codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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ALINORM 05/28/33

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-eighth Session Rome, Italy, 4 – 9 July 2005

REPORT OF THE TWENTY-FIRST (EXTRAORDINARY) SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES

Paris, France, 8-12 November 2004

Note: This document incorporates Circular Letter CL 2004/55-GP

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CX 4/10

CL 2004/55-GP November 2004

- 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 21st (Extraordinary) Session of the Codex Committee on General Principles (ALINORM 05/28/33)

MATTERS FOR ADOPTION BY THE $\mathbf{28}^{\mathrm{TH}}$ SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft Principles at Step 8 of the Procedure

- 1. Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants (para. 24, Appendix II)
- 2. Draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (para. 25, Appendix III)

Proposed Amendments to the Procedural Manual

- 3. Draft Revised Criteria for the Establishment of Work Priorities (para. 36, Appendix IV)
- 4. Draft Guidelines on Physical Working Groups and the Draft Guidelines on Electronic Working Groups (paras. 47 and 54, Appendices V and VI)
- 5. Draft Revised Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission (para. 81, Appendix VII)
- 6. Draft Guidelines for Cooperation with International Intergovernmental Organizations (para. 104, Appendix VIII)
- 7. Draft Amendment to the Rules of Procedure on the Right to Address the Chair (para. 109, Appendix IX)

Governments and international organizations wishing to submit comments on the above amendments 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 <u>before 15 March 2005</u>.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 21st (Extraordinary) Session of the Codex Committee on General Principles are as follows:

Matters for adoption by the Commission:

The Committee:

- endorsed and agreed to forward to the Commission the *Draft Risk Analysis Principles* Applied by the Committee on Food Additives and Contaminants (para. 24, Appendix II) and the *Draft CCFAC Policy for Exposure Assessment of Contaminants and Toxins in* Foods or Food Groups (para. 25, Appendix III);
- agreed to forward to the Commission the *Draft Revised Criteria for the Establishment of Work Priorities* (para. 36, Appendix IV);
- agreed to forward to the Commission the *Draft Guidelines on Physical Working Groups* and the *Draft Guidelines on Electronic Working Groups* (paras. 47 and 54, Appendices V and VI);
- agreed to forward to the Commission the Draft Revised Principles concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission (para. 81, Appendix VII);
- agreed to forward to the Commission the Draft Guidelines for Cooperation with International Intergovernmental Organizations (para. 104, Appendix VIII);
- agreed to forward to the Commission the Draft Amendment to the *Rules of Procedure* on the Right to Address the Chair (para. 109, Appendix IX).

Other Matters of Interest to the Commission:

The Committee:

- agreed to seek the guidance of the Commission on whether and how the Commission should pursue the consideration of the interpretation of the term "delegate" under Rule IV.1 of the Rules of Procedure (para. 132);
- agreed to inform the Commission of its discussions on co-chairmanship (paras. 56-59); facilitators (paras. 60-61); and webcasting of the sessions of the Executive Committee (paras. 62-69);
- agreed to consider further at its next session the amendments to abolish the provisions concerning acceptance of Codex standards (para. 122);
- agreed to consider further the clarification of the duration of the term of the Members of the Executive Committee at its next session (para. 117).

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INTRODUCTION

1) The Codex Committee on General Principles held its Twenty-first (Extraordinary) Session in Paris, France, from 8 to 12 November 2004 at the kind invitation of the Government of the French Republic. The Session was chaired by Professor Michel Thibier, Director-General of Education and Research, Ministry of Agriculture, Food, Fisheries and Rural Affairs. The session was attended by 149 delegates representing 59 members and 14 observer organizations. A full list of participants, including the Secretariat, is attached as Appendix I.

OPENING

2) The session was opened by Mr Guillaume Boudy, Directeur adjoint de Cabinet, who welcomed participants on behalf of Mr Hervé Gaymard, Minister of Agriculture, Food, Fisheries and Rural Affairs. Recalling the dual objective of Codex to protect consumers' health and to ensure fair practices in the international food trade, Mr. Boudy highlighted the role and responsibilities of the Codex Alimentarius in the establishment of international standards on agricultural and food products. Mr Boudy underlined the fact that the Committee on General Principles which is hosted by France since 1965, met frequently during the last two years as two extraordinary sessions were added (in November 2003 and November 2004) in order to take into account the recommendations of the Commission following the *Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and Other FAO and WHO Work on Food Standards*. He also stressed the importance of streamlining the operation of the Codex system, improving the efficiency and transparency of the process and enhancing cooperation with other intergovernemental organizations. Mr Boudy wished all success to delegates in this important work.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

3) The Committee agreed that the progress report of the working group on the *Proposed Draft Working Principles for Risk Analysis addressed to governments*, which met prior to the present session of the Committee, would be made orally under Other Business.

4) The Committee adopted the Provisional Agenda as presented in document CX/GP 04/21/1 as the Agenda for the session.

5) The Committee noted the declaration of division of competence between the European Community and its Member States according to Rule II.5 of the Rules of Procedure of the Commission 2 .

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2)³

CODEX ALIMENTARIUS COMMISSION

6) The Committee recalled that the 27th Session of the Commission had adopted the amendments to the *Procedures for the Elaboration of Codex Standards and Related Texts*, and had referred the comments made by India to the Committee on General Principles. The Commission had also asked the Committee to consider the possibility of developing a definition of "consensus".

7) The Delegation of India, referring to its written comments (CRD 2), made several proposals to amend the Elaboration Procedures, and in particular that the omission of Steps 6 and 7 of the Procedure be decided by "consensus" rather than by "a two thirds majority of votes cast", in view of the need to work by consensus in the Commission. The Delegation also proposed a definition of "consensus" for further consideration.

8) The Delegation of Malaysia supported the views of India that the role of the Executive Committee should not extend, in the framework of the Critical Review, to consideration of draft standards and related texts submitted to the Commission by its subsidiary bodies.

¹ CX/GP 04/21/1; Conference Room Document 1 (comments by India)

² CRDs 8, 9, and 10.

³ CX/GP 04/21/2, CRD 2 (comment of India), CRD 6 (comments of Consumers International), CRD 12 (comments of Japan), CRD 13 (comments of Malaysia)

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9) As regards the question of "consensus", several delegations expressed the view that the establishment of a definition should not be considered for the moment, and that it would be preferable to apply the *Measures to Facilitate Consensus* adopted by the 26^{th} Session of the Commission throughout Codex. Other delegations stressed the need for a definition of "consensus", or a clear understanding of its meaning for the purposes of Codex, in order to facilitate the decision making process and, in particular, to assist Codex chairs in their task.

10) The Committee agreed with the proposal of the Chairperson that no new work should be undertaken on a definition of "consensus" at this stage, until more experience had been gained in the application of the *Measures to Facilitate Consensus*. The Committee agreed that the detailed comments proposed by the Delegation of India on the Elaboration Procedure be considered by the next session of the Committee on General Principles.

COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

11) The Committee recalled that its 20th Session had considered the *Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants* and the *Draft Policies for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups* forwarded by the Committee on Food Additives and Contaminants. The Committee had not been able to come to a conclusion on their endorsement and agreed that they would be considered further at its 21st (Extraordinary) Session.

Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants

12) Some delegations expressed the view that additional guidance should be developed to facilitate the review of the documents on risk analysis forwarded by Codex Committees to the Committee on General Principles, and asked for some clarification on how to proceed with the review of the present document. The Secretariat recalled that the mandate given to the Committee by the Commission was to ensure as much consistency as possible between the guideline texts and especially between the texts developed by Codex Committees and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

13) The Committee agreed that changes relating to consistency with the adopted *Working Principles* and other general issues could be introduced directly into the document, while technical comments in the area of additives and contaminants would need to be referred back to the CCFAC. The Committee considered the Draft Risk Analysis Principles section by section and made the following amendments related to the general aspects of risk analysis.

14) The Committee noted that the use of tenses was not consistent throughout the document and did not correspond to current practice in similar texts, and agreed that the principles should be worded as recommendations (using the term "should").

<u>Scope</u>

15) The Committee had an exchange of views on the possible consideration of "recommendations arising from other internationally recognized expert bodies". Several delegations proposed to delete this text and to refer only to other Joint FAO/WHO expert bodies and consultations, so as to ensure consistency with the *Working Principles* and to avoid any confusion on the expert bodies concerned. Other delegations pointed out that scientific advice might be sought from other relevant bodies working in the area covered by the Committee on Food Additives and Contaminants, and in particular the IAEA as regards radionuclides. Some delegations proposed to include a reference only to IAEA, or to include a list of organizations concerned for clarification purposes. The Committee recalled that according to the adopted *Working Principles*, "responsibility for risk assessment lies primarily with the Joint FAO/WHO expert bodies and consultations". After some discussion the Committee agreed to retain the original text of the second sentence and to add a third sentence noting that the document should be read in conjunction with the adopted *Working Principles*. The Delegations of Cameroon, Malaysia and Mali expressed their reservation on this decision.

Section 2

16) The Committee agreed to add new wording in paragraph d) in order to ensure consistency with the *Working Principles* as regards confidentiality and the availability of documentation. It was also clarified that documentation would be available on request.

Section 3

17) The Committee agreed that paragraphs k) and q) should refer to "ensuring fair practices in food trade", for consistency with Codex terminology and amended the text accordingly.

18) Several delegations stressed the need to clarify the use of "other legitimate factors" in paragraphs k) and q), and the Committee added a reference to the *Criteria for the Consideration of Other Factors Referred to in the Second Statement of Principle*.

19) In paragraph s), the Committee agreed to refer to the Strategic Plan, the relevant plans of work and the *Criteria for the Establishment of Work Priorities*, as it had been decided to discontinue the elaboration of the Medium Term Plan. The Committee amended the fifth bullet to reflect the need to take into account data from developing countries. A new bullet point was also inserted concerning the needs and concerns of developing countries.

20) In paragraph u) the Committee noted that the CCFAC might refer risk management options to JECFA as part of the iterative risk analysis process, not only "when referring substances to JECFA", and the text was amended accordingly.

21) The Committee introduced some editorial amendments to Section 4. JECFA for clarification purposes.

22) The Representative of WHO recalled that several committees were in the process of developing guidelines or principles on risk analysis and stressed the importance of ensuring harmonization of the approach to risk analysis throughout Codex, while taking into account the specificities of each Committee dealing with food safety. The Representative pointed out that, when finalized, all documents on risk analysis might require further consideration as to their overall consistency with the *Working Principles* and with one another, especially in the perspective of risk management and risk communication. The Representative noted that some current issues, such as substances without ADI or MRLs, might have an impact on various areas of Codex work and might entail further review of the guidelines on risk analysis developed by relevant Codex Committees.

23) The Committee noted that the Risk Analysis Principles applied by the Committee on Food Additives and Contaminants might not necessarily be used by other Committees as a template to develop their guidelines on risk analysis.

24) The Committee endorsed the *Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants* (at Step 8) with the amendments made at the present session, for adoption by the 28th Session of the Codex Alimentarius Commission (see Appendix II).

