methods of Analysis Using the Criteria Approach, and to the Principles for the Establishment of Codex Methods of Analysis proposed by the Committee on Methods of Analysis and Sampling (para. 6, Appendix II);

- Agreed to forward to the Commission the Proposed Amendments to the Rules of Procedure concerning the Membership of Regional Economic Integration Organizations (para. 84, Appendix III)

- Agreed to advance to Step 8 the Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius (para. 31, Appendix IV);

Other matters of interest to the Commission:

The Committee

- agreed to return the Proposed Draft Working Principles for Risk Analysis for Food Safety to Step 2/3 for redrafting and further comments (para. 42);

- agreed to return the Proposed Draft Revised Code of Ethics for International Trade in Foods (including consideration of the definition of "Food") to Step 2/3 for redrafting and further comments (para. 73);

- agreed to consider the definition of traceability or product tracing at its next session (para. 97).

- agreed to consider further at its next session the guidelines for cooperation between the Codex Alimentarius Commission and international organizations in the elaboration of Codex standards and related texts (para. 107).
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INTRODUCTION

1. The Codex Committee on General Principles held its Eighteenth Session in Paris, France, from 7 to 11 April 2003 at the kind invitation of the Government of the French Republic. The Session was chaired by Docteur Michel Thibier, Director-General of Education and Research, Ministry of Agriculture, Food, Fisheries and Rural Affairs. The Session was attended by 157 delegates and advisors from 47 Member countries and 47 representatives of 28 international intergovernmental and non-governmental organizations. A full list of participants, including the Secretariat is given in Appendix I.

2. The session was opened by Mr. Renaud Dutreil, Secretary of State for Small and Medium Industries, Trade, Crafts, Professions and Consumer Affairs. Mr. Dutreil welcomed the participants and emphasized the enduring relevance of the original Codex mandate to deal with the new demands, coming from consumers’ expectations, on trade, and specifically international trade, which is the focus of Codex work. He stated that the work of this committee would contribute significantly to build up consumers’ confidence, by establishing a basic science-based framework, in which the protection of the consumers’ health and the promotion of fair practices in the food trade could be implemented at the international level. Several issues on the agenda of this session, such as risk analysis, the code of ethics in international trade, and traceability, were directly relevant from this perspective. Mr Dutreil stated that the legitimacy of Codex standards required that the two objectives in its mandate received equal attention and be pursued in a consensus-based manner. He also noted that the work of Codex had been evaluated by its two parent organizations and the follow-up of this evaluation may require additional work from this Committee. The French government would help moving forward in this reform of Codex, by offering to organize extra plenary sessions (or working groups), as the need arose.

ADOPTION OF THE AGENDA (Agenda Item 1) 1

3. On the suggestion of the Delegation of Belgium, the Committee agreed to discuss the role of the Committee in the follow-up to the Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and Other FAO and WHO Work on Food Standards under Agenda Item 8 - Other Business and Future Work.

4. The Committee adopted the Provisional Agenda as presented in CX/GP 03/1 as the Agenda for the Session.

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

COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

5. The Committee recalled that the Committee on Methods of Analysis and Sampling had proposed two amendments to the Procedural Manual in order to reflect the use of the criteria approach in the selection of methods of analysis in the framework of Codex.

6. The Committee endorsed the amendment to the current General Criteria for the Selection of Methods of Analysis Using the Criteria Approach (adopted in 2001) to extend the application of the criteria approach to Type II methods, in addition to Type III methods. The Committee also endorsed the proposal to add a new section Working Instructions for the Implementation of the Criteria Approach in Codex, for inclusion at the end of the Principles for the Establishment of Codex Methods of Analysis. These Proposed Amendments are presented in Appendix II.

COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

7. The Committee noted that the Committee on Additives and Contaminants had requested clarification as to whether its terms of reference allowed the consideration of analytical methods for both additives and contaminants.

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1 CX/GP 03/1
2 CX/GP 03/2
8. The Committee noted that the 26th Session of the Commission would consider the review of the mandates of Codex Committees and Task Forces, as part of the implementation of the Evaluation and therefore agreed that this question should not be discussed at this stage. The Committee also invited the CCFAC and CCMAS to cooperate in any revision that might be required in the future to their terms of reference, as they related to methods of analysis for additives and contaminants.

OTHER MATTERS

9. The Committee noted that updated information on the consideration of traceability/product tracing in other Codex Committees would be considered under Agenda Item 6. Consideration of Traceability/Product Tracing.

RISK ANALYSIS (Agenda Item 3)

DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS (AGENDA ITEM 3A)\(^3\)

10. The Committee recalled that the Draft Principles had been adopted at Step 5 by the 50th Session of the Executive Committee and circulated at Step 6 for comments. Some delegations noted that the text reflected the consensus achieved by the Committee on the main issues under consideration and stressed the importance of its finalization at the current session.

Scope

11. In paragraph 3, the Committee discussed whether the responsibility for risk assessment lies “normally” or in all cases with FAO and WHO expert bodies and consultations. The Committee noted that other international bodies, particularly IAEA and OIE cooperated with FAO and WHO to provide expert advice on specific issues, and therefore agreed that expert advice was “primarily” provided by FAO and WHO.

Risk Analysis – General Aspects

12. The Committee agreed to refer throughout the text to the “risk analysis” instead of the “risk analysis process” as risk analysis is defined as a process.

13. In paragraph 4, the Committee discussed the proposal of the Delegation of Brazil to reflect that risk analysis was a continuous process and should be evaluated in the light of new data. Some delegations pointed out that this should not be done continuously but when the review or evaluation of new data was necessary. It was agreed that changes in exposure scenarios (proposed by Brazil) would constitute new scientific data for this purpose. The Committee agreed that the risk analysis should be evaluated and reviewed “as appropriate”.

14. In paragraph 7 the Delegation of Brazil proposed to add a new paragraph on risk communication as this was a general aspect of risk analysis. Other delegations noted that the new text corresponded to paragraph 38, and that it was preferable to retain this as a detailed text under the section on Risk Communication. After some discussion the Committee decided to retain the current texts of both paragraph 7 and paragraph 38.

15. The delegation of India questioned the inclusion of the reference to precaution in paragraph 11 as it might be subject to various interpretations. However, the Committee retained the current text as it reflected a general approach to risk analysis and had been agreed as a result of detailed discussion in earlier sessions.

Risk Assessment Policy

16. The Committee made an editorial amendment to paragraph 14 for clarification purposes. Following a question of the delegation of Chile on the practical application of the recommendations on risk assessment policy, the Secretariat recalled that following the 22nd Session of the Commission (1997) Codex Committees had been asked to document their policies. It was also noted that the next session of the Commission would

\(^3\) ALINORM 03/33, Appendix II; CL 2002/38-GP; CX/GP 03/3 (comments of Canada, EC), CX/GP 03/4 - Add.1 (comments of Brazil); CRD 2 (comments of Colombia); CRD 6 (comments of India); CRD 12 (comments of Thailand); CRD 14 (comments of ICGMA); CRD 18 (comments of Mexico)
consider all matters regarding risk analysis under a specific agenda item, including how to proceed further if the Working Principles were adopted as a final text.

