

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 97/33

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-second Session
Geneva, 23-28 June 1997

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

Paris, France
25-28 November 1996

Note: This document incorporates Codex Circular Letter 1996/45-GP

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December 1996

TO: - Codex Contact Points
- Participants in the 12th Session of the Committee on General Principles
- Interested International Organizations

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

SUBJECT: Distribution of the Report of the Twelfth Session of the Codex Committee on General Principles (ALINORM 97/33)

MATTERS FOR ADOPTION BY THE 21st SESSION OF THE CODEX ALIMENTARIUS COMMISSION

AMENDMENT TO THE RULES OF PROCEDURE

1. Amendment to Rules II and IX to provide for the appointment of Members of the Commission as Coordinators and to confirm their attendance as Observers at sessions of the Executive Committee (para. 22, Appendix II)

AMENDMENTS TO THE PROCEDURAL MANUAL

Proposed Appendix to the Procedural manual

2. Inclusion of the four Statements of Principle on the *Role of Science in the Codex Decision-Making Process and the extent to which Other Factors are taken into Account*, to be incorporated into an Appendix to the Procedural Manual entitled "General Decisions of the Commission" (para. 7).
3. Inclusion of four *Statements of Principle relating to the Role of Food Safety Risk Assessment* in the above mentioned Appendix (para. 20, Appendix III).

Definitions for the Purposes of Codex Alimentarius

4. Inclusion of Definitions of Risk Analysis Terms related to Food Safety (para. 21, Appendix III).

Guidelines for Codex Committees (Section G)

5. Amendment to the **Composition of Codex Committees - Observers**, clarifying the modalities of participation of international organizations, and to the **Preparation and Distribution of Papers** concerning the publication of comments (paras. 41 and 43, Appendix IV)

Guidelines for the Inclusion of Specific Provisions in Codex Standards and Related Texts (Section H)

6. Deletion of the **Principles for the Establishment and Application of Microbiological Criteria to Foods** and the **Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex texts** (para. 40, Appendix IV)

Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission - Section J

7. Amendments to the current text to incorporate a reference to the Medium-Term Plan of Work and to strategic planning in specific project areas (para. 40, Appendix IV)

Relations between Commodity Committees and General Subject Committees - Section K

8. Recommendations to clarify the relations between the **Committee on Food Additives and Contaminants** and commodity committees (para. 40, Appendix IV)

Other recommendations

9. Recommendations providing for a clarification of the status of "advisory" Codes, Guidelines and related texts (para. 32)

Governments and international organizations wishing to submit comments on the above documents should do so in writing to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy, **before 1 April 1997**.

SUMMARY AND CONCLUSIONS

The summary and conclusions of the 12th Session of the Codex Committee on General Principles are as follows:

Matters for adoption by the Commission:

The Committee:

- recommended that Rules II and IX be amended to provide for the appointment of Members of the Commission as Coordinators and to confirm their attendance as Observers at sessions of the Executive Committee (para. 22, Appendix II)
- recommended the addition of an appendix to the Procedural Manual entitled "General Decisions of the Commission" including:
 - the four Statements of Principle on the Role of Science in the Codex Decision-Making Process and the extent to which Other Factors are taken into Account (para. 7)
 - the four Statements of Principle relating to the Role of Food Safety Risk Assessment (para. 20, Appendix III)
- agreed to revise the following sections of the Procedural Manual:
 - Definitions (para. 21, Appendix III)
 - Guidelines for Codex Committees (paras. 41 and 43, Appendix IV)
 - Guidelines for the Inclusion of Specific Provisions in Codex Standards (Section H) (para. 40, Appendix IV)
 - Criteria for the Establishment of Work Priorities (para. 40, Appendix IV)
 - Relations between Commodity Committees and General Subject Committees - Section K (para. 40, Appendix IV)
- proposed specific recommendations in order to clarify the status of "advisory" Codes, Guidelines and related texts (para. 32)

Other Matters of Interest to the Commission

The Committee:

- recommended that the Code of Principles concerning Milk and Milk Products be redrafted as a standard (para. 15)
- recommended that the Draft Guidelines for Codex Contact Points and National Codex Committees prepared by CCASIA be circulated to other regional Coordinating Committees (para. 8)

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

INTRODUCTION

1. The Codex Committee on General Principles held its Twelfth Session at the Headquarters of the Office International des Epizooties in Paris, from 25 - 28 November 1996, at the kind invitation of Government of France. Professor Jean-Jacques Bernier, Chairman of the French National Committee for Codex Alimentarius presided over the session. The Session was attended by 163 delegates, alternates and observers from 42 Member countries and 19 international organizations. A complete list of participants, including members of the Secretariat, is given in Appendix I.