Draft Policies for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups

25) The Committee made some editorial amendments to ensure consistency with the *Draft Risk Analysis Principles*. The Committee endorsed the *Draft Policies for Exposure Assessment* (at Step 8), as proposed by the Committee on Food Additives and Contaminants, for adoption by the 28th Session of the Codex Alimentarius Commission (see Appendix III).

OTHER MATTERS

26) The Delegation of Samoa, as Coordinator for North America and the South West Pacific, informed the Committee that the last session of the CCNASWP⁴ had agreed that, in view of the changed composition and new functions of the Executive Committee, there was a need to clarify the respective roles of the Regional Coordinators and the members elected on a geographical basis and had agreed to refer this issue to the Committee on General Principles. The Delegation therefore proposed to seek the views of Members through a Circular Letter and to consider this issue at the next session. The Chairperson however noted that since CCNASWP had been held very recently, it was not possible to take a decision on its recommendations at the present session. However, the issue mentioned by the Delegation of Samoa could be raised at the next session, if required.

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ALINORM 05/28/32, para. 89

PROCESSES FOR STANDARDS MANAGEMENT (INCLUDING THE CRITICAL REVIEW): REVISION OF THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES (Agenda Item $3)^5$

27) The French Secretariat introduced the *Draft Criteria for the Establishment of Work Priorities* and recalled that the Committee at its 19th Session, after having agreed on the amended text on the section "*General criterion*", due to time constraints, could not conclude the consideration of the draft text. The Committee was therefore invited to review, at the present session, sections on criteria applicable to general subjects as well as those applicable to commodities.

28) The Delegation of the United States stated that the review of the Codex committee structure and mandates of Codex Committees and Task Forces, currently underway, might lead to significant changes in the number of Codex subsidiary bodies and in their terms of reference as well as working priorities in the near future. The Delegation proposed that the revision of the Criteria for the Establishment of Work Priorities be suspended until the above-mentioned review would have advanced, in order to take due account of the outcome of the review in the revision of these Criteria. Referring to its written comments, the Delegation also stated that the criteria were not consistent with the Codex mandate; there was overlap between the criteria applicable to general subjects and those applicable to commodities, and the distinction between these two sets of criteria was not necessary and proposed to establish a single set of criteria. This position was supported by several delegations.

29) After some debate, the Committee agreed to continue the revision of the Criteria while limiting the number of amendments to the extent possible and to forward, as foreseen, the amended *Draft Criteria* to the forthcoming session of the Commission, which would then decide whether to adopt the proposed amendment or to keep it on hold pending the progress of the review of the Codex committee structure and mandates of Codex Committees and Task Forces.

30) The Delegation of India, referring to its written comments, proposed that point (a) of the Criteria applicable to commodities refer to numerical expressions such as production volume in a percentage of Gross Domestic Product and trade pattern in percentage of the volume of production and consumption.

31) Some delegations stated that point (b) of the Criteria applicable to general subjects should be further clarified if it was to be retained.

32) The Delegation of the Netherlands, speaking on behalf of the Member States of the European Union present at the session and referring to its written comments, proposed that a reference to "work requested by the relevant international intergovernmental body(ies)" be added to point (c) of the Criteria applicable to general subjects and to point (g) of the Criteria applicable to commodities, arguing that WTO, for instance, could make such requests to international standard-setting bodies by virtue of Article 12.6 of the SPS Agreement.

33) The Delegation of Argentina, supported by Malaysia, expressed its concern with this proposal, since the organizations concerned were not identified and coordination with other international organizations was addressed in the Statutes of the Commission.

34) The Observer from Consumers International, referring to its written comments, proposed to amend "General criterion" to the effect that the needs of developing countries be identified by the Commission. The Observer also proposed the deletion of the second part of point (a) of the Criteria applicable to general subjects and of point (b) of the Criteria applicable to commodities which referred to "apparent resultant or potential impediments to international trade".

35) The Committee agreed to amend point (c) of the Criteria applicable to general subjects and point (g) of the Criteria applicable to commodities by adding the reference to "work suggested by the relevant international intergovernmental body(ies)". The Delegations of Malaysia and Argentina expressed their reservation on this amendment.

CX/GP 04/21/3; CRD 3 (comments of India); CRD 6 (comments of Consumers International); CRD 11 (comments of the United States of America); CRD 14 (comments of the EC)

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36) The Committee agreed to forward the *Draft Criteria*, as amended, to the Commission for consideration (see Appendix IV) and requested its views on the appropriate course of action, particularly whether to adopt them or keep them on hold.

REVIEW OF THE GUIDELINES FOR CODEX COMMITTEES AND OTHER ADDITIONAL TEXT: DRAFT GUIDELINES ON PHYSICAL WORKING GROUPS AND DRAFT GUIDELINES ON ELECTRONIC WORKING GROUPS (Agenda Item 4a)⁶

37) The French Secretariat introduced the working document that had been redrafted in the light of the discussion held at the last session and the comments received in reply to CL 2003/45-GP. In particular, the document had been simplified to allow more flexibility and not to duplicate the areas already covered in other sections of the Procedural Manual. The Committee considered the *Draft Guidelines on Physical Working Groups* and the *Draft Guidelines on Electronic Working Groups* section by section and made the following amendments.

DRAFT GUIDELINES ON PHYSICAL WORKING GROUPS

Introduction

38) The Committee recognized that the Rules of Procedures and the guidelines governing the work of Codex committees would apply to working groups and amended the text accordingly.

Membership

39) The Committee agreed to specify that the membership of working groups could be notified to the host country secretariat of the Committee, in addition to the chairperson, to reflect current practice in several committees.

Observers

40) After an exchange of views on the participation of observers, the Committee agreed with the proposal of a number of Observer NGOs that the general practice should be to admit observers, in order to ensure openness and transparency, unless otherwise specified by the Committee members. The text of the section was therefore rearranged, with some further amendments for clarification purposes.

Duties and Terms of Reference

41) The Committee had an extensive discussion on the provisions concerning the languages to be used in working groups. The Delegation of Argentina, supported by other delegations, stressed the importance of ensuring interpretation and translation into three working languages in order to ensure transparency in the decision-making process and to allow effective participation of member countries, especially developing countries. The Delegation of Tunisia expressed the view that reference should not be made only to interpretation into three languages and that the use of Arabic should also be considered.

42) Other delegations pointed out that the use of three languages in working groups would create an additional burden for host countries and might significantly limit the possibility of convening working groups, especially when the host was a developing country. Some delegations noted that according to the Committee concerned, and especially for Regional Coordinating Committees, interpretation in the three languages might not be required, and some flexibility should be provided in this regard. After some further discussion, the Committee agreed that interpretation and translation should be provided in all languages of the Committee, unless decided otherwise by the Committee.

43) The Committee agreed to clarify that "no decision on behalf of the Committee" shall take place in working groups.

⁶

CL 2003/45-GP , CX/GP 04/2/4, CRD 4 (comments of India), CRD 6 (comments of CI), CRD 14 (comments of EC), CRD 17 (comments of 49P)

Date and Place

44) Following its earlier decision to retain only provisions that were specific to working groups, the Committee agreed to delete the term "place" in the title of the section. It was also agreed that sessions could be held "in conjunction with" Committee sessions in order to cover all possibilities.

Working Group Notification and Provisional Agenda

45) The Committee noted that specific arrangements were limited to working groups held between sessions of the Committee, and that the invitation to working groups held in conjunction with Codex meetings was included in the official invitation sent for the session.

Reports

46) Some delegations pointed out that the term "report" was used in practice in physical working groups and could be retained. After an exchange of views, the Committee however agreed to refer to "conclusions" of working groups, recognizing that the term "report" was usually associated with Codex subsidiary bodies. The section was amended for consistency with the decision taken during the discussion of the *Draft Guidelines for Electronic Working Groups* (see para. 53).

Status of the Draft Guidelines for Physical Working Groups

47) The Committee agreed to forward the Draft Guidelines, as amended at the present session, for adoption by the 28th Session of the Codex Alimentarius Commission (see Appendix V).

DRAFT GUIDELINES ON ELECTRONIC WORKING GROUPS

48) The Committee agreed to insert several consequential amendments resulting of its decisions on the Draft Guidelines on Physical Working Groups, in order to ensure consistency, and considered the document section by section as follows.

Membership

49) Some delegations pointed out that the notion of members and observers, as understood in Codex sessions or physical working groups, was not relevant in the case of electronic exchange of views. The Committee noted that the term "observers" included both international organizations and the countries that were not part of the region concerned in Regional Coordinating Committees. After some discussion, the Committee agreed to delete the second sentence referring to members from outside the region in working groups of Regional Coordinating Committee as this was covered by the provisions applicable to such Committees in the Procedural Manual.

50) The Committee agreed to insert a new sentence to the effect that the membership of electronic working groups should be representative of the membership of the Commission, in order to ensure consistency with the *Draft Guidelines on Physical Working Groups*.

Organization and Duties

51) The Committee had an extensive debate on the procedures for notifying the Host of participants in a working group. Some delegations stressed the need for Codex Members to notify through their Codex Contact Point. Other delegations expressed the view that the modalities of notification should be left to the government concerned, since administrative structure and procedures differed from one country to another. The Committee agreed that participation should be notified by the Members through the Codex Contact Points and amended the text accordingly.

52) The Committee noted the proposal from the Delegation of Australia to allow electronic working groups to convene a physical meeting, if required. The Committee agreed that such an amendment was not necessary, given that Codex Committees could decide to establish working groups that would use both electronic communication and physical meetings and that in such a case the decision should be taken by the Committee concerned and the provisions of both guidelines on physical and electronic working groups would apply.

Reports

53) The Committee clarified that the conclusions of the working group could be in the form of a discussion paper or a working document, that the list of participants should also be distributed, and that the conclusions should be sent to the host country secretariat of the Committee.

Status of the Draft Guidelines for Electronic Working Groups

54) The Committee agreed to forward the Draft Guidelines, as amended at the present session, for adoption by the 28th Session of the Codex Alimentarius Commission (see Appendix VI).

OTHER PROPOSALS: CO-CHAIRMANSHIP AND FACILITATORS (Agenda item 4b)⁷

55) The Committee recalled that its last session had agreed to defer consideration of co-chairmanship and facilitators until its next extraordinary session and had a general discussion on these proposals.

Co-chairmanship

56) Several delegations stressed the importance of measures intended to facilitate participation of developing countries and especially the holding of Codex sessions in developing countries, that had contributed to the involvement of the regions where Codex sessions were held. These delegations indicated that the development of guidelines for co-chairmanship was premature at this stage, as an experimental approach should be taken on a case-by-case basis.

57) Some delegations pointed out that in view of the responsibilities of host countries and the costs involved, the practical implications of decentralizing Codex committees and co-chairing required careful consideration.

58) The Representative of FAO noted that the hosting of Codex Committee and co-chairmanship were very useful in order to develop capacity building in the area of Codex and food safety and indicated that FAO and WHO were ready to provide assistance to countries that wished to host Codex committees.

59) The Committee encouraged Codex committees to hold sessions in developing countries and to consider cochairing of sessions. The Committee also agreed that the elaboration of guidelines was premature at this stage, but might be considered in the future in the light of the results of such practical measures.