Risk Assessment

17. The Committee agreed to amend paragraph 17 to clarify the relationship between the risk assessment and risk assessment policy, and paragraph 18 to reflect that the declaration should refer to the independence of the experts in addition to their expertise and experience.

18. In paragraph 22, it was agreed that the data should be “relevant” and to add a reference to “analytical data”. The Delegation of Brazil proposed to delete the specific reference to data from developing countries in the first sentence, since the specific problems of those countries were clearly addressed in the third sentence of the paragraph. Other delegations however supported the specific reference to developing countries and the current text was retained.

19. In paragraph 25, the Committee discussed the proposal of the Delegation of Brazil to rephrase the reference to minority opinions. The Delegation of Canada proposed that the recording of minority opinions might be included in the first sentence along with the reference to any constraints, uncertainties and assumptions allowing for the impact of each of these on the final risk assessment to be considered. Other delegations pointed out that this would be difficult to achieve in practice. The Committee noted that according to the WHO Regulations for Expert Advisory Panels and Committees “any divergent views shall be recorded in or appended to the report” and agreed that consistency should be ensured with these regulations. After some discussions, the Committee confirmed its current approach and agreed that minority opinions should be recorded.

Risk Management

20. In paragraph 28 the Committee noted the proposal of the Delegation of Mexico to add a reference to “a documented risk profile” as an alternative to risk assessment, but retained the current text as risk management decisions should be based on a risk assessment, in application of the first Statement of the Statements of Principle Relating to the Role of Food Safety Risk Assessment.

21. The Committee noted that the Joint FAO/WHO Consultation on Principles and Guidelines for Incorporating Microbiological Risk Assessment in the Development of Food Safety Standards had agreed to replace the term “risk evaluation” by “preliminary risk management activities” and to refer to the “evaluation” of risk management options. Although some delegations indicated that the term “risk evaluation” could be retained, the Committee agreed to make the relevant changes throughout the section. The text of the current definition of “risk evaluation” was transferred to a footnote listing the “preliminary risk management activities” for the purpose of clarity.

22. The Delegation of Brazil, supported by several delegations, expressed the view that other legitimate factors could be taken into account “provided they do not create unjustified barriers to trade” and that the third sentence should be amended accordingly. Several other delegations pointed out that this was not necessary since the same paragraph referred to the Criteria for the Consideration of Other Factors Referred to in the Second Statement on Principles, that addressed this issue. It was also proposed to consider all questions related to trade barriers in paragraph 34. After an extensive discussion, the Committee agreed to retain the current text of paragraph 28.

23. In paragraph 33, the Committee discussed the proposal of the Delegation of India to refer to “the outcome of the risk assessment”. The Delegation of Canada pointed out that “preliminary risk management activities” had a broader scope and included consideration of risk assessment, and that the paragraph did not address risk assessment but the risk management framework. After some discussion, the Committee agreed to refer both to preliminary risk management activities and to risk assessment. It was also agreed to place this paragraph before the current paragraph 32.

24. In paragraph 34 concerning trade barriers, the Committee agreed that the measures selected should not be more trade-restrictive than necessary and amended the text accordingly. On the proposal of the Delegation

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of Morocco, the Committee also agreed to refer to “the Commission and its subsidiary bodies” instead of “risk managers” for clarification purposes in paragraphs 34 and 35.

**Risk Communication**

25. In paragraph 39, the Committee agreed that risk communication considered all information and opinion “required” for effective risk management. The Committee also agreed to delete the end of paragraph 39 and paragraph 40 as reciprocal communication was already covered in paragraph 38.

26. In paragraph 41 (now 40) the Committee discussed the approach to be taken for minority opinions following its earlier discussion under Risk Assessment. After an exchange of views, the Committee agreed that risk communication should indicate minority opinions “that had been expressed in the course of the risk assessment”.

27. The Committee agreed to address the issue of confidentiality in paragraph 42 (now 41) and inserted the text already used in paragraph 6.

**Definitions**

28. The Committee had an exchange of views on the question of “confidentiality” and recalled that an internationally accepted definition of that term existed in Article 39.3 of the WTO TRIPS Agreement. Some delegations proposed to include the TRIPS definition in the list of Codex definitions. Other delegations however noted that the context of the TRIPS Agreement was very different and that the TRIPS definition might not be appropriate in relation to food safety. The Committee also noted that FAO and WHO were in the process of organizing an expert consultation on scientific advice that would consider such questions as confidentiality. The Committee agreed to take note of the TRIPS definition but not to include a separate definition in the Working Principles. The Committee also agreed to delete the footnote on this issue.

29. The Committee deleted the definition of “Risk Evaluation” as decided earlier (see para. 21) and agreed to clarify the definition of Risk Assessment Policy. The other definitions were retained as proposed.

30. The Committee recalled its earlier decision that the Definitions, when finalized, would be included in the List of Definitions for the Purpose of the Codex Alimentarius in the Procedural Manual.

**Status of the Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius**

31. The Committee agreed to advance the Draft Working Principles to Step 8 for adoption by the 26th Session of the Codex Alimentarius Commission (see Appendix IV).

**PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY (AGENDA ITEM 3B)**

32. The Secretariat recalled that the 16th Session of the Committee had requested the Commission to clarify the scope of its (the Committee’s) work on risk analysis and whether the principles to be developed were intended exclusively for application in the framework of Codex, or by member governments, or both. The Commission at its 24th Session (2001) confirmed that the initial mandate of the Committee was to complete the principles of risk analysis within Codex as a high priority and also agreed that the Committee should develop guidance to governments subsequently, or in parallel, as appropriate in view of its programme of work (ALINORM 01/41, para. 75). The 17th Session (2002) of the Committee therefore agreed to initiate the elaboration of working principles intended for application by governments. The Executive Committee subsequently approved this as new work (ALINORM 03/3A, para. 64, Appendix III). A text was prepared by the Secretariat, based on the Proposed Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, that had been advanced to Step 5 (see Agenda Item 3a) and drawing upon the recommendations of the FAO/WHO Expert Consultations on Risk Analysis, Risk Management and Risk Communication.

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5 Codex Circular Letter 2002/39-GP; CX/GP 03/4 (Comments of Argentina, Brazil, Canada, Chile, New Zealand, El Salvador, South Africa, Thailand, United States, EC, CI, CRN, ICMSE, IFAH); Conference Room Documents containing comments from United States (CRD 9), Mexico (CRD 18), Europabio (CRD 4) and ICGMA (CRD 15).
The Committee discussed the overall structure and concept of the document. Most delegations expressed the view that the document should not contain excessive detail and should not be in the form of a manual on how to undertake risk analysis. Some delegations questioned the need for the document as other Codex committees had already developed (or were in the process of developing) risk analysis guidance that applied to member countries in specific areas of work (foods derived from biotechnology, food hygiene, etc). The Representative of FAO noted that FAO and WHO were also developing practical guidance in the form of a Manual on the application of risk analysis, especially for use by developing countries.