2. The Session was opened by Mme. Marion Guillou, Director-General for Food on behalf of M. Philippe Vasseur, Minister of Agriculture, Fisheries and Food. Mme. Guillou stressed the new importance placed upon Codex Standards as a result of the adoption of the Marrakesh Agreements and of the importance of the Committee on General Principles in assuring the successful and correct functioning of the Codex Alimentarius Commission and its other subsidiary bodies.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

3. The Delegation of India, noting the late despatch of documents for Agenda Items 5, 6, 8 and 9, proposed that discussion of these items be postponed. The Delegation pointed out that the Rule V.7 of the Commission's Rules of Procedure required documents to be made available normally not less than 2 months before the Session and therefore strongly opposed the adoption of the Provisional Agenda. The Delegation of India also proposed discussion of special and differential treatment to be applied to developing countries; the Committee agreed to take this matter up under Agenda Item 6. The Committee agreed to consider the recommendations of the Executive Committee concerning establishment of deadlines for the submission of government comments under Agenda Item 9.

4. The Committee adopted the Provisional Agenda as modified as the Agenda for the Session.

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

ROLE OF SCIENCE IN THE DECISION MAKING PROCESS

5. The Committee recalled the decision of the Commission to adopt the four *Statements of Principle concerning the Role of Science in the Codex Decision Making Process and the Extent to which Other Factors are Taken into Account* and discussed a proposal to incorporate them in the Procedural Manual.

6. Some delegations supported their inclusion in the General Principles of Codex in view of their essential importance as a basis for Codex policy. Other delegations expressed the view that their inclusion in the Procedural Manual had not been explicitly requested by the Commission and was in any case inappropriate. Moreover, the implications of the statements might require further discussion, especially as regards the reference to acceptance in the fourth statement.

¹ CX/GP 96/1

² CX/GP 96/2

7. The Committee agreed to recommend to the Commission that the Statements of Principle be incorporated into an appendix to the Procedural Manual entitled "General Decisions of the Commission" which would be published in the 10th Edition of the Procedural Manual. This Appendix would be further developed to incorporate other policy decisions which provided essential guidance from the Commission to its subsidiary bodies. In this respect, it was recalled that the 9th session of the Committee (1989) had considered a similar proposal, and it was suggested that such a document be prepared for consideration by the next session of the Committee.

CODEX COMMITTEE FOR ASIA

8. The Committee noted that the last session of Executive Committee had adopted at Step 5 Draft Guidelines for Codex Contact Points and National Codex Committees and that general advice was needed on how to proceed with such Guidelines developed on a regional basis. Several delegations stressed that the development of such advice was very useful to National Codex Committees and that guidelines should allow for enough flexibility according to the region or country. The Committee agreed that the Draft Guidelines should be circulated to the other regional committees, to be examined to determine if the Draft Guidelines would be suited to their regional situation and could therefore be transformed into a single text.

CODEX COMMITTEE FOR FISH AND FISHERY PRODUCTS

9. With reference to the proposal from the Codex Committee on Fish and Fishery Products to define "non safety mandatory requirements" and, while noting that the revision of the Codes of Practice was still at an early stage, agreed that the use of the terms "advisory" and "mandatory" would be considered from a general perspective under Agenda Item 7.

CODEX COMMITTEE ON MILK AND MILK PRODUCTS

10. The Committee considered a proposal to align the Code of Principles concerning Milk and Milk Products with other relevant Codex texts, through conversion into a standard as it essentially contained labelling requirements, and deletion of general requirements which were already covered by Codex general texts (Preamble, Article 1 and 8).