Facilitators

60) The Delegation of the United States, supported by other delegations and observers, expressed its concerns with the additional burden that the mandatory use of facilitators would entail for the host country; the criteria to be applied for their selection; and the possibility to introduce additional bias in the decision process. The Delegation of Brazil expressed the view that a more informal approach was preferable, and noted the important role of the host country to facilitate consensus in a committee. It was also noted that delegations could hold informal consultations during Codex sessions to try to resolve controversial issues.

61) The Committee agreed to report these views to the Commission and proposed that committees consider the use of facilitators on an experimental basis with modalities to be defined, taking into account issues related to efficiency, transparency and the costs involved.

CONSIDERATION OF THE STATUS OF OBSERVERS IN THE EXECUTIVE COMMITTEE: WEBCASTING AND PUBLICIZING OF THE PROCEEDINGS OF THE EXECUTIVE COMMITTEE (Agenda Item 5)⁸

62) At its 19th Session, the Committee had examined the issue of the participation of observers in the Executive Committee. As a result of the debate, the Committee had agreed that, at that stage, no guidelines needed to be developed as to the participation of observers in the Executive Committee and requested the Codex Secretariat to prepare, for the 21st session of the Committee, a discussion document elaborating further possible alternative options, with particular reference to cost and legal and institutional implications of any of the envisaged options.

⁷ CX/GP 04/21/5, CRD 5 (comments of India), CRD 6 (comments of Consumers International)

⁸ CX/GP 04/21/6; CX/GP 04/21/6 Add.1; CRD 6 (comments of Consumers International); CRD 7 (comments of India); CRD 14 (comments of the EC)

63) The Representative of the Legal Counsels of FAO and WHO introduced document CX/GP 04/21/6, which had been prepared in consultation with other organizations, both within and outside the United Nations system. The Representative stated that an arrangement whereby observers and the public would be able to listen to proceedings of a meeting of the Executive Committee without however being able to attend it or to exercise the applicable rights of participation, under such conditions as the Commission or the Executive Committee would decide, would not pose difficulties of principle to FAO and WHO, having regard to their own procedures and practices and also seen in light of the information received from other organizations, with particular reference to the organizations of the United Nations system. The Representative stated that it would be up to the Commission or the Executive Committee to decide whether all, or only particular proceedings, should be publicized under particular agenda items in light of the criteria that they could establish, as appropriate, and that the Commission or the Executive Committee could always decide that particular issues would be deliberated upon in private meetings and not be publicized.

64) The Secretariat also introduced document CX/GP 04/21/6 Add.1, which provided further information on the analysis of feasibility and cost implications of webcasting and other options for publicizing the proceedings of the Executive Committee. The Committee was informed that arrangements involving the use of large-capacity conference facilities would have significant cost implications while the cost for webcasting a one-and-half day session of the Executive Committee was roughly estimated as US\$ 50,000 (i.e. US\$ 200,000 for a biennium).

65) The Committee noted that there were no impediments of an institutional or legal nature to the proposed webcasting or publicizing of the proceedings, as an alternative to participation of observers in meetings of the Executive Committee, an issue that had been under review since a considerable period of time. In this connection, the Committee also noted that the proposal, justified in light of the particular nature of the work of the Codex Alimentarius Commission, would not set a precedent for other FAO bodies. The Delegation of Cameroon stated that the issue of webcasting or publicizing of proceedings of the Executive Committee should be considered in the framework of the relevant policy of the parent organizations. Several delegations emphasized that the proposed webcasting would reinforce transparency in the proceedings of the Executive Committee, without hampering the effective operation of the Executive Committee as the management body. Reference was made, in this context, to the webcasting of the proceedings of the Management Board of the European Food Safety Authority.

66) The Committee agreed with the views expressed by a number of delegations that the solution of the webcasting of the proceedings, as opposed to the establishment of listening rooms, would be the acceptable one, insofar as it would not lead to discrimination between "privileged" international non-governmental organizations, able to finance travel of their representatives to the venue of the meeting, and those which would not be able to do so.

67) However, in light of the information received on the significant cost implications of the webcasting of meetings, the Committee was of the view that the matter could not be considered exclusively on the basis of the above position. In this regard, several delegations underlined that they could not consider the webcasting of the proceedings of the Executive Committee as a priority of the Commission, given the financial constraints with which the Commission was faced. These delegations emphasized that ensuring timely distribution of relevant documents in relevant languages of the Commission was a far more efficient tool to achieve transparency of all the proceedings of the Codex Alimentarius Commission and its subsidiary bodies and that this should be addressed in a satisfactory manner, before consideration could be given to webcasting the proceedings of the Executive Committee at such a high cost. In this connection, it was proposed to consider an option of webcasting audio channels only.

68) Having taken note of all the views expressed, both by delegations and observers, the Committee restated the position that the objective of ensuring transparency of the proceedings of the Executive Committee should continue to be pursued actively. The Committee emphasized, however, that the issue of the substantial financial implications of the proposed webcasting could not be ignored or avoided.

69) The Committee therefore agreed that efforts should continue within the Commission with a view to finding a satisfactory solution for the issue at hand, at the lowest cost, without compromising the efficiency of the Executive Committee.

REVIEW OF THE PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION (Agenda Item 6)⁹

70) The Committee considered document CX/GP 04/21/7, which had been prepared by the Secretariat in response to a request by the Committee at its 20th Session. The document contained the draft revised *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, which had been prepared to take account of the proposed amendment to Rule VIII of the Rules of Procedure (see Appendix III of ALINORM 04/27/33A), as well as on the basis of the views expressed at the 19th and 20th sessions of the Committee. The Committee agreed to consider the draft revised principles section by section, focusing on those sections where amendments were proposed.

Organization Eligible for "Observer Status"

71) The Delegation of India, supported by some delegations, proposed to require that an organization requesting observer status should have carried out food safety activities in at least three countries and two geographic regions of Codex.

72) Several other delegations and observers opposed to the proposal made by India, on the ground that the number of regions in which the activities of an organization were carried out was not an indicator of the potential of the organization to contribute to the work of Codex, the number of countries contained in a region was highly variable and the organizations could make significant contributions in areas other than food safety.

73) The Observers from NHF and 49P questioned the usefulness and efficiency of the requirement that the organization should have been established three years before applying for observer status. The Secretariat clarified that the requirement was meant to assist in the effective evaluation of the organization's nature and activities and that a related proposal was made in point (1) of the annex to this effect.

74) The Committee agreed to amend the section as proposed in the working document, without further changes.

Procedure for Obtaining "Observer Status"

75) The Committee agreed that the title of Sections 4.1 and 4.2 should read, respectively, "International Non-Governmental Organizations Having Status with FAO and/or Official Relations with WHO" and "International Non-Governmental Organizations Neither Having Status with FAO nor Official Relations with WHO".

76) The Committee agreed to amend the penultimate paragraph addressing the case of rejection, by referring to "a written explanation of the decision" instead of "the motivation of the Directors-General".

Privileges and Obligations

77) The Committee agreed to amend the section as proposed in the working document, without further changes.

Review of "Observer Status"

78) The Delegation of India, supported by the Observer from NHF, proposed to delete the first sentence of section 6. The Committee agreed to amend the first paragraph to the effect that the Directors-General may terminate observer status for reasons of an exceptional nature, in accordance with the procedures set out in the section, in order to warrant sufficient caution with which termination of observer status should be exercised.

Annex: Information Required of Non-Governmental Organizations Requesting "Observer Status"

79) The Committee agreed to amend point (b) to read "Full postal address, Telephone, Facsimile and Email as well as Telex and Website Addresses as appropriate".

80) It was also agreed to add guidance to point (h) to the effect that substantive activities with other international organizations be documented.

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CX/GP 04/21/7; CRD 6 (comments of Consumers International); CRD 7 (comments of India); CRD 14 (comments of the EC)

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<u>Status of the Draft Revised Principles Concerning the Participation of International Non-Governmental</u> <u>Organizations in the Work of the Codex Alimentarius Commission</u>

81) The Committee agreed to forward the *Draft Revised Principles*, amended as above, to the Commission for adoption at its 28th Session (see Appendix VII). It was understood that the Revised Principles would take effect when the proposed amendment to Rule VIII of the Rules of Procedure would enter into force.

GUIDELINES FOR COOPERATION WITH INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda item 7)¹⁰

82) The Committee recalled that following the request of the Commission to provide guidance on cooperation with international intergovernmental organizations, the development of guidelines in this area had been considered at the 17th, 18th and 20th Sessions of the Committee. The 20th Session had agreed that the Secretariat would redraft the document in the light of the discussions held at the session. The Committee considered the revised *Draft Guidelines for Cooperation with International Intergovernmental Organizations* (IGOs) and made the following amendments and comments.

83) The Observer from OIE presented updated information on the activities of the OIE Working Group on Animal Production Food Safety and highlighted its relevance to ensure close cooperation between OIE and Codex in the area of food safety. The Observer also introduced CRD 16 proposing some specific amendments to the Draft Guidelines under consideration.

Title

84) The Committee agreed to refer to "elaboration" of standards in consistency with Codex terminology.^(*)

Types of Cooperation

85) The Committee agreed to reorganise the section and to separate paragraphs 4 and 5 (new paras. 5 and 6) related to the cooperating organization from the other paragraphs addressing the type of cooperation.

86) Several delegations pointed out that the requirement for the same principles of membership and standard setting in a cooperating organization was too restrictive and difficult to implement and therefore proposed to delete paragraph 5 (new para. 6). Other delegations proposed to retain this provision as it was essential to ensure that the cooperating organization followed the same principles as the Codex Alimentarius Commission. The Committee discussed the replacement of the current text with a reference to "equivalent principles", that would allow some flexibility.

87) The Representative of the FAO Legal Counsel informed the Committee further consideration should be given to the use of the term "equivalent" principles of membership by the Legal Counsels of FAO and WHO before adopting the text, and the Committee agreed to place this term in square brackets pending further advice. The Committee agreed that the principles of standards setting should be "equivalent" and amended the text accordingly.

Cooperation at the initial drafting stages of a Codex standard or related text

Paragraph 7

88) The Observer from OIE proposed to insert specific provisions to address cooperation with the organisations mentioned under Annex A of the WTO SPS Agreement, in view of their status under the SPS Agreement and their particular relevance to Codex work. This proposal was supported by several delegations.

89) The Committee agreed that when the initial drafting was entrusted to an IGO, this should be subject to approval by the Commission and taking into account the Critical Review, and amended the first sentence accordingly.

90) The Delegation of Malaysia, supported by several delegations, expressed its objections to entrusting the initial drafting to a cooperating organization in view of the importance of the first draft for the orientation of

¹⁰ CX/GP 04/21/8, CRD 7 (comments of India), CRD 13 (comments of Malaysia), CRD 14 (comments of the EC), CRD 15 and CRD 16 (information and comments from OIE)

^(*) only in English.

further debate, since the cooperating organisation might not give due attention to factors such as scientific basis, geographical diversity and the concerns of developing countries. The Delegation however proposed, as a compromise, to allow this procedure only in the case of the organizations mentioned in Annex A of the WTO SPS Agreement (OIE and IPPC), in view of their specific relevance for Codex work. This position was supported by several delegations.