Some delegations questioned the need for such additional guidance as contained in the document, stating that it may not be of benefit to Members in view of their rights and obligations that were defined under the WTO Agreements. Other delegations were of the opinion that a relatively brief statement of general principles could be of assistance to Members and assist in the application of the scientific principles referred to in the SPS Agreement. One delegation pointed out that this would be useful in the cases where specific Codex standards or guidelines were not available. The Observer from the EC also stated that such a text could provide guidance to governments on the provisional establishment of measures as described in Article 5.7 of that Agreement, to ensure that these would not be arbitrary.

In this regard, several delegations pointed out that the Commission had no authority to interpret the provisions of the SPS Agreement, and that it was not appropriate for the Committee to do so.

The Observer from the EC also stated that since Members of the WTO were obliged to take into account risk assessment techniques developed by the relevant international organizations, Codex was under an obligation to develop such techniques for the use of its Members. The Representative of the WTO confirmed that guidance for governments on how to undertake risk assessments would be welcomed.

Delegations raised a number of areas of concern that needed to be addressed in the context of the document. These included: responding to potential consumers’ health situations where complete scientific data were not available; traceability/product tracing within a risk management system; ensuring fair practices in the food trade within the risk analysis framework; the protection of producers’ interests as well as consumers’ health; and the need to ensure that these issues could not be used as a form of disguised protectionism. The Committee did not explore any of these issues in detail.

Many delegations were of the view that it was indeed the mandate of the Commission to advise governments on the subject matters contained in the proposed draft working principles and drew attention to the fact that the Commission had explicitly agreed that the Committee should develop guidance to governments (See para. above). Attention was also drawn to paragraph 10 of the Strategic Framework 2003-2007, adopted by the Commission at its 24th Session that stated, *inter alia*, that “The CAC will also need to accord high priority to ongoing development of concepts and principles and the establishment of sound working principles for the application of risk analysis both at international and national levels”.

The Committee discussed possible modalities to proceed with the further elaboration of the document including the establishment of an inter-sessional working group that would work by email and internet and that would convene immediately prior to the next session of the Committee. Many members supported this proposal as a means of making the most rapid progress possible. However, many other members were of the opinion that the establishment of a working group would be to the disadvantage of developing countries due to their limited access to the Internet, problem of language, and the additional costs of attending meetings of such a working group even if held in close association with meetings of the Committee.

The Committee decided that, although the idea of a working group could be retained in principle, it would be premature to establish such a group on the basis of the present debate and in view of the fact that the current text was not sufficiently advanced for consideration by a working group. It requested the Codex Secretariat to redraft the present document on the basis of the following considerations:

- The points raised during the current debate, including the written comments submitted;
- Additional comments to be submitted by governments and interested international organizations within a reasonable timeframe;
- An analysis of existing work developed by Codex Committees and Task Forces that provided advice to governments on specific risk analysis issues, with a view to avoiding duplication of work and to identifying gaps; and
• An analysis of related work undertaken by FAO and WHO, including on the practical application of risk analysis.

41. Some delegations proposed that the document could be developed on a modular basis, with a relatively small set of core principles, to be supplemented over a period of time with additional annexes as consensus was reached on specific issues where more precise guidance was needed.

Status of the Proposed Draft Working Principles for Risk Analysis for Food Safety

42. On the basis of the above discussion, the Committee returned the text to Step 2 for re-drafting by the Codex Secretariat and subsequent circulation for further comments at Step 3.

PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS (Agenda Item 4) 6

43. The Committee recalled that its last session had returned the Proposed Draft Code to Step 3 for redrafting by the Secretariat in the light of the discussions held at the session and the written comments received. The Committee noted that the revised document incorporated the decisions made at the last session and the proposals made in written comments; however, few substantial changes had been introduced as some important issues remained to be addressed.

44. Several delegations expressed the view that before proceeding further with the consideration of the Code, several issues of principles remained to be addressed, as follows: the role and purpose of a code of ethics in the framework of Codex; its relationship with other Codex texts addressing similar issues, and in particular the Principles for Food Import and Export Inspection and Certification; and how it could address the specific problems of developing countries.

45. Following some questions concerning the status of different Codex texts under WTO and the need to seek clarification, the Secretariat recalled that the advice of the SPS Committee had been sought in 1998 and was recorded in the report of the 13th Session of the Committee (ALINORM 99/33, para. 50). In particular, the reply indicated that “the Agreement does not differentiate between “standards”, guidelines” and “recommendations”” and that “how a text would be applied depended on its substantive content rather than on the category of the text”.

46. As the Preamble had been discussed by the last session, the Committee considered the text section by section from Article 1 onwards, and made the following comments and amendments.

Article 1 - Objective

47. The Delegation of the United States expressed its concern with the term “standards of ethical conduct” used in the current Code and proposed to replace it with “advice” to governments, as the text was advisory. This position was supported by several delegations. Several other delegations proposed to refer to “guidance” since all Codex texts were advisory and the purpose of the Code was to provide guidance to governments. The Committee did not come to a conclusion and agreed to retain both “guidance” and “advice” in square brackets for further discussion. The sentence was also re-arranged for clarification purposes.

48. The Committee discussed the proposal of the Delegation of India to specify that the objective of the Code was also “to facilitate international trade” as it was an important aspect of the text, especially for developing countries. Several delegations supported this proposal as this was consistent with the purpose of the Code of Ethics. Several other delegations pointed out that the facilitation of trade might be a consequence of international standardization, but it was not included in the Codex mandate and should not be mentioned in the Code. The Observer from Consumers International expressed the view that the facilitation of trade was not within the mandate of Codex and that consideration of trade aspects should not detract from the main objective of Codex to ensure the protection of consumers’ health.

6 CX/GP 03/5; CX/GP 03/5-Add.1 (comments of Canada, IBFAN, ISDI); CRD 1 (comments of Colombia); CRD 3 (comments of ICGMA); CRD7 (comments of EC); CRD 10 (comments of India); CRD 13 (comments of Thailand)
49. The Committee agreed that the facilitation of trade could be addressed through the addition of additional text in the Preamble, based on paragraph 1 of the General Principles of the Codex Alimentarius.

50. The Committee agreed to amend Article 1.2 to clarify the use of the Code by member governments, by those engaged in international trade in food and by producers and consumers.

51. The Delegation of Bolivia proposed to include an additional sentence at the end of the Article to the effect that “the objective of the Code is to provide advice to governments so that their agricultural policies should have no negative consequences for the health of consumers”. The Delegation expressed the view that the experience of the last years had demonstrated that the agricultural policies of some countries had had a direct negative effect on the health of consumers. This position was supported by several delegations and an observer. Several other delegations pointed out that agricultural policy was outside the mandate of Codex and should not be mentioned in a Codex text. Although the Delegation of Bolivia requested a listing in the report of those delegations that had objected to these proposals, due to time constraints the Committee did not seek the views of all delegations. The Committee also noted the proposal of the Delegation of Chile to refer to “sanitary measures that were not based on a scientific basis”, in order to address the problem of unjustified barriers to trade. The Committee did not come to a consensus on this question.