11. Several delegations supported the deletion of general requirements, while emphasizing the necessity for consistency throughout Codex and the prevalence of the horizontal approach, especially where labelling was concerned, it being understood that matters relating specifically to milk products were under the responsibility of the Codex Committee on Milk and Milk Products (CCMMP). The Observer from IDF agreed that all general requirements could be deleted and the technical contents (sections 2 to 7) should be retained to be redrafted as a standard.

12. Several delegations supported the deletion of provisions on the monitoring of the Code, as regular review of Codex texts was a general principle of Codex there was no need to specify it in an additional text for milk products. The Delegations of France expressed the view that the opportunity of retaining Article 8 should be left to the CCMMP in view of its specific objectives.

13. After an extensive exchange of views on this issue and Committee reasserted that the approach taken by the CCMMP in the elaboration of Codex texts should be consistent with that taken by other Codex committees. The Committee reasserted that the actual technical content of the Code was under the responsibility of the CCMMP, that the general approach should be followed as regards labelling, and all relevant provisions should be endorsed by the Codex Committee on Food Labelling.

14. The Committee recommended that the Code be redrafted in the form of a standard, with the deletion of the general provisions which were covered by other general Codex texts. This included the Preamble and Article 1; Article 8 should also be deleted unless the CCMMP demonstrated that there were specific reasons for the inclusion of the provisions therein. It was noted that this recommendation did not affect the status of the Proposed Draft Code, forwarded for adoption at Step 5, but that the Commission may wish to take into account the recommendations of this Committee.

CODEX COMMITTEE ON FOOD HYGIENE³

15. The Committee noted that the last session of the Codex Committee on Food Hygiene had proposed an amended text for inclusion in the Procedural Manual (Section H) in order to clarify the approach to the inclusion of food hygiene provisions in Codes of Practice, in the perspective of the revised General Principles of Food Hygiene.

RISK ANALYSIS: DEFINITIONS, PROCEDURES AND PRINCIPLES (Agenda Item 4)⁴

16. The Committee noted that work on incorporating risk assessment principles into Codex decision-making and procedures had been initiated on the basis of the recommendations of the Joint FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, held in Rome in 1991. On the basis of these recommendations the Commission at its 19th and 20th Sessions had agreed on the incorporation of risk assessment principles in its procedures. To assist the Commission FAO and WHO convened a Joint FAO/WHO Expert Consultation of the Application of Risk Analysis to Food Standards Issues in March 1995. The 21st Session of the Commission agreed that the report and recommendations of this Consultation should be considered by relevant Codex Committees, especially the Committee on General Principles, so that the risk analysis concept would be incorporated into the Codex procedures. It also invited governments to comment on the definitions proposed by the Expert Consultation for use in this area.⁵

17. The Committee noted that the question of setting an appropriate level of protection was a matter for sovereign governments within their obligations under the SPS Agreement, but that governments were required by the Agreement to base their sanitary and phytosanitary measures on risk assessment principles and that efforts were being made to harmonize their decision-making processes. As a result, there was a need for Codex to provide a clear, transparent and well-documented system for risk analysis in its own decision-making process so that governments would be able to determine their position when deciding on the use of Codex standards and related texts and in harmonizing their requirements on the basis of Codex standards.

18. The Committee made a number of modifications to the proposed statements incorporating risk analysis principles into the general procedures of the Commission with a view to providing a harmonized approach in these matters. It recognized that in order to facilitate the application of the risk analysis process when developing standards and related texts, it was necessary to take into account the concept that different processes and procedures may achieve the same food safety objectives. This would enable governments to examine alternative requirements in the light of their national situation. This concept would be developed as part of further statements of principle relating to the role of risk analysis in Codex. The Committee drew attention to the need to harmonize approaches in different Codex Committees to the matter of intake assessment in relation to risk analysis.

19. In regard to risk assessment and risk management, the Committee recognized that adequate flexibility should be provided where appropriate to meet any special needs of developing countries.