91) The Delegation of India, supported by several delegations, expressed the view that the possibility to entrust any remaining step of the Procedure to another body should not exist, and that only subsidiary bodies of the Commission should carry out the steps of the Elaboration Procedure.

92) Several other delegations expressed the view that the possibility of entrusting the initial drafting to an IGO should not be limited to OIE and IPPC since several other organizations could contribute constructively to the work of Codex. In this regard, reference was made to IAEA, UN/ECE and the International Olive Oil Council. The Delegation of Sweden asked for clarification in relation to Article1c) of the Statutes concerning cooperation with other organizations.

93) The Observers from OIV and IIR supported the form of cooperation proposed in paragraph 7 and its extension to other intergovernmental organizations, in addition to OIE and IPPC, as they could provide valuable contribution to the elaboration of Codex standards. Some delegations noted that Annex A of the SPS Agreement referred, for matters not covered by Codex, OIE and IPPC, to other relevant organizations.

94) After further debate, the Committee agreed on a text specifying that the initial drafting may be entrusted to an IGO with competence in the relevant field, in particular one of those referred to in Annex A of the SPS Agreement. The Committee noted the concern and proposal of the Delegation of Malaysia to qualify this statement with requirements to the effect that the cooperating organization should provide a justification that it had given due consideration to several important factors. However, other delegations pointed out that these concerns were already taken into account by the Elaboration Procedure. Consequently, this additional text was not included.

95) The Committee further amended the text to reflect that the IGOs referred to in Annex A of the SPS Agreement shall be associated in the drafting of standards and related texts at Step 2 of the Elaboration Procedure. The Committee agreed that the remaining steps of the Procedure would be entrusted to the relevant Codex subsidiary body and the last sentence was amended accordingly.

96) In response to a question, the Secretariat informed the Committee that the reference to an "other body" in the Elaboration Procedure, from which the text under consideration had been derived, did not refer to IGOs but had been meant to address the development of standards by bodies such as the Joint FAO/WHO Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products and the Joint ECE/Codex Alimentarius Group of Experts on Standardization. These bodies were not Codex Committees but followed the Codex Procedure in the elaboration of standards and related texts and were subsequently superseded by Codex subsidiary bodies.

Paragraphs 8, 9 and 10

97) The Committee retained paragraphs 8, 9, and 10 as proposed in the working document.

Paragraph 11

98) Some delegations sought clarification as to the participation of representatives of the Commission in the work of another organization, and stressed the differences between the modalities of participation in meetings of other organizations, as compared to Codex meetings, that were open to all Members and Observers.

99) The Committee agreed that it was not necessary to specify that Codex would participate "as an observer" in meetings of other organizations and this term was deleted.

Paragraph 12

100) As regards the submission of comments by the Commission to the cooperating organization, the Delegation of Argentina sought clarification on the procedure to be followed, in particular whether the comments forwarded on behalf of Codex would require a specific decision by the Commission, or whether they

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would be conveyed by a representative of Codex participating in a personal capacity in the activities of other organizations.

101) The Chairperson of the Commission informed the Committee that in the case of the OIE Working Group on Animal Production Food Safety he participated as an expert, providing information on Codex adopted texts and current work that were of relevance to the work of OIE but that he did not intervene in areas that were the competence of OIE.

102) The Committee further noted that while paragraph 11 covered cases where physical participation of Codex representatives was possible, paragraph 12 addressed the submission of written comments and other information to the cooperating organizations.

103) The Committee retained paragraphs 12 and 13 as proposed in the working document.

<u>Status of the Proposed Draft Guidelines on Cooperation between the Codex Alimentarius Commission</u> and International Intergovernmental Organizations in the Elaboration of Standards and Related Texts

104) The Committee agreed to forward the Proposed Draft Guidelines, as amended at the present session, to the 28th Session of the Codex Alimentarius Commission for adoption (See Appendix VIII).

CONSIDERATION OF AN AMENDMENT TO THE RULES OF PROCEDURE ON THE RIGHT TO ADDRESS THE CHAIR (Agenda item 8)¹¹

105) The Committee recalled that the Joint FAO/WHO Evaluation of the Codex Alimentarius Commission and other FAO and WHO Work on Food Standards had expressed some concerns about the composition of national delegations to Codex Committees and the right of non-government advisors in these delegations to speak. On the basis of a recommendation of the Joint FAO/WHO Evaluation, the Commission, at its 26th Session, had decided to ask the Committee on General Principles to consider a new rule modelled on a comparable rule of the Rules of Procedure of the World Health Assembly to the effect that, in plenary meetings of the Commission, the chief delegate may designate another delegate who shall have the right to speak and vote in the name of the delegation on any question. Moreover, upon the request of the chief delegate or any delegate so designated, the Chairperson may allow an adviser to speak on any particular point. Document CX/GP 04/21/9 proposed an amendment to the Rules of Procedure along these lines.

106) While being fully aware of the underlying reasons for the proposal, some delegations questioned the actual need for a formal amendment to the Rules of Procedure and noted, in addition, that the *Guidelines on the Conduct of Meetings of Codex Committees and Ad hoc Intergovernmental Task Forces* already dealt with the issue of the right to address the Chair.

107) The Delegation of the United States noted that document CX/GP 04/21/9 did not address the concerns about the composition of national delegations to Codex sessions.

108) However, the Committee also noted that the Commission had specifically requested it to consider the inclusion of a new rule in the Rules of Procedure on the issue of the right to address the Chair, that the guidelines did not apply to the sessions of the Commission and that there was an overall sense that it might be useful to clarify the matter further.

Status of the proposed amendment to the Rules of Procedure on the right to address the Chair

109) Therefore, the Committee endorsed the amendment, as proposed in document CX/GP 04/21/9, and decided to forward it to the 28^{th} session of the Codex Alimentarius Commission for adoption. The proposed amendment to the Rules of Procedure, to be inserted in "*Rule V - Sessions*", between current paragraphs 4 and 5. - is set out in Appendix IX of this report.

CX/GP 04/21/9

CLARIFICATION OF THE DURATION OF THE TERM OF OFFICE OF THE MEMBERS OF THE EXECUTIVE COMMITTEE (Agenda Item 9)¹²

110) At its 20th Session, upon the proposal of the United States of America which enquired whether the terms of office of the various members of the Executive Committee should not be aligned, the Committee had agreed to request the Codex Secretariat, in cooperation with the Legal Counsels of FAO and WHO, to prepare a discussion paper for the 21st Session of the Committee to clarify the current rules of the Commission. Document CX/GP 04/21/10, prepared in response to that request, was presented by the Representative of the Legal Counsels of FAO and WHO.

111) The document recalled that once the set of proposed amendments to the Rules of Procedure were adopted by the Commission, the Executive Committee would consist of the Chairperson and Vice-Chairpersons of the Commission, the members elected on a geographical basis and the Coordinators. The document recalled further that the Chairperson and the Vice-Chairpersons are elected at each session of the Commission and hold office from the end of the session at which they are elected until the end of the following regular session. They are eligible for re-election, but, after having served two consecutive terms, are ineligible to hold such office for the next succeeding term. Comparable provisions apply to the Members elected on a geographic basis, but for a term twice as long as that for the Chairperson and Vice-Chairpersons. As regards the Coordinators, they hold office from the end of the session of the Commission at which they are appointed, until not later than the end of the third succeeding regular session, the precise term being determined by the Commission in each instance. The practice of the Commission had consisted in appointing the Coordinators for periods of two years, renewable once.

112) The Committee noted that the enlargement of the Executive Committee to include Coordinators as its members would result in a difference in the duration of the terms of office of (1) the Chairperson and Vice-Chairperson of the Commission, (2) the members elected on a geographic basis and (3) the Coordinators. The document admitted the desirability of establishing the term of office for all the members of the Executive Committee on the basis of a given number of years, which would be independent from the interval between the sessions of the Commission, likely to vary.

113) The ensuing debate revealed that the issue was a complex one, on which there was initially a wide range of views. In general, all delegations recognized that the matter had acquired importance as a result of the decision taken by the Commission to hold annual sessions, thus shortening the duration of the term of office of the Chairperson and Vice-Chairpersons to one year. Similarly, all delegations emphasized that, for the sake of the efficiency of the Executive Committee and, beyond that, of the Commission as a whole, there was a need for continuity in the office of all members of the Executive Committee. In turn, this called for a sufficiently long duration for their term of office and, if possible, for staged renewals of their term of office. While a solution whereby the duration of the terms of office of all the office bearers would be defined on the basis of a number of years appeared to be a simple one, it might, in practice, be difficult to implement.

114) Several delegations supported the view that reference to the regular sessions of the Commission, in view of its inherent flexibility, was still the best tool for the determination of the duration of the terms of office for the Chairperson, the Vice-Chairpersons and the members elected on a geographic basis. A proposal whereby the Commission would elect at regular sessions these members for a term of office finishing at the second succeeding regular session of the Commission, with a possibility of one renewal for the same duration, attracted support. However, it was also considered that, in the event that the Commission should decide to revert to biennial sessions, this would result in a possibility for those members elected on a geographic basis to hold office for up to eight years, which was considered manifestly too long. Therefore, the Committee was of the duration of the terms of office, might not obviate the need, anyway, to refer to a maximum number of years in office. In this connection, it was generally felt that consecutive terms of office equal to two sessions, renewable once, and not exceeding four (or perhaps three) years might reflect a suitable balance between continuity and rotation in office.

¹² CX/GP 04/21/10; CRD 5 (comments of India); CRD14 (comments of EC); CRD6 (comments of Consumers International).

115) The Delegation of Cameroon proposed that the terms of office of two years be synchronized to the biennium of the parent organizations so that the terms of office of members of the Executive Committee finish at the end of the Commission session held immediately after the end of a biennium.

116) A few members expressed the view that, given the different nature of their functions, the duration of the term of office of the Coordinators might require separate treatment. In general, some delegations underlined the desirability that any solutions to be implemented, and ultimately reflected in the Rules of Procedure, should aim at limiting to a minimum the number of any required amendments.

117) Having noted the complex nature of the matter, as well as the fact, pointed out by some delegations, that the Commission had not specifically requested the Committee on General Principles to proceed with the consideration of a possible revision of the Rules of Procedure in this matter, the Committee asked the secretariat to prepare another discussion paper for its next session. The paper should seek to present possible options for harmonising, to the extent possible, the duration of the terms of office of all Members of the Executive Committee, their implications, as well as all relevant scenarios, mainly based on the terms of office being equal to two regular sessions of the Commission, renewable once, with a limit of three or four years. Such document would allow the Committee to develop concrete proposals on the issue, for consideration by the Commission at its forthcoming session.

ACCEPTANCE AND NOTIFICATION PROCEDURES FOR CODEX STANDARDS (Agenda item 10)¹³

118) The Codex Secretariat introduced the document prepared at the request of the last session in order to facilitate discussion on the relevance of the acceptance procedure. The Secretariat recalled that the Committee had initiated the revision of the acceptance procedure at the request of the 21^{st} Session of the Commission, and that proposals for amendments had been discussed at three consecutive sessions of the Committee. However it had not been possible to reach consensus on the revision and the Committee had decided not to proceed with consideration of this issue at its 14^{th} Session (1999).