52. The Delegation of Bolivia expressed its serious concern with the form in which the Proposed Draft Code was being considered, as it considered that the proposals presented by developing countries were not considered or were set aside.

**Article 2 – Scope**

53. The Committee agreed to retain the current Article 2.1 and to delete Article 2.2 as it duplicated the provisions of Article 1.1 concerning the Objectives.

**Article 3 - Definition**

54. The expression “for the purposes of this code” was deleted in view of the general nature of the definition. The Committee recalled that the definition of “food” was identical to the Codex definition in the Procedural Manual. However, several delegations indicated that further consideration was required to address the following questions: a scientific basis for the definition; the clarification of the term “human consumption” taking into account translation difficulties; the specific inclusion of “chewing gum” in the definition; the reference to substances that were obviously not covered.

55. The Committee agreed that the definition could not be amended at this stage only for the purposes of the Code, but that it should be considered more generally for the purposes of Codex. However, it should not delay consideration of the Code. The Committee therefore agreed that, in conjunction with the further revision of the Proposed Draft Code, the Secretariat would prepare a discussion paper considering the issues relating to the definition, if possible taking into account other existing definitions at the international level.

**Article 4 – General Principles**

56. In Article 4.1, several delegations proposed to replace the reference to “consumer protection” in the current text with “consumers' health protection” to reflect the main objective of Codex. Other delegations and observers expressed the view that “consumer protection” should be retained as it addressed protection against misleading practices in addition to food safety. After some discussion, the Committee agreed that international trade in food and food aid transactions should be conducted “in a manner that is consistent with the objectives of ensuring the protection of consumers’ health and fair practices in food trade, especially taking into account the Codex Principles for Food Import and Export Inspection and Certification” as it reflected the objectives of Codex.

57. Several delegations and observers proposed to delete Article 4.2 that referred to the obligations of Members under the WTO SPS and TBT Agreement, as it was not the role of Codex to make recommendations to governments concerning agreements concluded by other international organizations. In addition it was pointed out that not all members of Codex were members of the WTO, and that the rules applying to WTO membership and to Codex membership were different. It was also proposed to refer not only to the obligations but to the rights of Members under the Agreements. Some delegations stressed that clarification was required concerning the application of Article 4.2 in case of trade between members and
non-members of the WTO. The WHO Legal Counsel indicated that a solution would be either to delete the Article, or to clarify that it applied to trade “between member countries that are members of the WTO”.

58. The Observer from 49P, supported by some delegations, pointed out that a number of relevant international agreements existed and there was no reason for a specific reference to the WTO Agreements. The Observer also expressed the view that WTO should refer to Codex and not Codex to WTO. Other delegations expressed the view that such a reference was essential in the framework of a Code intended to address food import and export issues. It was also pointed out that there were other references to the WTO Agreements in the Proposed Draft Code in Articles 6 and 10. The Delegation of Canada noted that the general reference to bilateral or multilateral agreements currently included in Article 6.1.c) could provide a solution to this question.

59. The Representative of WTO informed the Committee that the WTO Agreements applied to members of WTO and that the inclusion or deletion of an additional Article in the Code would not affect the rights and obligations of members under the Agreements.

60. The Delegation of Sweden, supported by several delegations, proposed the following compromise text in order to address the question of member countries’ obligations under multilateral agreements:

“4.2 Signatories of bilateral and multilateral agreements, including the SPS and TBT agreements, relating to international trade in food should conform to the provisions of these agreements.”

61. The Delegation of Mexico, supported by other delegations, stressed the need to refer to the WTO Agreements to ensure that all members of Codex, even if they were not members of WTO, conducted trade according to the intent of the Agreements. The Delegation of Switzerland requested the Committee to include the proposal made by the Delegation of Sweden in the text currently under revision. The Secretariat proposed to refer to the “objectives” of the Agreements rather than to the obligations, as the latter were applicable only to WTO members. The Committee could not come to a consensus on Article 4.2 and agreed to retain the current text of the article in square brackets for further comments and consideration at the next session.

62. In Article 4.3, some delegations noted that the current reference to Article 5 (on specific requirements) was no longer relevant as Article 5 had been substantially amended, and that it should be replaced with a reference to Article 6.1, that addressed similar issues.

63. The Delegation of the United States pointed out that many of the terms used in Article 4.3 were not clear and proposed either to define them more clearly, in conjunction with the provisions of Article 6, or to delete the section. Several delegations and observers however expressed the view that this section was essential in order to define unethical practices. The Delegation of Mexico proposed to merge Articles 4.3 a) and b) in order to simplify and clarify the text.

64. The Committee had an extensive discussion on the inclusion of Article 4.3 f) concerning the remaining shelf life of food in international trade. The Delegation of India supported its inclusion with the addition of a specific percentage of the shelf-life. Several delegations supported the inclusion of provisions concerning shelf-life in order to address a problem that had been raised in earlier discussions and affected many developing countries. A few delegations questioned the practicability of this Article as the Code was directed to governments and it was not possible in practice to determine the destination of all exported foods and the shelf-life that would remain at the import stage. The Committee could not come to a conclusion on this question.

65. As a number of issues remained to be addressed in Article 4.3, the entire text was retained in square brackets for further discussion.

66. The Committee agreed to include in Article 4.4 the amendments proposed by the Delegation of Greece, speaking on behalf of the Member States of the European Union, and modified by the Delegation of Malaysia in order to clarify the text.

67. The Committee could not complete the discussion of the other Articles due to time constraints. Noting the difficulties that appeared in the revision of the text due to lack of consensus, the Chair asked the Committee to clearly express its willingness to pursue or not the revision of the Code in the framework of Codex.
68. The Delegation of Greece, speaking on behalf of the Member States of the European Union, indicated that the Code was essential to ensure consumer health protection and fair practices in food trade world-wide, and especially for developing countries. The Delegation also mentioned that community legislation already provides that these objectives are enforced by EU Member States. While supporting the revision of the Code, the Delegation of Greece raised questions about continuing the work on the Code if such work would concentrate on trade issues and not on the issues within the Codex mandate.

69. The Delegation of Australia expressed the view that the Code may no longer be necessary in view of major changes at the international level since its adoption, especially the conclusion of the WTO SPS Agreement and the development of Codex texts addressing issues of food import and export.

70. Many delegations expressed the view that the Code should be retained and revised as it was complementary to the Codex standards and related texts, and should provide recommendations to member countries on the ethical conduct of international trade. The Secretariat informed the Committee that the only Codex text covering food aid transactions was the Code of Ethics and that it was of great relevance in relation to food aid provided by the United Nations, especially the World Food Programme. The Secretariat also suggested that some element of the Strategic Framework (capacity building and participation) could usefully be considered for incorporation into the Code. It was also recalled that these issues were of great importance to developing countries.

71. Several delegations pointed out that the purpose of the Code should conform to the Codex objectives and that it was not intended to facilitate trade per se, as trade issues were the responsibility of WTO. Several other delegations pointed out that the Code should protect consumers and should not be used for the purpose of establishing trade barriers, and that it should address the concerns of developing countries.