20. The Committee recommended that the statements be included in the Procedural Manual in the Appendix of General Decisions (see para. 7), following *the Four Statements of Principle on the Role of Science in the Codex Decision-making Process and the extent to which Other Factors are taken into Account*. The statements are reproduced in Appendix II of the present report.

³ CX/GP 96/2-Add.1

⁴ CX/GP 96/3; CX/GP 96/3 - Add. 1.

⁵ ALINORM 95/37, paras. 27-30; Circular Letter CL 1995/40-CAC; WHO/FNU/FOS/95.3.

21. The Committee noted that the proposed definitions had been the subject of several revisions in the light of comments. Recognizing the urgent need for guidance in the use of terms and definitions, but also recognizing that there were several efforts underway to harmonize definitions in this area, the Committee proposed that the Definitions be adopted by the Commission on an interim basis and published in the Definitions Section of the Procedural Manual with a note to the effect that they would be subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize definitions across various disciplines.

REVIEW OF THE RULES OF PROCEDURE (Agenda Item 5)⁶

22. The Committee endorsed and transmitted to the Commission proposals to amend the Rules II and IX of the Rules of Procedure to provide for the appointment of Members of the Commission as Coordinators and to confirm their attendance as Observers at sessions of the Executive Committee. The proposed amendments may be found in Appendix III to the present report.

REVIEW OF THE ACCEPTANCE PROCEDURE FOR CODEX STANDARDS IN THE PERSPECTIVE OF THE WTO SPS AND TBT AGREEMENTS (Agenda Item 6)⁷

23. The Committee supported the view that the current acceptance procedures, although they offered transparency in the use of Codex Standards, had not completely achieved this goal and in any case were no longer appropriate in the light of the SPS and TBT Agreements. It noted the linkages between the acceptance procedures and the procedures for the elaboration and adoption of standards to be discussed under Item 8 (below) and the implications of instituting a new acceptance and/or notification procedure. The Committee noted the Secretariat proposals for a procedure to replace the current acceptance procedures, but requested revised proposals to be prepared and distributed to all Members for comments well in advance of the Committee's next Session. These proposals should provide for:

- clearly defined objectives; and
- simple acceptance procedures, the least bureaucratic possible; and/or
- simple notification procedures, the least bureaucratic possible.

24. The Committee noted that the SPS Committee was developing procedures for the monitoring of the use of international standards and encouraged that Committee to make such procedures the least bureaucratic possible when dealing with food standards.

REVIEW OF THE STATUS OF CODES, GUIDELINES AND RELATED TEXTS (Agenda Item 7)⁸

25. The Committee recalled that the Executive Committee had requested the Secretariat to undertake an analysis of all texts other than standards with a view to clarifying the status of these texts, and considered a number of recommendations to this effect.

26. The Delegation of the United Kingdom proposed that a distinction should be made between Codex texts which would be relevant to the SPS and TBT Agreements and those which should not be defined as international standards for the purpose of the Agreements. The Committee however recalled that all types of Codex texts when applied to foods in international trade would be covered either by the definitions of "international standards, guidelines and recommendations" under SPS or the definition "technical regulation" or "standard" under TBT, and any qualification proposed to the texts within Codex could not alter their status under the WTO Agreements.

⁶ CX/GP 96/4

⁷ CX/GP 96/5; CX/GP 96/5 - Add.1.

⁸ CX/GP 96/6

27. The Committee discussed the opportunity of referring to "advisory" texts within Codex and recognized that this term had no clear meaning, especially as the WTO Agreements did not recognize such distinctions. Some delegations pointed out that Codex texts were also intended to provide advice to governments and that this aspect should be taken into consideration. To avoid potential confusion the Committee agreed to recommend that the use of the terms "advisory" and "mandatory" should be discouraged.

28. The Committee recommended that Codex Committees review the codes, guidelines and related texts under their responsibility in order to determine to what extent they should be redrafted as standards.