119) The Delegation of the European Community expressed the view that since acceptance of standards was irrelevant in the framework of the WTO Agreements and had not been used in practice for a long time by member countries, all provisions concerning acceptance and notification should be abolished. The Delegation of the United States, while supporting the abolition of the acceptance procedure, pointed out that further clarification was needed as to the specific provisions to be abolished or amended.

120) The Observer from Consumers International proposed to revise the acceptance procedure to increase its use by Members, as notification under the SPS Agreements did not serve the same purpose and did not provide a clear indication of the use of Codex standards at the national level. The Delegation of Argentina stated that notification under the SPS Agreement provided only partial information on the standards applied by member countries.

121) The Secretariat informed the Committee that in the framework of the review of the operation of the SPS Agreement currently underway, notification of sanitary and phytosanitary measures was under review and that there were "proposals to extend the scope" of notifications to also cover those proposed measures based on international standards. It was also pointed out that the monitoring of the use of international standards was a standing agenda item in the SPS Committee of WTO.

122) The Committee agreed that the Secretariat would prepare a revised paper presenting the amendments to the Procedural Manual that would result from the abolition of the Acceptance Procedure, in particular the General Principles of Codex, the Guidelines for the Acceptance Procedure for Codex Standards and the Statutes of the Codex Alimentarius Commission. The Secretariat informed the Committee that the Commission had taken no formal decision on discontinuation of work on the amendment of acceptance procedures and therefore it did not require approval as new work.

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CX/GP 04/21/11, CRD 5 (comments of India), CRD 6 (comments of Consumers International), CRD 14 (comments of the EC)

INTERPRETATION OF THE TERM "DELEGATE" UNDER RULE IV.1 OF THE RULES OF PROCEDURE (Agenda Item 11)¹⁴

123) The Committee recalled that at its 20th session it had considered briefly an agenda item entitled "Particular situation of the North America Region in the context of Rule IV.1 of the Rules of Procedure", as a follow-up to the discussion at its 19th session, and had requested the Legal Counsels of FAO and WHO to submit to the current session a document providing further clarification on whether the Chairperson and Vice-Chairpersons of the Executive Committee could not be considered as "delegates" for the purpose of Rule IV.1 of the Rules of Procedure.

124) On the basis of the presentation of document CX/GP 04/21/12, the Representative of the Legal Counsels of FAO and WHO noted that under Rule IV.1 of the Rules of Procedure, the Executive Committee consists of the Chairperson and Vice-Chairpersons of the Commission, together with seven further members, elected by the Commission at regular sessions from among the Members of the Commission, one each coming from the following geographic locations: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, South West Pacific; "it being understood that not more than one delegate from any one country shall be a member of the Executive Committee" (emphasis added).

125) The Representative noted concerns expressed that in view of the membership of the North America Region and the relevant provisions of the Rules of Procedure on the composition of the Executive Committee, a situation could arise where the region in question might not be represented in the Executive Committee. The Representative further noted that, under Rule III.1 of the Rules of Procedure, the Chairperson and Vice-Chairpersons were elected from among the delegates of the Members of the Commission but served in their elective capacity as individuals, not as representatives of their countries. From the point of view of their roles and functions, they were, therefore, supposed to reflect the position and interests of the Commission and the Executive Committee, as a whole, rather than those of their respective countries. Consequently, there was a clear difference between them, on the one hand, and the members elected on a regional basis and the Coordinators, on the other hand. Accordingly, the term "delegate" could be considered as applying only to the Members elected on a geographic basis and the Coordinators.

126) The Representative indicated that if the Commission wished to review its practice in the implementation of Rule IV.1, it could choose to adopt an interpretative statement along the above lines or even consider a formal amendment to Rule IV.1.

127) The ensuing debate revealed that there was no consensus in respect of the above course of action. Several delegations supported retaining the current practice whereby the term "delegate" should encompass the Chairperson and Vice-Chairpersons of the Commission for the purpose of determining the composition of the Executive Committee. Some delegations recalled that, according to Rule III.1 of the Rules of Procedure, these Officers may remain in office only with the continuing endorsement of their respective Members.

128) The Delegation of the Netherlands, speaking on behalf of the Member States of the European Union present at the Session, supported by several other delegations, expressed the view that an appropriate solution to the difficulties experienced by the region having a small number of member countries regarding representation within the Executive Committee might be found by reviewing the membership of the region. Furthermore, some delegations pointed out that the suggested interpretation of the term "delegate" would run counter to other provisions of the Rules of Procedure and would increase the current overrepresentation of one region in the Executive Committee.

129) The Delegation of Belgium, supported by other delegations, suggested a practical solution with the aim of merging the North America Region with the South West Pacific Region, as it had already been done for the corresponding Regional Committee.

130) The Delegations of the United States of America and Canada, supported by several other delegations, reaffirmed the view that the Chairperson and Vice-Chairpersons, when exercising their roles as members of the Executive Committee, are not delegates of their countries but represent the interest of Codex as a whole, that there was a need to take better into account the particular situation of the North America region within the

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¹⁴ CX/GP 04/21/12.

Executive Committee and stated that they would continue to seek practical means to accommodate their concerns regarding their representation within the Executive Committee.

131) The Chairperson of the Commission stated that this matter should preferably be clarified at the earliest opportunity to avoid difficulties in conducting the election of the Officers during the session of the Commission.

132) The Committee agreed that all practical approaches to address the issue at hand should be explored by all the parties concerned and suggested that the Commission, at its forthcoming session, might wish to provide guidance on whether and how the consideration of this matter should be pursued within the Commission.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

133) As indicated under Agenda Item 1 (see para. 3), the Committee was informed that the Working Group on the *Proposed Draft Working Principles for Risk Analysis* had been held on Saturday 6 November 2004, co-chaired by Canada and Argentina. The conclusions of the Working Group, as well as the list of participants, would be compiled by the French Secretariat and the Co-Chairs and would be circulated for comments before the next session of the Committee.

134) In view of the anticipated retirement of Dr. Henri Belvèze (European Community), the Committee expressed its whole-hearted gratitude to him, in recognition of his long-standing contribution to the work of Codex.

FUTURE WORK AND DATE AND PLACE OF NEXT SESSION

135) The Committee noted that in addition to and following the items under discussion from the last (regular) session of the Committee, the agenda of the next session would include the following items:

- Clarification of the duration of the term of office of the members of the Executive Committee; and
- Provisions concerning Acceptance of Codex standards.

136) The Committee was informed that its next (22^{nd}) session would be held in Paris from 11-15 April 2005, pending further confirmation by the host country and Codex Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 05/28/33
Draft Risk Analysis Principles Applied by the Committee on Food Additives and Contaminants		Governments 28 th CAC	para. 24 Appendix II
Draft CCFAC Policy for Exposure Assessment		Governments 28 th CAC	para. 25 Appendix III
Draft Revised Criteria for the Establishment of Work Priorities		Governments 28 th CAC	para. 36 Appendix IV
Draft Guidelines on Physical Working Groups		Governments 28 th CAC	para. 47 Appendix V
Draft Guidelines on Electronic Working Groups		Governments 27 th CAC	para. 54 Appendix VI
Review of the Principles concerning the Participation of International Non- Governmental Organizations in the Work of the Codex Alimentarius Commission		Governments 28 th CAC	para. 81 Appendix VII
Draft Guidelines for Cooperation with International Intergovernmental Organizations		Governments 28 th CAC	para. 104 Appendix VIII
Draft Amendment to the Rules of Procedure on the Right to Address the Chair		Governments 28 th CAC	para. 109 Appendix IX
Interpretation of the term "delegate" under Rule IV.1		28 th CAC	para. 132
Provisions concerning acceptance of Codex standards		Secretariat 22 nd CCGP	para. 122
Clarification of the duration of the term of the Members of the Executive Committee		Secretariat Legal Counsels 22 nd CCGP	para. 117

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ALINORM 05/28/33 APPENDIX II

DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS

(At Step 8 of the Procedure)

1. SCOPE

- a) This document addresses the respective applications of risk analysis principles by the Codex Committee on Food Additives and Contaminants (CCFAC) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). For matters which cannot be addressed by JECFA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies.
- b) This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*

2. CCFAC and JECFA

- c) CCFAC and JECFA recognize that communication between risk assessors and risk managers is critical to the success of their risk analysis activities.
- d) CCFAC and JECFA should continue to develop procedures to enhance communication between the two committees.
- e) CCFAC and JECFA should ensure that their contributions to the risk analysis process involve all interested parties and are fully transparent and thoroughly documented. While respecting legitimate concerns to preserve confidentiality, documentation should be made available, upon request, in a timely manner to all interested parties.
- f) JECFA, in consultation with CCFAC, should continue to explore developing minimum quality criteria for data requirements necessary for JECFA to perform risk assessments. These criteria are used by CCFAC in preparing its Priority List for JECFA. The JECFA Secretariat should consider whether these minimum quality criteria for data have been met when preparing the provisional agenda for meetings of JECFA.

3. CCFAC

- g) CCFAC is primarily responsible for recommending risk management proposals for adoption by the CAC.
- h) CCFAC shall base its risk management recommendations to the CAC on JECFA's risk assessments, including safety assessments¹, of food additives, naturally occurring toxicants, and contaminants in food.
- i) In cases where JECFA has performed a safety assessment and CCFAC or the CAC determines that additional scientific guidance is necessary, CCFAC or CAC may make a more specific request to JECFA to obtain the scientific guidance necessary for a risk management decision.
- j) CCFAC's risk management recommendations to the CAC with respect to food additives shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Food Additives.
- k) CCFAC's risk management recommendations to the CAC with respect to contaminants and naturally occurring toxicants shall be guided by the principles described in the Preamble and relevant annexes of the Codex General Standard for Contaminants and Naturally Occurring Toxins in Food.

¹ A Safety Assessment is defined as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when JECFA definition will be available).