72. The Committee agreed to proceed with the revision of the Code and agreed that the following suggestions made during the discussion should be taken into account in the redrafting: the revision of Article 3; the need to improve the structure, especially the relationship between Article 4, 5 and 6, that might be combined; the inclusion of Article 10 in the general considerations; and the relevance of Codex texts addressing food import and export inspection and certification.

Status of the Proposed Draft Revised Code of Ethics for International Trade in Food

73. The Committee agreed to return the text to Step 2 for redrafting by the Secretariat in view of the above discussion, circulation at Step 3 and consideration by the next session.

MEMBERSHIP IN THE CODEX ALIMENTARIUS COMMISSION OF REGIONAL ECONOMIC INTEGRATION ORGANIZATIONS (Agenda Item 5) 7

74. The Representative of the Legal Counsel of FAO recalled that the matter had been discussed on several previous occasions, including the Committee’s 16th Session in April 2001, 17th Session in April 2002, and the Commission in June/July 2001. The Committee’s last session (2002) noted that the Director-General of FAO would be seeking the views of the Committee on Constitutional and Legal Matters (CCLM), a Committee of the FAO Council, on the proposed amendments to the Rules of Procedure at its Seventy-fourth Session, 2 - 3 October 2002. The CCLM had found the proposed amendments to the Rules of Procedure of the Codex Alimentarius Commission to be consistent with the provisions governing the status of Member Organizations in FAO and, as requested, offered its views and appropriate guidance on the specific issues that had been raised, but noted that the question of participation of the Member Organization in the Executive Committee depended on the nature and functions of the latter and, as such, should be dealt with by the Codex Committee on General Principles and ultimately by the Commission. The CCLM also proposed some amendments to the proposals, and these were before the Committee for discussion. The report of the CCLM was endorsed by the Council of FAO at its Hundred and Twenty-third Session in November 2002.

75. The Observer from the European Community noted that since the previous discussions on this subject, new legislation had entered into force in the European Union that required the European Community to take into account the international food standards of Codex when introducing new or harmonizing existing food legislation. Also, in accordance with its obligations under the SPS and TBT Agreements concerning the

7 CX/GP 03/6; CX/GP 06/6-Add.1 (Information provided by the European Community); CRD.16 (Comments of ICGMA), CRD 19 (proposals from the United States), CRD 20 (proposed amendment to Rule II.8).
participation of Members of the WTO in the international standards-setting bodies, the European Community that is a member of WTO was looking forward to meeting these obligations as a Member of the Codex Alimentarius Commission.

76. The Observer from the EC submitted to the Committee the following declaration concerning the participation of the European Community in the Executive Committee:

Declaration by the European Community concerning Participation in the Executive Committee of the Codex Alimentarius Commission

Although the Committee on Constitutional and Legal Matters of the FAO considered that the participation of a Member Organization in the Executive Committee depended on the functions and activities of this Committee, the European Community declares formally that it gives up in every case the possibility of taking part in the proceeding of the Executive Committee when a Member State of the European Community is elected for the Region of Europe and that an agenda item would be of European Community competence.

77. In response to a question, it was noted that the question referred to in the above Declaration would not arise if a non-member state of the European Union was elected to the Executive Committee.

78. In response to questions raised by Members, the Observer from the European Community assured the Committee that the proposals guaranteed that there would be no additional rights or privileges accrued to members of Regional Economic Integration Organizations as a result of the changes to the Rules. The Committee welcomed the CCLM’s endorsement of the proposal to limit voting rights to the number of members of Regional Economic Integration Organizations present at the time a vote was taken (Proposed Rule II.3). At the request of several delegations, a parallel provision was drafted and included in Proposed Rule II.8 on the matter of quorum.

79. Also in response to a question, the Committee noted that where the membership of a Regional Economic Integration Organization included Members of two or more Codex regions, the Organization could participate in all relevant regional Codex Committee meetings and at these meetings the number of votes to be exercised by the Regional Economic Integration Organization would not exceed the number of member states in each region (counted separately) and not the total membership of the organization.

80. Several delegations, while welcoming the changes allowing for the membership of Regional Economic Integration Organizations in Codex, stated that there were practical considerations to be taken into account, especially in the case of mixed competence between the Regional Economic Integration Organization and its member states. It was pointed out that this would put an additional burden on the Chairpersons of Codex meetings in their efforts to assess the consensus present.

81. In this regard the Delegation of the United States, supported by the Delegation of Australia, presented the following amendments to the proposals to clarify the question of competence:

Changes Proposed by the United States to the Proposed Amendments to the Rules of Procedure

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

II.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. Should the areas of respective competence between the Member Organization and its Member States change, the Member
Organization and its Member States will declare the scope and timing of such change to the Commission and each subsidiary body in which a Member Organization is entitled to participate.

II.7. In cases where an agenda item covers both matters in respect of which competence has been transferred to the Member Organization and matter which lie within the competence of its Member States, both the Member Organization and its Member States may participate in the discussions with respect to the specific matters on which each has competence. 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.

82. Several delegations stated their opposition to the changes to the proposed amendments. Concern was also expressed at the submission of such proposals at this stage, and as the proposals seemed to be contradictory to the expressed wishes of the delegation presenting the proposals, to preserve the rich diversity of opinion in debates within Codex.

83. Some delegations stated that if the proposals were aimed at assisting delegations and Chairpersons in understanding how to evaluate consensus when the competence between the Regional Economic Integration Organization and its member states was mixed, then this might be better addressed by developing appropriate guidelines.

Status of the Proposed Amendments to the Procedural Manual

84. The Committee agreed to transmit the proposed amendments as contained in Appendix III of this report to the Commission for its consideration. It noted that this section of the present report would also be attached to the working paper to be submitted to the Commission.

CONSIDERATION OF TRACEABILITY/PRODUCT TRACING (Agenda Item 6)\(^8\)

85. The Secretariat introduced the paper, which had been prepared on the basis of discussions that had taken place at meetings of the Regional Coordinating Committees, pursuant to the decision of the 17\(^{th}\) Session of the Committee (ALINORM 03/33, paras. 5-13). The document contained several options that the Committee might wish to take in pursuit of this matter.

86. The Delegation of Switzerland provided the Committee with an overview of the status of work being carried out by the Working Group on traceability/product tracing of the Codex Committee on Food Import and Export Inspection and Certification Systems.

87. In relation to the text under discussion, the many delegations stated that a system of traceability/product tracing that would serve multiple purposes would most likely be costly, especially for producers and small-scale enterprises in developing countries. Most of these countries expressed their willingness to consider traceability/product tracing as a food safety risk management measure but were of the opinion that the system should not be extended to non-food safety related areas such as the verification of authenticity or for labelling purposes. Many of these delegations stated that they could not support work in this area other than consideration of the definition, noting that the general ISO definition was not appropriate for Codex purposes. Several of these delegations supported the technical work currently underway in the Codex Committee on Food Import and Export Inspection and Certification Systems. Some delegations and observers supported the use of traceability/product tracing for a food safety objective (i.e. as a SPS measure) as well as for a non-food safety objective (i.e. as a TBT measure) such as for consumer information.