29. The Committee reasserted that all Codex texts should be elaborated with the same scientific rigour, and clarified that this also applied to those aspects not directly related to food safety

30. The Committee had an extensive discussion on the status of quality criteria intended for voluntary application by commercial partners and their relevance under the TBT Agreement. Some delegations pointed out that following the recommendations of the Commission, only essential requirements had been retained in the standards; other provisions had been transferred to an annex, thereby making it clear they were not intended for use by governments for assessment of imports. The Committee agreed that, notwithstanding the status of such provisions as standards under the TBT Agreement, a statement should be included to specify that they were not intended as a standard or as a relevant text in the context of the SPS and TBT Agreements.

31. The Committee recommended that explanatory material contained in Codex texts should be adequate for the interpretation of the text.

32. Following the above discussion, the Committee agreed to put forward the following recommendations for consideration by the Commission:

- In view of the confusion created by the use of the term "advisory" and as the term cannot be defined satisfactorily and the SPS and TBT Agreements do not appear to distinguish between mandatory and advisory texts, its use within the Codex framework should be discouraged, as well as the use of the term "mandatory";
- All Codex texts specific to the control of food moving in international trade should be elaborated with the same degree of rigour and scientific justification where appropriate as Codex standards;
- Codex standards or any other texts which establish quality criteria for products additional to essential quality factors should clearly indicate that such criteria are intended for voluntary application by commercial partners, as follows: "This text is not intended as a standard, guideline recommendation, or technical regulation within the meaning of the SPS and TBT Agreements";
- The degree of explanatory material contained in Codex texts should be adequate for the interpretation of the text.

REVIEW OF THE ELABORATION PROCEDURE (Agenda Item 8) ⁹

33. The Committee recalled that at its last session it had asked the Secretariat to conduct a survey of procedures used by other standardization organizations and study the possibility of introducing alternative procedures for obtaining consensus on draft standards at various stages in the elaboration process.

34. Several delegations questioned the proposal to introduce postal voting procedures at Step 5. They supported the current procedures because they allowed for full exchange of views on issues in open sessions, thereby facilitating the achievement of consensus and transparency.

35. The Delegation of India, supported by the Delegation of Ghana, emphasized the difficulties for developing countries to participate in Codex; thus it was necessary for the decision making process to reflect the views of all member countries, which was not always the case with the current procedure. Consequently, India supported the introduction of voting by correspondence in order to allow all members to express their position.

36. The Committee was generally of the view that decisions should normally be arrived at by consensus. However, it recognized that in view of the importance and complexity of the issues involved, detailed consideration should be given to all aspects of the Elaboration Procedure, including the quorum, and rules and procedures concerning voting. It called for a document suggesting a number of options to be prepared for consideration at its next session.

37. It was suggested that a group of interested countries might meet between the sessions to prepare proposals. However, the Committee noted that the issues under consideration included those that were legal in nature and thus the input of the Legal Counsels of FAO and WHO would be required. With the agreement of the Chairperson of the Committee on General Principles, consideration might be given at a later date to convening a small group of advisors, consisting of representatives of each Region or group of countries defined in Codex, might be considered at a later date, if necessary.

38. The Committee agreed that a document proposing alternative options for addressing all relevant aspects of the elaboration procedure, would be prepared with input from the Legal Counsels of FAO and WHO, in consultation with the Chairman of the Committee, for circulation and consideration by the next session.

QUORUM (RULE IV.6)

39. The Committee recalled that there had been no support for an earlier proposal to reduce the quorum for adopting amendments of, or additions to the Rules of Procedure. At the Commission's request, the Secretariat had provided several alternative proposals which might be considered in cases when this quorum could not be obtained. After an exchange of views on these alternative proposals, the Committee agreed that the present provisions concerning this quorum should be retained for the time being.

REVISION OF THE PROCEDURAL MANUAL (Agenda Item 9)¹⁰

40. The Committee endorsed the proposals of the Secretariat to make technical changes to certain sections of the Procedural Manual so as to reflect current practices and recent decisions of the Commission. The proposals as amended by the Committee are set forth in detail in Appendix IV to the present report and are submitted to the Commission for approval.

41. The Committee endorsed the proposal concerning participation in an observer capacity of international organizations other than those in formal relation with either FAO or WHO. It noted that such organizations were considered as "recognized" if they were listed as "international organizations" in the Yearbook of International Organizations published annually by the Union of International Organizations. The Delegation of Indonesia suggested that invitations should be extended only to international organizations whose work was relevant to the work of the Commission or Committee concerned.