- 1) CCFAC's risk management recommendations to the CAC that involve health and safety aspects of food standards shall be based on JECFA's risk assessments and other legitimate factors relevant to the health protection of consumers and to ensuring 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.*
- m) CCFAC's risk management recommendations to the CAC shall take into account the relevant uncertainties and safety factors described by JECFA.
- n) CCFAC shall endorse maximum use levels only for those additives for which 1) JECFA has established specifications of identity and purity and 2) JECFA has completed a safety assessment or has performed a quantitative risk assessment.
- o) CCFAC shall endorse maximum levels only for those contaminants for which 1) JECFA has completed a safety assessment or has performed a quantitative risk assessment and 2) the level of the contaminant in food can be determined through appropriate sampling plans and analysis methods, as adopted by Codex. CCFAC should take into consideration the analytical capabilities of developing countries unless public health considerations require otherwise.
- p) CCFAC shall take into account differences in regional and national food consumption patterns and dietary exposure as assessed by JECFA when recommending maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants in food.
- q) Before finalising proposals for maximum levels for contaminants and naturally occurring toxicants, CCFAC shall seek the scientific advice of JECFA about the validity of the analysis and sampling aspects, about the distribution of concentrations of contaminants and naturally occurring toxicants in foods and about other relevant technical and scientific aspects, including dietary exposure, as necessary to provide for a suitable scientific basis for its advice to CCFAC.
- r) When establishing its standards, codes of practice, and guidelines, CCFAC shall clearly state when it applies any other legitimate factors relevant to the health protection of consumers and to ensuring 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*, in addition to JECFA's risk assessment, and specify its reasons for doing so.
- s) CCFAC's risk communication with JECFA includes prioritizing substances for JECFA review with the view towards obtaining the best available risk assessment for purposes of elaborating safe conditions of use for food additives and elaborating safe maximum levels or codes of practice for contaminants and naturally occurring toxicants in food.
- t) CCFAC shall consider the following when preparing its priority list of substances for JECFA review:
 - Consumer protection from the point of view of health and prevention of unfair trade practices;
 - CCFAC's Terms of Reference;
 - JECFA's Terms of Reference;
 - The Codex Alimentarius Commission's Strategic Plan, its relevant plans of work and *Criteria for the Establishment of Work Priorities*;
 - The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
 - The prospect of completing the work in a reasonable period of time;
 - The diversity of national legislation and any apparent impediments to international trade;
 - The impact on international trade (i.e., magnitude of the problem in international trade;
 - The needs and concerns of developing countries; and,
 - Work already undertaken by other international organizations;
- u) When referring substances to JECFA, CCFAC shall provide background information and clearly explain the reasons for the request when chemicals are nominated for evaluation;

- v) CCFAC may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.
- w) CCFAC requests JECFA to review any methods and guidelines being considered by CCFAC for assessing maximum use levels for additives or maximum levels for contaminants and naturally occurring toxicants. CCFAC makes any such request with a view toward obtaining JECFA's guidance on the limitations, applicability, and appropriate means for implementation of a method or guideline for CCFAC's work.

4. JECFA

- x) JECFA is primarily responsible for performing the risk assessments upon which CCFAC and ultimately the CAC base their risk management decisions.
- y) JECFA's scientific experts should be selected on the basis of their competence and independence, taking into account geographical representation to ensure that all regions are represented.
- z) JECFA should strive to provide CCFAC with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCFAC's risk-management discussions. For contaminants and naturally occurring toxicants, JECFA should determine to the extent possible the risks associated with various levels of intake. Because of the lack of appropriate information, including data in humans, however, this may be possible in only a few cases for the foreseeable future. For additives, JECFA should continue to use its safety assessment process for establishing ADIs.
- aa) JECFA should strive to provide CCFAC with science-based quantitative risk assessments and safety assessments for food additives, contaminants, and naturally occurring toxicants in a transparent manner.
- bb) JECFA should provide CCFAC with information on the applicability and any constraints of the risk assessment to the general population to particular sub-populations and should as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g., children, women of child-bearing age, the elderly).
- cc) JECFA should also strive to provide CCFAC with specifications of identity and purity essential to assessing risk associated with the use of additives.
- dd) JECFA should strive to base its risk assessments on global data, including data from developing countries. These data should include epidemiological surveillance data and exposure studies.
- ee) JECFA is responsible for evaluating exposure to additives, contaminants, and naturally occurring toxicants.
- ff) When evaluating intake of additives or contaminants and naturally occurring toxicants during its risk assessment, JECFA should take into account regional differences in food consumption patterns.
- gg) JECFA should provide to CCFAC its scientific views on the validity and the distribution aspects of the available data regarding contaminants and naturally occurring toxicants in foods which have been used for exposure assessments, and should give details on the magnitude of the contribution to the exposure from specific foods as may be relevant for risk management actions or options of CCFAC.
- hh) JECFA should communicate to CCFAC the magnitude and source of uncertainties in its risk assessments. When communicating this information, JECFA should provide CCFAC with a description of the methodology and procedures by which JECFA estimated any uncertainty in its risk assessment.
- ii) JECFA should communicate to CCFAC the basis for all assumptions used in its risk assessments including default assumptions used to account for uncertainties.
- jj) JECFA's risk assessment output to CCFAC is limited to presenting its deliberations and the conclusions of its risk assessments and safety assessments in a complete and transparent manner. JECFA's communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence. Should JECFA include risk assessments of alternative risk management options, JECFA should ensure that these are consistent with the Working Principles for Risk Analysis for the Application in the Framework of the Codex Alimentarius and Risk Analysis Principles applied by the Codex Committee on Food Additives and Contaminants.

- kk) When establishing the agenda for a JECFA meeting, the JECFA Secretariat work closely with CCFAC to ensure that CCFAC's risk management priorities are addressed in a timely manner. With respect to food additives, the JECFA Secretariat should normally give first priority to compounds that have been assigned a temporary ADI, or equivalent. Second priority should normally be given to food additives or groups of additives that have previously been evaluated and for which an ADI, or equivalent, has been estimated, and for which new information is available. Third priority should normally be given to food additives that have not been previously evaluated. With respect to contaminants and naturally occurring toxicants, the JECFA Secretariat should give priority to substances that present both a significant risk to public health and are a known or expected problem in international trade.
- 11) When establishing the agenda for a JECFA meeting, the JECFA Secretariat should give priority to substances that are known or expected problems in international trade or that present an emergency or imminent public health risk.

DRAFT CCFAC POLICY FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

(At Step 8 of the Procedure)

INTRODUCTION

- 1. Maximum Limits (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the Codex General Standard for Contaminants and Toxins in Foods (GSCTF) states in Section 1.3.2 that "maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected". Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.
- 2. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g., PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.
- 3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by CCFAC to conduct a dietary exposure assessment.
- 4. The following components highlight aspects of JECFA's exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of CCFAC. CCFAC will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

1. ESTIMATION OF TOTAL DIETARY EXPOSURE TO A CONTAMINANT OR TOXIN FROM FOODS/FOOD GROUPS

- 5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g., PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.
- 6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food Regional diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food Regional diets are likely to approach or exceed the tolerable intake.
- 7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.
- 8. JECFA performs exposure assessments if requested by CCFAC using the GEMS/Food Regional Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCFAC about these risk management options.

2. IDENTIFICATION OF FOODS/FOOD GROUPS THAT CONTRIBUTE SIGNIFICANTLY TO TOTAL DIETARY EXPOSURE OF THE CONTAMINANT OR TOXIN

- 9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to CCFAC's criteria for selecting food groups that contribute to exposure.
- 10. The CCFAC determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Regional diets) for which dietary exposures exceed that percentage.
- 11. The criteria are as follows:
- a) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%² or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Regional diets;

or,

b) Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5%1 or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Regional diets;

or,

c) Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Regional diets. These would be considered on a case-by-case basis.

3. GENERATION OF DISTRIBUTION CURVES FOR CONCENTRATIONS OF THE CONTAMINANT IN SPECIFIC FOODS/FOOD GROUPS (concurrent with <u>section 2</u>, or subsequent step)

- 12. If requested by CCFAC, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. CCFAC will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.
- 13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.
- 14. In presenting the distribution curves to CCFAC, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

4. ASSESSMENT OF THE IMPACT OF AGRICULTURAL AND PRODUCTION PRACTICES ON CONTAMINANT LEVELS IN FOODS/FOOD GROUPS (concurrent with <u>section 2</u>, or subsequent step)

- 15. If requested by CCFAC, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. CCFAC takes this information into account when considering risk management options and for proposing Codes of Practice.
- 16. Taking this information into account, CCFAC proposes risk management decisions. To refine them, CCFAC may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.

² Rounded to the nearest 1/10th of a percent.

ALINORM 05/28/33 APPENDIX IV

DRAFT CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

When a Codex Committee proposes to elaborate a standard, code of practice or related text within its terms of reference, it should first consider the priorities established by the Commission in the strategic plan, the relevant outcomes of the critical review conducted by the Executive Committee, and the prospect of completing the work within a reasonable period of time. It should also assess the proposal against the criteria set out below.

If the proposal falls in an area outside the Committee's terms of reference the proposal should be reported to the Commission in writing together with proposals for such amendments to the Committee's terms of reference as may be required.

CRITERIA

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.

(b) Scope of work and establishment of priorities between the various sections of the work.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

Criteria applicable to commodities

(a) Volume of production and consumption in individual countries and volume and pattern of trade between countries.

(b) Diversification of national legislations and apparent resultant or potential impediments to international trade.

- (c) International or regional market potential.
- (d) Amenability of the commodity to standardisation.

(e) Coverage of the main consumer protection and trade issues by existing or proposed general standards.

(f) Number of commodities which would need separate standards indicating whether raw, semiprocessed or processed.

(g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies).

ALINORM 05/28/33 APPENDIX V

DRAFT GUIDELINES ON PHYSICAL WORKING GROUPS

INTRODUCTION

Working groups should be *ad hoc*, open to all members, take into account the problems of developing country participation and only be established where there is consensus in the Committee to do so and other strategies have been considered.

The Rules of Procedure and the guidelines governing the work of a Codex Committee shall apply, mutatis mutandis, to the working groups this Committee establishes, unless stated otherwise in these Guidelines.³

The Guidelines applying to physical working groups (hereinafter, "working groups") established by Codex Committees as described in these guidelines apply also to those established by Regional Coordinating Committees and by Codex ad hoc Intergovernmental Task Forces.

COMPOSITION OF WORKING GROUPS

MEMBERSHIP

Membership of a working group is notified to the chairperson of the Codex Committee_and to the host country secretariat of the Committee.

When establishing a working group, a Codex Committee should ensure, as far as possible, that the membership is representative of the membership of the Commission.

OBSERVERS

Observers should notify the Chairperson of the Codex Committee and to the host country secretariat of the Committee of their wish to participate in a working group. Observers may participate in all sessions and activities of a working group, unless otherwise specified by the Committee members.

ORGANIZATION AND DUTIES

A Codex Committee may decide that the working groups will be managed by the Host Government Secretariat, or by another member of the Commission, having volunteered to undertake this responsibility and having been accepted by the Committee (hereinafter "the Host").

CHAIRPERSON

The Host is responsible for appointing the chairperson of the working group. While selecting of the appointee, the Host may consider applying, where relevant, the *Codex Criteria for the appointment of chaipersons*⁴.

SECRETARIAT

The Host is responsible for providing all conference services, including the secretariat, for the working group and should meet all the requirements agreed upon by the Committee, when the working group was established.

DUTIES AND TERMS OF REFERENCE

The terms of reference of the working group shall be established by the Committee during its plenary session, shall be limited to the immediate task at hand and normally shall not be subsequently modified.

³ The provisions of the "Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and Ad Hoc Intergovernmental Task Forces" and the "Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces" are especially relevant in this matter.

⁴ See ALINORM 04/27/5 -- Appendix IV. These criteria have been adopted during the 27th session of the Codex Alimentarius Commission and will be inserted in the next edition of the Procedural Manual.

The terms of reference shall clearly state the objective(s) to be achieved by the establishment of the working group and the language(s) to be used. Interpretation and translation services should be provided in all languages of the Committee, unless decided otherwise by the Committee.

The terms of reference shall clearly state the time frame by which the work is expected to be completed. The proposals/recommendations of a working group shall be presented to the Committee for consideration.