88. Many other delegations supported the elaboration of a Codex definition as well as for Codex guidelines for both purposes, taking into account the work of the Codex Committee on Food Import and Export Inspection and Certification Systems and in cooperation with the Codex Committee on Food Hygiene and the Codex Committee on Food Labelling within their respective mandates. They agreed that the use of a system of traceability/product tracing should be consistent with the provisions of the WTO SPS and TBT Agreements and be not more trade-restrictive than necessary.

89. Although some delegations questioned the necessity of developing a definition for traceability/product tracing, only a few delegations expressed their opposition to the development of a definition. Some delegations noted that the same terminology was used to describe very different systems.

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\(^8\) CX/GP 03/7; CRD 8 (Comments of the European Community).
90. Many delegations were of the opinion that the options contained in the Secretariat paper could form the basis of future work by the Committee in regard to the definition, guidelines for use in risk management and the determination of product origin and authenticity. Many other delegations, while supporting the need for work on a definition, did not support the need for other work. Some delegations noted that the costs of such systems should be borne by all concerned, but that certification and auditing bodies could also underwrite these systems.

91. A number of delegations stated that traceability/product tracing would be more difficult for developing countries to implement. Several of these delegations stated that the provisions of current Codex texts that were aimed at ensuring food safety and the protection of consumers’ health were sufficient. In their opinion, even “trace-back” was not practical for developing countries where most agricultural production was on small farms. These delegations stated that economic considerations had to be taken into account and that traceability/product tracing could only be considered as an optional tool for those industries that could afford to use it.

92. Some delegations noted that the HACCP System required similar record-keeping and provided the tools necessary for food safety risk management. These delegations were of the opinion that it was premature to undertake work on either a definition or guidelines for traceability/product tracing before the technical work of the Committees cited above was completed. In this regard, one observer pointed out that the Codex General Principles of Food Hygiene provided adequate protection of consumers’ health and already contained the elements of record-keeping that were necessary to establish a traceability/product tracing system that would be applicable to all food products throughout the food chain as pointed out in the Secretariat’s paper.

93. Several delegations were of the opinion that this system should only be used as a risk management option on a voluntary basis and that there should be a cost/benefit analysis before proceeding with the use of traceability/product tracing. The view was also expressed that if a cost/benefit analysis was to be carried out then the costs of not implementing the traceability system should also be analyzed. The Delegation of India, supported by several delegations, stated that traceability/product tracing should be well defined and should be applicable only to processed foods and exclude primary foods and processes. It was further stated that it should be used only for the purposes of product recall as a management option on a case-by-case basis, upon the application of strict criteria set out in paragraph 81 of the report of the FAO/WHO (Codex) Regional Coordinating Committee for Asia held in September, 2002.

94. Several delegations stated their view, in addition to the views noted above, that the FAO/WHO (Codex) Regional Committee for North America and the South West Pacific had noted that once a system of traceability/product tracing had been installed it could be used for various purposes.

95. In relation to the use of traceability/product tracing to determine the authenticity of products, several delegations stated that, although there may be such a need, this would have to be consistent with the WTO TBT Agreement. Several delegations and observers pointed out that, as an example, state-regulated systems of traceability/product tracing for the determination of product authenticity would benefit developing countries wishing to market and export “organic” foods. It was noted that such regulations were in force in some developed countries. However, many delegations stated that such a system should not be extended to the regulation of commercial “Identity Preservation”.

96. Some delegations and observers were of the opinion that the use of traceability/product tracing for these purposes was a commercial response to consumer demand and could therefore be left to market forces to determine when and how the system should be applied, as was already the case.

**Status of the Discussion**

97. The Committee concluded that there was sufficient support only to proceed with the development of a definition of “traceability/product tracing” for Codex purposes and agreed to establish an open-ended electronic working group under the direction of the Delegation of France to develop a draft for the consideration of the next regular session of the Committee.

98. In view of the divergence of opinions on the other options contained in the Secretariat’s paper, the Committee was unable to arrive at a consensus opinion, but agreed to keep the matter under review in the light of the ongoing work in the Codex Committee on Food Import and Export Inspection and Certification Systems.
GUIDELINES FOR COOPERATION WITH INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 7)\(^9\)

99. The Committee recalled that its last session had considered a document prepared by the Secretariat, following the decision of the 24\(^{th}\) Session of the Commission to develop guidance on cooperation with other International Intergovernmental Organizations (IGO\(s\)) on the elaboration of Codex Standards and Related Texts (ALINORM 01/41, para. 31). The Committee had agreed that the document should be revised in the form of guidelines by the Secretariat for further consideration.

100. The Secretariat indicated that the proposed guidelines addressed three types of cooperation: a) the elaboration of a joint standard or related text with a cooperating organization; b) the elaboration of a Codex standard or related text by a cooperating organization on behalf of the CAC; or c) substantial cooperation at the initial drafting stages of a Codex standard or related text. Specific conditions for cooperation with such organizations had been included in the Guidelines, in view of the concerns expressed by member countries in earlier discussions. The Secretariat noted that the proposed Guidelines were closely related to Objective 3 of the Strategic Framework and to the recommendations of the Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and Other FAO and WHO Work on Food Standards as regards cooperation with international organizations.

101. The Observer from the OIE informed the Committee of ongoing consultations between OIE and Codex through the OIE Working Group on Food Safety in order to coordinate work on animal production food safety and to strengthen joint activities. The Observer welcomed the establishment of procedures that would allow Codex to formalize the cooperation between the organizations, and proposed to include a new clause concerning the possibility for the Codex Alimentarius Commission to participate in the elaboration process of OIE standards, where necessary.

102. The Observers from IIR and OIV indicated that as international intergovernmental organizations that participated actively in Codex work, they supported the development of the guidelines.

103. The Delegation of Malaysia stated that it could support the first type of cooperation on joint standards provided the decision to elaborate such standards was taken by the Commission on a case-by-case basis; objected to the second type of cooperation as Codex should not delegate the elaboration of standards to other organizations; and objected to cooperation at the initial drafting stages in view of the importance of the first draft in the further development of standards. The Delegation was also of the opinion that the procedures to be followed by a joint body should be the Codex procedures. This position was supported by several delegations. The Secretariat noted that the question of procedures would be determined on a case-by-case basis by the Commission and by the cooperating intergovernmental organization.

104. The Delegation of Australia supported the establishment of the guidelines as proposed for the three types of cooperation. Several delegations expressed their support in principle for cooperation with international organizations and for the first and third types of cooperation, but expressed concerns as to the second proposal and the possibility for the Commission to delegate its work to other organizations. The main objections put forward related to the different procedures applied by other organization; their degree of transparency; and the difficulties that developing countries might face to participate in the work of other organizations.