42. The Committee agreed that members of the press should be registered separately at Codex sessions and that all persons attending Codex sessions should be issued with name badges which clearly indicated their status.

¹⁰ CX/GP 96/8

43. The Committee also agreed that host government secretariats responsible for Codex Committees should not be obliged to reproduce comments submitted in response to Codex Circular Letters if they were received less than one month before a Committee session. This would not, however, prevent participants (Delegations and Observers) from circulating memoranda on issues on the Agenda as was their right under the Rules of Procedure. It was pointed out that the timing and distribution of Circular Letters should allow adequate time for comment. The Delegation of Malaysia, supported by other delegations, stressed the importance of distributing documents in conformity with the Rules and well in time in order to determine a national position through appropriate coordination. Several delegations and observers stated that consideration should be given to strengthening the Codex Secretariat to accommodate the increased work load.

44. The Committee also noted a request that provisions be included in the Procedural Manual on special and differential treatment of developing countries in the work of Codex, based on similar provisions in the SPS and TBT Agreements. The Committee requested that a document on this matter be prepared for consideration at its next Session.

CONSUMER PARTICIPATION IN CODEX WORK (Agenda Item 10)¹¹

45. The Observer from Consumers International introduced a document on consumer participation in Codex work, stressing the difficulties faced by consumer organizations to be represented at the national and international level. These difficulties were primarily due to financial constraints which were especially felt in developing countries. The Observer noted that good progress had been made on representation in National Codex Committees, as well as on consumer education, but that more needed to be done especially to encourage consumer participation in delegations at Codex sessions.

46. The Observer restated the organization's request that consumers be represented as observers in the Executive Committee. The Committee however recognized that the non-admission of observers to sessions of the Executive Committee was general and applied to member countries as well as international organizations. The Delegation of Norway expressed the view that it would not be opposed to positive discrimination in favour of consumer representation in the Executive Committee. It was also recommended that more efforts should be made to appoint experts proposed by consumers' organizations in FAO and WHO expert panels and consultations, where appropriate. Reference was also made to the recommendations of the Executive Committee at its 43rd Session concerning the role of consumers organizations in Codex work¹².

47. Several delegations reported on the measures taken to improve consumer involvement in Codex matters at the national level, as well as consumer information.

48. The Secretariat informed the Committee of ongoing projects and activities for the strengthening of National Codex Committees in a number of countries, with special emphasis on the multi-sectorial nature of Codex work and the importance of consumer participation.

49. The Observer from Consumers International expressed its appreciation to the Committee for the opportunity to discuss this matter and it was noted that Commission would continue its discussions on participation by consumer and other organizations.

OTHER BUSINESS, FUTURE WORK AND DATE AND PLACE OF NEXT SESSION (Agenda Item 11)

50. The Committee noted that its future work would include, *inter alia*:

- Further consideration of issues relating to the integration of risk analysis principles in the work of Codex, in particular in the application of risk management;
- Consideration of proposals concerning the quorum for conducting normal business, voting rules and procedures, and other measures aimed at improving consensus;

¹¹ CX/GP 96/9

¹² ALINORM 97/3, paras. 9-11.

- Consideration of proposals concerning possible acceptance and notification procedures;
- Consideration of provisions for special and differential treatment for developing countries;
- Other matters referred to it by the Commission and other Codex Committees.

51. The Committee noted that its next regular session would be held in Paris in November 1998, the exact dates and place to be determined by the Codex and host government Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 97/33
Amendment of the Rules of Procedure		Governments 22nd CAC	para. 22 Appendix II
Revision of the Procedural Manual: - Definitions - Statements of Principle on 1) the Role of Science 2) the Role of Risk Assessment - Guidelines for Codex Committees - Guidelines for the Inclusion of Specific Provisions - Relations between Committees - Criteria for the Establishment of Work Priorities		Governments 22nd CAC	para. 21 Appendix III paras. 7 and 21 Appendix III para. 40 to 44 Appendix IV
Recommendations concerning Codes and related texts		Governments 22nd CAC	para. 32
Review of the Acceptance Procedure		Secretariat 13th CCGP	para. 24
Review of the Elaboration Procedure		Secretariat 13th CCGP	para. 38