They shall not be binding on the Committee.

The working group shall be dissolved after the specified work has been completed or when the time limit allocated for the work has expired or at any other point in time, if the Codex Committee which has established it, so decides.

No decision on behalf of the Committee, nor vote, either on point of substance or of procedure, shall take place in working groups.

SESSIONS

DATE

A session of a working group may be held at any time, in-between two sessions or in conjunction with the session of the Committee, which has established it.

When convened in-between two sessions of the Committee, the session of the working group should be scheduled as to allow the working group to report to the Committee well in advance of the next meeting so that countries and other interested parties, that were not members of the working group, can comment on the proposals that the working group might put to the Committee.

When convened during a session of a Committee, a working group should be scheduled so as to allow participation of all delegations present at the session.

WORKING GROUP NOTIFICATION AND PROVISIONAL AGENDA

Sessions of a working group shall be convened by the Chairperson designated by the Host.

If the working group is scheduled in-between two sessions of the Committee, a notice of the working group meeting and provisional agenda shall be prepared, translated and distributed by the Host. It shall be issued to all Members and Observers who have expressed the willingness to attend the meeting. These documents should be distributed as far in advance of the meeting as possible.

ORGANIZATION OF WORK

Written comments will be circulated to all concerned by the secretariat of the Host.

PREPARATION AND DISTRIBUTION OF PAPERS

The secretariat of the Host should circulate the papers at least two months before the opening of the session.

Paper for the session prepared by the participants should be sent to the secretariat of the Host, in good time.

CONCLUSIONS

The Secretariat of the Host should, as soon as possible after the end of the session of a working group, send a copy of the final conclusions, in the form of either a discussion paper or a working document, and the list of participants, to the Joint FAO/WHO Secretariat and to the host country secretariat of the Committee.

Conclusions of a working group shall be distributed to all Codex Contact Points and observers by the Joint FAO/WHO Secretariat in time to allow full consideration of the working group's recommendations.

The Joint FAO/WHO Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex Committee.

The working group shall report, through its Chairperson, on the progress of its work at the next session of the Committee, which has established the working group.

ALINORM 05/28/33 ANNEX VI

DRAFT GUIDELINES ON ELECTRONIC WORKING GROUPS

INTRODUCTION

The search for world-wide consensus and for greater acceptability of Codex Standards requires the involvement of all the Members of Codex and the active participation of developing countries.

Special efforts are needed to enhance the participation of developing countries in Codex Committees, by increased use of written communications, especially through remote participation via email, internet and other modern technologies, in the work done between sessions of Committees.

Codex Committees, when deciding to undertake work between sessions, should give the first priority to considering the establishment of electronic working groups.

The Rules of Procedure and the guidelines governing the work of a Committee shall apply, mutatis mutandis, to the electronic working groups this Committee establishes, unless stated otherwise in these Guidelines.⁵

The Guidelines applying to electronic working groups established by Codex Committees, as described in these Guidelines, apply also to those established by Regional Coordinating Committees and by Codex *ad hoc* Intergovernmental Task Forces.

COMPOSITION OF ELECTRONIC WORKING GROUPS

MEMBERSHIP

Membership of an electronic working group is notified the chairperson of the Codex Committee and to the host country secretariat of the Committee.

When establishing an electronic working group, a Codex Committee should ensure, as far as possible, that the membership is representative of the membership of the Commission.

OBSERVERS

Observers should notify the Chairperson of the Committee and to the host country secretariat of the Committee, of their wish to participate in a working group. Observers may participate in all the activities of an electronic working group, unless otherwise specified by Committee members.

ORGANIZATION AND DUTIES

Codex Committees may decide that the electronic working group will be managed by the Host Government Secretariat, or by another member of the Commission, having volunteered to undertake this responsibility and having been accepted by the Committee (hereinafter "the Host"). The Host should be notified of the participants in an electronic working group by Codex Members through their Codex Contact Points and by Observer organizations.

MANAGEMENT

The Host is responsible for the management of the electronic working group for which it has been appointed.

The business of an electronic working group is transacted exclusively by electronic means.

⁵ The provisions of the "Guidelines to Host Governments of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines on the Conduct of Meetings of Codex Committees and Ad Hoc Intergovernmental Task Forces", the "Guidelines to Chairpersons of Codex Committees and Ad Hoc Intergovernmental Task Forces" and the "Guidelines on Physical Working Groups" are especially relevant in this matter.

SECRETARIAT

The Host is responsible for providing the secretariat of the electronic working group with all services needed for its functioning, including suitable Information Technology (IT) equipment, and should meet all the requirements agreed upon by the Committee.

DUTIES AND TERMS OF REFERENCE

The terms of reference of the electronic working group shall be established by the Committee during its plenary session, shall be limited to the immediate task at hand and normally shall not be subsequently modified.

The terms of reference shall clearly state the objective(s) to be achieved by the establishment of the electronic working group and the language(s) to be used. Interpretation and translation services should be provided in all languages of the Committee, unless decided otherwise by the Committee.

The terms of reference shall clearly state the time frame by which the work is expected to be completed.

The electronic working group shall be dissolved after the specified work has been completed or when the time limit allocated for the work has expired or at any other point in time, if the Codex Committee which has established it, so decides.

No decision on behalf of the Committee, nor vote, either on point of substance or of procedure, shall take place in electronic working groups.

ELECTRONIC WORKING GROUP NOTIFICATION AND PROGRAMME OF WORK

A notice indicating when the electronic working group starts to operate and a programme of work shall be prepared, translated and distributed by the Host to all Members and Observers who have expressed the willingness to contribute.

ORGANIZATION OF WORK

Circulation of drafts and calls for comments shall include a request for the names, positions and e-mail addresses of all the persons willing to contribute to the business of the electronic working group.

Comments from participants should be submitted exclusively by electronic means. These submissions shall be circulated to all concerned by the Host.

Any participant should be made aware of the materials contributed by all others.

An update on the progress of its work shall be presented by the Host at each session of the Codex Committee which has established it, indicating the number of countries having sent contributions by mail. A compilation of these contributions should be made available.

PREPARATION AND DISTRIBUTION OF MATERIALS

Materials should be sent to the secretariat of the Host, in good time.

The Host is responsible for the distribution of all the materials submitted by a participant during the business of the electronic working group to all other participants of the electronic working group.

Attention should be given to constraints of a technical nature (file sizes and formats, limited band width, ...) and special care should be taken to ensure the widest distribution of all the available materials.

CONCLUSIONS

As soon as possible after the end of the business of an electronic working group, the secretariat of the Host should send a copy of the final conclusions, in the form of either a discussion paper or a working document and of the list of participants to the Joint FAO/WHO Secretariat and to the host country secretariat of the Committee.

The conclusions of an electronic working group and the list of participants shall be distributed to Codex Contact Points and observers by the Joint FAO/WHO Secretariat in time to allow full consideration of the electronic working group's recommendations.

The Joint FAO/WHO Secretariat should ensure that these conclusions are included in the distribution of papers for the next session of the Codex Committee, which has established the electronic working group.

ALINORM 05/28/33 APPENDIX VII

DRAFT REVISED PRINCIPLES CONCERNING THE PARTICIPATION OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN THE WORK OF THE CODEX ALIMENTARIUS COMMISSION

1. PURPOSE

The purpose of collaboration with International Non-Governmental Organizations is to secure for the Codex Alimentarius Commission, expert information, advice and assistance from international non-governmental organizations and to enable organizations which represent important sections of public opinion and are authorities in their fields of professional and technical competence to express the views of their members and to play an appropriate role in ensuring the harmonizing of intersectoral interests among the various sectoral bodies concerned in a country, regional or global setting. Arrangements made with such organizations shall be designed to advance the purposes of the Codex Alimentarius Commission by securing maximum cooperation from International Non-Governmental Organizations in the execution of its programme.

2. TYPES OF RELATIONSHIP

Only one category of relationship shall be recognized, namely "Observer Status"; all other contacts, including working relations, shall be considered to be of an informal character.

3. ORGANIZATIONS ELIGIBLE FOR "OBSERVER STATUS"

1. The following shall be eligible for Observer Status:

• International Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO;

- International Non-Governmental Organizations having official relations with WHO; and
- International Non-Governmental Organizations that:

(a) are international in structure and scope of activity, and representative of the specialized field of interest in which they operate;

(b) are concerned with matters covering a part or all of the Commission's field of activity;

(c) have aims and purposes in conformity with the Statutes of the Codex Alimentarius Commission;

(d) have a permanent directing body and Secretariat, authorized representatives and systematic procedures and machinery for communicating with its membership in various countries. Its members shall exercise voting rights in relation to its policies or action or shall have other appropriate mechanisms to express their views; and

(e) have been established at least three years before they apply for observer status.

2. For the purpose of paragraph (a), International Non-Governmental Organizations shall be considered "international in structure and scope of activity" if they have members and carry out activities in at least three countries. The Directors-General of FAO and WHO may, upon the advice of the Executive Committee, grant observer status to Organizations not meeting this requirement if it is clear from their application that they would make a significant contribution to advancing the purposes of the Codex Alimentarius Commission.

4. PROCEDURE FOR OBTAINING "OBSERVER STATUS"

4.1 INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS HAVING STATUS WITH FAO AND/OR OFFICIAL RELATIONS WITH WHO

"Observer status" shall be accorded to those International Non-Governmental Organizations in consultative status, specialized consultative status or liaison status with FAO or International Non-Governmental Organizations having official relations with WHO that inform the Secretary of the Codex Alimentarius Commission of their desire to participate in the work of the Commission and/or any or all of the Commission's subsidiary bodies⁶ on a regular basis. They may also request invitations to participate at specific sessions of the Commission or its subsidiary bodies on an ad hoc basis.

4.2 INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS NEITHER HAVING STATUS WITH FAO NOR OFFICIAL RELATIONS WITH WHO

Before any form of formal relationship is established with a Non-Governmental Organization, such Organization shall supply the Secretary of the Commission with the information outlined in the Annex to these Procedures.

The Secretary of the Commission will verify the completeness of the information provided by the Organization, and will also perform an initial assessment of whether the Organization appears to meet the requirements indicated in Section 3 of these Principles. In case of doubts, he or she will consult with the Directors-General of FAO and WHO and may seek further information and clarifications from the Organization as appropriate.

Upon satisfactory completion of the verification and assessment referred to in the previous paragraph, the Secretary of the Commission will submit the application and all relevant information received from the applicant to the Executive Committee for its advice, pursuant to Rule VIII.6 of the Rules of Procedure of the Codex Alimentarius Commission.

The Secretary of the Commission will transmit the application, together with all relevant information received from the applicant and the advice of the Executive Committee, to the Directors-General who will decide whether an Organization is to be granted observer status. In case of rejection of an application, a re-application by the same Organization shall not normally be considered until two years have elapsed since the Directors-General's decision on the original application.

The Secretary of the Commission shall inform each Organization of the Directors-General's decision on its application, and shall provide a written explanation of the decision in case of rejection.

Observer Status at specific meetings will not normally be granted to individual organizations that are members of a larger organization authorized and that intends to represent them at these meetings.