105. Some delegations expressed the view that the title of the Guidelines referred only to intergovernmental organizations, while the second paragraph of the preamble also referred to non-governmental organizations and proposed to change the title to refer only to “international organizations” if the text was intended to apply to both types of organizations. Other delegations proposed to delete the reference to NGOs in the second bullet of the Preamble. The Secretariat noted that the substantive text was intended to apply only to intergovernmental organizations, but that the preamble referred to the Commission’s mandate and responsibility to cooperate with both types of international organizations (Article 1.b of the Statutes). The Committee did not come to a conclusion on this question.

106. The Committee agreed that in view of the concerns put forward, the reference to the second type of cooperation could be deleted and also noted that as the third type of cooperation largely reflected existing cooperation practices, it might not be essential to retain it at this stage. The Committee therefore discussed

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\(^9\) CX/GP 03/8, CRD 5 (comments of Malaysia); CRD 11 (comments of India); CRD 17 (comments of ICGMA)
whether it would be possible to send an amended text including only the first type of cooperation for consideration by the Commission in order to facilitate further cooperation with other IGOs. Several delegations indicated that these proposals required careful consideration in view of their importance and it was preferable to consider the text further at the next session before taking a decision.

107. The Committee recognized that due to time constraints, it was not possible to discuss the text in detail at this stage and to come to a conclusion on a final text that could be forwarded to the Commission. The Committee agreed that the Secretariat would redraft the proposed Guidelines in the light of the comments made in the discussion, for further consideration at the next session.

OTHER BUSINESS, FUTURE WORK, AND DATE AND PLACE OF NEXT SESSION
(Agenda Item 8)

FOLLOW-UP TO THE JOINT FAO/WHO EVALUATION OF CODEX ALIMENTARIUS AND OTHER FAO AND WHO WORK ON FOOD STANDARDS

108. The Committee noted that the 25th (Extraordinary) Session of the Commission had agreed that the implementation of the results of the Joint FAO/WHO Evaluation of Codex Alimentarius and Other FAO and WHO Work on Food Standards should be undertaken expeditiously. As a result Codex Circular Letter CL 2003/8-CAC had been issued to obtain comments from governments and interested international organizations on the report of the Evaluation, to allow the Secretariat to prepare options and strategies for consideration by the 26th Session of the Commission for action in the following areas:

- Review of the Codex Committee structure and mandates of Codex Committees and Task Forces, including Regional Committees (Recommendations 16, 17);
- Review of the functions of the Executive Committee (Recommendations 9, 10);
- Improved processes for standards management (Recommendations 18, 20, 23, 24);
- Review of the Rules of Procedure and other procedural matters (Recommendations 8, 22, 23, 24, 26, 27, 28); and
- Implementation of other recommendations not addressed above.

109. The Committee was of the opinion that the implementation of the recommendations related to a significant number of the matters referred to above could fall within the mandate of the Committee on General Principles. In this regard, a number of delegations made reference to the generous offer made by the Delegation of France at the 25th Session of the Commission, and confirmed by Mr. Dutreil in his opening remarks, to convene one or more additional sessions of the Committee to deal with such matters as may be referred to it by the Commission as a matter of priority.

110. An Observer Organization expressed the view that if the Commission were to consider extra sessions of the Committee then this should be closely linked to the use of the FAO/WHO Trust Fund in order to ensure adequate participation of developing countries.

111. The Committee looked forward to the decisions of the 26th Session of the Commission in this matter.

FUTURE WORK AND DATE AND PLACE OF NEXT SESSION

112. The Committee noted that its immediate future work and the priorities to be assigned to that work would depend on the outcome of the 26th Session of the Commission, especially in regard to the follow-up of the Evaluation.

113. The Committee was informed that tentative arrangements had been made to convene a special session of the Committee in Paris, 17-21 November 2003, should the need arise, with the next regular session of the Committee being scheduled for 3-7 May 2004, also in Paris.
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PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL

1. AMENDMENT TO THE GENERAL CRITERIA FOR THE SELECTION OF METHODS OF ANALYSIS USING THE CRITERIA APPROACH

In the case of Codex Type II and 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.

2. WORKING INSTRUCTIONS FOR THE IMPLEMENTATION OF THE CRITERIA APPROACH IN CODEX

(for inclusion at the end of the Principles for the Establishment of Codex Methods of Analysis after the above General Criteria)

Any Codex Commodity Committee may continue to propose an appropriate method of analysis for determining the chemical entity, or develop a set of criteria to which a method used for the determination must comply. In some cases a Codex Commodity Committee may find it easier to recommend a specific method and request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to “convert” that method into appropriate criteria. The Criteria will then be considered by the CCMAS for endorsement and will, after the endorsement, form part of the commodity standard replacing the recommended method of analysis. If a Codex Commodity Committee wishes to develop the criteria by itself rather than allowing the CCMAS to do so, it should follow instructions given for the development of specific criteria as outlined below. These criteria must be approved for the determination in question.

However, the primary responsibility for supplying methods of analysis and criteria resides with the Commodity Committee. If the Commodity Committee fails to provide a method of analysis or criteria despite numerous requests, then the CCMAS may supply an appropriate method and “convert” that method into appropriate criteria.

The minimum “approved” Codex analytical characteristics will include the following numeric criteria as well as the general criteria for methods laid down in the Analytical Terminology for Codex Use (see page 66):

- precision (within and between laboratories, but generated from collaborative trial data rather than measurement uncertainty considerations)
- recovery
- selectivity (interference effects etc.)
- applicability (matrix, concentration range and preference given to ‘general’ methods)
- detection/determination limits if appropriate for the determination being considered
- linearity

CCMAS will generate the data corresponding to the above criteria.
Conversion of Specific Methods of Analysis to Method Criteria by the CCMAS

When a Codex Commodity Committee submits a Type II or Type III method to CCMAS for endorsement, it should also submit information on the criteria listed below to enable the CCMAS to convert it into suitable generalized analytical characteristics:

- accuracy
- applicability (matrix, concentration range and preference given to 'general' methods)
- detection limit
- determination limit
- precision; repeatability intra-laboratory (within laboratory), reproducibility inter-laboratory (within laboratory and between laboratories), but generated from collaborative trial data rather than measurement uncertainty considerations
- recovery
- selectivity
- sensitivity
- linearity

These terms are defined in the Analytical Terminology for Codex Use (see page 66), as are other terms of importance.

The CCMAS 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 CCMAS and will be inserted in the appropriate Codex Commodity Standard.

In addition, the CCMAS will identify numeric values for the criteria for which it would wish such methods to comply.

Assessment of the Acceptability of the Precision Characteristics of a Method of Analysis

The calculated repeatability and reproducibility values can be compared with existing methods and a comparison made. If these are satisfactory then the method can be used as a validated method. If there is no method with which to compare the precision parameters then theoretical repeatability and reproducibility values can be calculated from the Horwitz equation. (M. Thompson, Analyst, 2000, 125, 385-386).

Additions to ANALYTICAL TERMINOLOGY FOR CODEX USE¹

Terms to Be Used in the Criteria Approach

Detection Limit

The detection limit is conventionally defined as field blank + 3σ, where σ is the standard deviation of the field blank value signal (IUPAC definition).