5. PRIVILEGES AND OBLIGATIONS

International Non-governmental Organizations in Observer status shall have the following privileges and obligations:

5.1 PRIVILEGES OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN "OBSERVER STATUS"

An Organization in Observer Status:

(a) shall be entitled to send an observer (without the right to vote) to sessions of the Commission, who may be accompanied by advisers; to receive from the Secretary of the Commission, in advance of the session, all working documents and discussion papers; to circulate to the Commission its views in writing, without abridgement; and to participate in discussions when invited by the Chairperson⁷;

⁶ The term "subsidiary bodies" means any body established under Rule IX of the Commission's Rules of Procedure.

⁷ An invitation to a Codex meeting and representation thereat by an observer shall not imply the granting to an international non-governmental organization of a status different from that which it already enjoys

(b) shall be entitled to send an observer (without the right to vote) to sessions of specified Subsidiary Bodies, who may be accompanied by advisers; to receive from the Secretaries of the Subsidiary Bodies, in advance of the session, all working documents and discussion papers; to circulate to these Bodies its views in writing, without abridgement; and to participate in discussions when invited by the Chairperson7;

(c) may be invited by the Directors-General to participate in meetings or seminars on subjects organized under the Joint FAO/WHO Food Standards Programme which fall within its fields of interest, and if it does not so participate it may submit its views in writing to any such meeting or seminar;

(d) will receive documentation and information about meetings planned on subjects agreed upon with the Secretariat;

(e) may submit, under the authority of its governing body, written statements on matters before the Commission, in one of the languages of Commission, to the Secretary, who may communicate them to the Commission or the Executive Committee as appropriate.

5.2 OBLIGATIONS OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS IN "OBSERVER STATUS"

An Organization in Observer Status shall undertake:

(a) to cooperate fully with the Codex Alimentarius Commission for the furtherance of the objectives of the Joint FAO/WHO Food Standards Programme;

(b) in cooperation with the Secretariat, to determine the ways and means of co-ordinating activities within the scope of the Joint FAO/WHO Food Standards Programme, with a view to avoiding duplication and overlapping;

(c) to contribute, as far as possible, and at the request of the Directors-General, to the promotion of a better knowledge and understanding of the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme through appropriate discussions or other forms of publicity;

(d) to send to the Secretary of the Commission on an exchange basis, its reports and publications concerned with matters covering all or part of the Commission's field of activity;

(e) to promptly report to the Secretary of the Commission changes it its structure and membership, important changes in its secretariat as well as any other important changes in the information provided in accordance with the Annex to the present Principles.

6. REVIEW OF "OBSERVER STATUS"

The Directors-General may terminate observer status if an Organization no longer meets the criteria that applied at the time it was granted observer status, or for reasons of exceptional nature, in accordance with the procedures set out in this section.

Without prejudice to the preceding paragraph, an international non-governmental organization in Observer Status which has neither attended any meetings nor provided any written comments during a period of four years shall be deemed not to have sufficient interest to warrant the continuance of such relationship.

If, in the view of the Directors-General, the conditions indicated in the previous paragraphs materialize, they shall inform the Organization concerned accordingly and invite it to submit its observations. The Directors-General will seek the advice of the Executive Committee and will submit any observation received from the Organization to it. The Directors-General, taking into account the advice of the Executive Committee and any observation submitted by the Organization, shall decide whether to terminate its observer status. A reapplication from the same Organization shall not normally be considered until two years have elapsed since the Directors-General's decision to terminate its observer status.

The Secretary shall report to the Codex Alimentarius Commission on the relations between the Codex Alimentarius Commission and international nongovernmental organizations established in accordance with the present Procedures and shall provide a list of organizations granted Observer Status, with an indication of the membership that they represent. He or she shall also report to the Commission the termination of the observer status of any Organization.

The Commission shall periodically review these principles and procedures and shall consider, as necessary, any amendments which may seem desirable.

ANNEX: INFORMATION REQUIRED OF INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS REQUESTING "OBSERVER STATUS"

(a) Official name of the organization in different languages (with initials)

(b) Full postal address, Telephone, Facsimile and Email, as well as Telex and website addresses as appropriate

(c) Aims and subject fields (mandate) of organization, and methods of operation. (Enclose charter, constitution, by-laws, rules of procedures, etc.). Date of establishment

(d) Member organizations (name and address of each national affiliate, method of affiliation, giving number of members where possible, and names of principal officers. If the organization has individual members, please indicate approximate number in each country. If the organization is of a federal nature and has international non-governmental organizations as members, please indicate whether any of those members already enjoy observer status with the Codex Alimentarius Commission)

(e) Structure (assembly or conference; council or other form of governing body; type of general secretariat; commissions on special topics, if any; etc.)

(f) Indication of source of funding (e.g., membership contributions, direct funding, external contributions, or grants)

(g) Meetings (indicate frequency and average attendance; send report of previous meeting, including any resolutions passed) that are concerned with matters covering all or part of the Commission's field of activity

(h) Relations with other international organizations:

- UN and its organs (indicate consultative status or other relationship, if any)
- Other international organizations (document substantive activities)

(i) Expected contribution to the Joint FAO/WHO Food Standards Programme

(j) Past activities on behalf of, or in relation to, the Codex Alimentarius Commission and the Joint FAO/WHO Food Standards Programme (indicate any relationship by national affiliates with the Regional Coordinating Committees and/or the National Codex Contact Points or Committees for at least the last three years preceding the application)

(k) Area of activity in which participation as an observer is requested (Commission and/or Subsidiary Bodies). If more than one organization with similar interests is requesting observer status in any field of activity, such organizations will be encouraged to form themselves into a federation or association for the purpose of participation. If the formation of such a single organization is not feasible, the application should explain why this is so.

(1) Previous applications for observer status with the Codex Alimentarius Commission, including those made by a member organization of the applicant organization. If successful, please indicate why and when observer status was terminated. If unsuccessful, please indicate the reasons you were given.

(m) Languages (English, French or Spanish) in which documentation should be sent to ther international nongovernmental organization

(n) Name, Function and address of the person providing the information

(o) Signature and date

ALINORM 05/28/33 APPENDIX VIII

DRAFT GUIDELINES ON COOPERATION BETWEEN THE CODEX ALIMENTARIUS COMMISSION AND INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS IN THE ELABORATION OF STANDARDS AND RELATED TEXTS

SCOPE AND APPLICATION

- 1) These guidelines establish the modalities of cooperation between the Codex Alimentarius Commission and international intergovernmental organizations when elaborating food standards or related texts.
- 2) These guidelines should be read in conjunction with the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

TYPES OF COOPERATION

- 3) The Codex Alimentarius Commission may undertake the elaboration of any standard or related text in cooperation with another intergovernmental body or organization.
- 4) Such cooperation may consist of:
 - a) Cooperation at the initial drafting stages of a Codex standard or related text;
 - b) Cooperation through mutual exchange of information and participation in meetings.

COOPERATING ORGANIZATION

- 5) The cooperating organization shall have observer status with the Codex Alimentarius Commission.
- 6) The cooperating organization shall have [equivalent]⁸ principles of membership⁹ that form the basis for membership in the Codex Alimentarius Commission and equivalent principles of standards-setting¹⁰.

COOPERATION AT THE INITIAL DRAFTING STAGES OF A CODEX STANDARD OR RELATED TEXT^{11}

7) The Commission, or a subsidiary body of the Commission subject to approval by the Commission and taking into account the Critical review conducted by the Executive Committee, as appropriate, may entrust the initial drafting of a proposed draft standard or related text to an international intergovernmental organisation with competence in the relevant field, in particular one of those referred to in Annex A of the WTO/SPS Agreement, on a case-by case basis, provided that the willingness of the cooperating organization to undertake such work has been ascertained. Such texts shall be circulated at Step 3 of the « Uniform Procedure for the Elaboration of Codex Standards and Related Texts ». When appropriate, the international intergovernmental organisations referred to Annex A of the WTO/SPS Agreement shall be associated in the drafting of standards or related texts at Step 2 of the Elaboration Procedure. The Commission shall entrust the remaining steps to the relevant Codex subsidiary body within the Codex Elaboration Procedure.

⁸ This term is in square brackets pending advice from the Legal Counsels of FAO and WHO on the meaning of the term *« equivalent »*

⁹ [Equivalent] principles of membership" shall be taken to mean that the membership of the orgaization is open to all Members and Associate Members of FAO and of WHO.

¹⁰ "<u>Equivalent</u> principles of standards-setting" refers to the General Decisions of the Commission set out in the Appendix to the Procedural Manual.

¹¹ See also Article 1 of the Statutes of the Codex Alimentarius Commission, Step 2 of the Uniform Procedure for the Elaboration of Codex Standards and Related Texts, and the Terms of reference of the Codex Committee on Fresh Fruits and Vegetables (*in* Procedural Manual of the Codex Alimentarius Commission, 14th Edition - to be published).

8) The Commission, or a subsidiary body of the Commission, may use, in whole or in part, an international standard or related text developed by an international intergovernmental organization with competence in the relevant field as a basis for preparing a proposed draft standard or related text at Step 2 of the Elaboration Procedure, subject to concurrence of the cooperating organization. The proposed draft standard or related text shall be circulated at Step 3 of the "Uniform Procedure for the Elaboration of Codex Standards and Related Texts".

COOPERATION THROUGH MUTUAL EXCHANGE OF INFORMATION AND PARTICIPATION IN MEETINGS

- 9) The Commission or a subsidiary body of the Commission may identify an international intergovernmental organization having specific expertise of particular importance to the work of the Commission. Such organization may be encouraged to actively participate in the elaboration of standards by the Commission and its subsidiary bodies.
- 10) The Commission or a subsidiary body of the Commission may invite a cooperating organization having specific expertise of particular importance to the work of the Commission to report about its relevant work at their sessions on an *ad hoc* or regular basis.
- 11) The Commission or a subsidiary body of the Commission may recommend that the Chairperson of the Commission, the Chairperson of the subsidiary body, or, if they are not available, a Vice-chairperson or the Secretary of the Commission, as appropriate, participate in meetings of the cooperating organization, subject to the concurrence of the cooperating organization.
- 12) The Commission or a subsidiary body of the Commission may recommend that the Chairperson or the Secretary of the Commission forward comments, opinions or other relevant information of the Commission to the cooperating organization as regards international standard setting work in areas of mutual interest.
- 13) The Codex Alimentarius Commission may recommend to the Directors-General of FAO and WHO the conclusion of an appropriate arrangement with the executive head of the cooperating organization with a view to agreeing upon specific modalities to facilitate continuing cooperation between the Commission and the cooperating organization, as set out in the paragraphs above.

ALINORM 05/28/33 APPENDIX IX

DRAFT AMENDMENT TO THE RULES OF PROCEDURE ON THE RIGHT TO ADDRESS THE CHAIR

RULE V - NEW PARAGRAPH 5

In plenary meetings of the Commission, the representative of a Member may designate an alternate who shall have the right to speak and vote in the name of his or her delegation on any question. Moreover, upon the request of the representative or any alternate so designated, the Chairperson may allow an adviser to speak on any particular point.

(*Current paragraphs 5 and 6 shall be renumbered accordingly*)