However, an alternative definition which overcomes most of the objections to the above approach (i.e. the high variability at the limit of measurement can never be overcome) is to base it on the rounded value of the reproducibility relative standard deviation when it goes out of control (where 3 σR = 100%; σR = 33%, rounded to 50% because of the high variability). Such a value is directly related to the analyte and to the measurement system and is not based on the local measurement system.

¹ These Definitions are proposed on an interim basis: they are subject to modification as a result of further harmonization.
Determination limit

As for detection limit except that $6\sigma$ or $10\sigma$ is required rather than $3\sigma$.

However, an alternative definition that corresponds to that proposed for the detection limit is to use $\sigma_R = 25\%$. This value does not differ much from that assigned to the detection limit because the upper limit of the detection limit merges indistinguishably into the lower limit of the determination limit.

Recovery

Proportion of the amount of analyte present or added to the test material which is extracted and presented for measurement.

Selectivity

Selectivity is the extent to which a method can determine particular analyte(s) in mixtures or matrices without interferences from other components.

Selectivity is the recommended term in analytical chemistry to express the extent to which a particular method can determine analyte(s) in the presence of interferences from other components. Selectivity can be graded. The use of the term specificity for the same concept is to be discouraged as this often leads to confusion.

Linearity

The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quality of analyte to be determined in the laboratory sample. This proportionality is expressed by an a priori defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model can be applied with a known confidence level (generally taken to be equal to 1%).
PROPOSED AMENDMENTS TO THE RULES OF PROCEDURE OF THE CODEX ALIMENTARIUS COMMISSION

Membership of Regional Economic Integration Organizations

Add a new Rule 1.3 to the Rules of Procedure, and re-number current Rule 1.3 as Rule 1.4:

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

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

4. A Member Organization shall not be eligible for election or designation, nor to hold office in the Commission or any subsidiary body. A Member Organization shall not participate in voting for any elective places in the Commission and its subsidiary bodies.

5. Before any meeting of the Commission or a subsidiary body of the Commission in which a Member Organization is entitled to participate, the Member Organization or its Member States shall indicate in writing which, as between the Member Organization and its Member States, has competence in respect of any specific question to be considered in the meeting and which, as between the Member Organization and its Member States, shall exercise the right to vote in respect of each particular agenda item. Nothing in this paragraph shall prevent a Member Organization or its Member States from making a single declaration in the Commission and each subsidiary body in which a Member Organization is entitled to participate for the purposes of this paragraph, which declaration shall remain in force for questions and agenda items to be considered at all subsequent meetings, subject to such exceptions or modifications as may be indicated before any individual meeting.

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.³

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 and are present at the time the quorum is sought, to the extent that it is entitled to vote under the relevant agenda item."

Renumber the subsequent Rules accordingly.

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² The word ‘decisions’ should be understood to mean both voting and situations where a decision is taken by consensus.
³ The above is without prejudice to the question of whether or not the views of the party not having the right to vote shall be reflected in the report of the meeting. Where the views of the party not having the right to vote are reflected in the report, the fact that they are the views of the party not having the right to vote shall also be reflected in the report.
DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN THE FRAMEWORK OF THE CODEX ALIMENTARIUS

(At Step 8 of the Procedure)

SCOPE

1) These principles for risk analysis are intended for application in the framework of the Codex Alimentarius.

2) The objective of these Working Principles is to provide guidance to the Codex Alimentarius Commission and the joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis.

3) Within the framework of the Codex Alimentarius Commission and its procedures, the responsibility for providing advice on risk management lies with the Commission and its subsidiary bodies (risk managers), while the responsibility for risk assessment lies primarily with the joint FAO/WHO expert bodies and consultations (risk assessors).

RISK ANALYSIS - GENERAL ASPECTS

4) The risk analysis used in Codex should be:
   − applied consistently;
   − open, transparent and documented;
   − conducted in accordance with both the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account and the Statements of Principle Relating to the Role of Food Safety Risk Assessment; and
   − evaluated and reviewed as appropriate in the light of newly generated scientific data.

5) The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission, each component being integral to the overall risk analysis.

6) The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.

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

8) The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

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

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2 For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”)
10) When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.\(^3\)

11) Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

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

**Risk Assessment Policy**

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

14) Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

15) The mandate given by risk managers to risk assessors should be as clear as possible.

16) Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

**RISK ASSESSMENT\(^4\)**

17) The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

18) Experts responsible for risk assessment should be selected in a transparent manner on the basis of their expertise, experience, and their independence with regard to the interests involved. The procedures used to select these experts should be documented including a public declaration of any potential conflict of interest. This declaration should also identify and detail their individual expertise, experience and independence. Expert bodies and consultations should ensure effective participation of experts from different parts of the world, including experts from developing countries.

19) Risk assessment should be conducted in accordance with the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and should incorporate the four steps of the risk assessment, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization.

20) Risk assessment should be based on all available scientific data. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

21) Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

22) Risk assessment should seek and incorporate relevant data from different parts of the world, including that from developing countries. These data should particularly include epidemiological surveillance data, analytical and exposure data. Where relevant data are not available from developing countries, the Commission should request that FAO/WHO initiate time-bound studies for this purpose. The conduct of the risk assessment

\(^3\) Statement adopted by the 24th Session of the Commission (ALINORM 01/41, paras. 81-83)

\(^4\) Reference is made to the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*
should not be inappropriately delayed pending receipt of these data; however, the risk assessment should be reconsidered when such data are available.

23) Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

24) Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

25) The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

26) The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

RISK MANAGEMENT

27) While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.

28) Risk management should follow a structured approach including preliminary risk management activities, evaluation of risk management options, monitoring and review of the decision taken. The decisions should be based on risk assessment, and taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles.

29) The Codex Alimentarius Commission and its subsidiary bodies, acting as risk managers in the context of these Working Principles, should ensure that the conclusion of the risk assessment is presented before making final proposals or decisions on the available risk management options, in particular in the setting of standards or maximum levels, bearing in mind the guidance given in paragraph 10.

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

31) The risk management process should be transparent, consistent and fully documented. Codex decisions and recommendations on risk management should be documented, and where appropriate clearly identified in individual Codex standards and related texts so as to facilitate a wider understanding of the risk management process by all interested parties.

32) The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

33) Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

5 For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

6 These criteria have been adopted by the 24th Session of the Commission (see Procedural Manual 12th Edition - Appendix, page 165)
34) In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.

35) Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers’ health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.

36) Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

RISK COMMUNICATION

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

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

39) Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

40) Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The need for specific standards or related texts and the procedures followed to determine them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para.25).

41) The guidance on risk communication in this document is addressed to all those involved in carrying out risk analysis within the framework of Codex Alimentarius. However, it is also of importance for this work to be made as transparent and accessible as possible to those not directly engaged in the process and other interested parties while respecting legitimate concerns to preserve confidentiality (See para. 6).
DEFINITIONS

Definitions included in the Procedural Manual

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

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

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

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

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

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

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

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

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

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

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

Other Definitions

Risk Assessment Policy: Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk profile
The description of the food safety problem and its context

Risk estimate
The quantitative estimation of risk resulting from risk characterization.