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PROPOSED AMENDMENT TO THE RULES OF PROCEDURE
(RULES II AND IX)

Rule II - Officers

Amend the following¹³:

- 4.(a) The Commission may appoint a Coordinator from among ~~the delegates of the Member of the Commission~~ **the Members of the Commission** for any of the geographic locations enumerated in Rule III.1 (hereinafter referred to as "regions") or for any group of countries specifically enumerated by the Commission (hereinafter referred to as 'groups of countries'), whenever it may find, on the basis of a proposal of a majority of the Members of the Commission which constitute the region or group, that work for the Codex Alimentarius in the countries concerned so requires.
- 4.(b) Appointment of Coordinators shall be made exclusively on the proposal of a majority of the Members of the Commission which constitute the region or group of countries concerned. Coordinators shall hold office from the end of the session of the Commission at which they were ~~elected~~ **appointed** until not later than the end of the third succeeding regular session, the precise term being determined by the Commission in each instance. After having served two consecutive terms, the Coordinators shall be ineligible to hold such office for the next succeeding term.
- 4.(d) Delete

Add new 4.(d) to read as follows:

- 4.(d) In order to carry out their functions, Coordinators shall participate in the Executive Committee as Observers.
- 4.(e) Delete

Rule IX.7 (consequential amendment)

..and in the case of bodies established under Rule IX.1(b)(ii), after consultation with the Coordinator for the region or group of countries concerned, if any ~~or with the Chairperson of the Coordinating Committee.~~

Rule IX.10 (consequential amendment)

The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule IX.1(b)(i) **and Rule IX.1(b)(ii)** shall be designated at each session by the Commission...

¹³ Deletions are marked by text ~~struck out~~ and additions by text in **bold**.

RISK ANALYSIS: DRAFT STATEMENTS OF PRINCIPLE AND DEFINITIONS

a. Statements of Principle relating to the Role of Food Safety Risk Assessment

1. Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances.
2. Food safety risk assessment should be soundly based on science, should incorporate the four steps of the risk assessment process, and should be documented in a transparent manner.
3. There should be a functional separation of risk assessment and risk management, while recognizing that some interactions are essential for a pragmatic approach.
4. Risk assessments should use available quantitative information to the greatest extent possible and risk characterizations should be presented in a readily understandable and useful form.

b. Definitions of Risk Analysis Terms related to Food Safety¹⁴

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

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

RISK ANALYSIS: A process consisting of three components : risk assessment, risk management and risk communication.

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

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

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

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

¹⁴ These Definitions are proposed on an interim basis: they are subject to modification in the light of developments in the science of risk analysis and as a result of efforts to harmonize similar definitions across various disciplines

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

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

RISK MANAGEMENT: The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

RISK COMMUNICATION: The interactive exchange of information and opinions concerning risk among risk assessors, risk managers, consumers and other interested parties.

PROPOSED AMENDMENTS TO THE PROCEDURAL MANUAL¹⁵

GUIDELINES FOR CODEX COMMITTEES (Section G)

Composition of Codex Committees (P.67)

Observers

(last sentence)

“International organizations which have formal relations with either FAO or WHO should also be invited to attend in an observer capacity sessions of those Codex Committees which are of interest to them. Other recognized international organizations may also be invited to attend in an observer capacity sessions of those Codex Committees which are of interest to them”.

Preparation and distribution of papers

(b) (after last sentence)

The Secretariat shall not be responsible for the publication of Circular Letter comments from member countries, observer countries and international organizations pertaining to Agenda Items for Codex Committees later than one month from the opening of the Committee session.

GUIDELINES FOR THE INCLUSION OF SPECIFIC PROVISIONS IN CODEX STANDARDS AND RELATED TEXTS (Section H)

Principles for the Establishment and Application of Microbiological Criteria to Foods

Deleted

Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Codex Texts

Deleted

CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES:AND FOR THE ESTABLISHMENT OF SUBSIDIARY BODIES OF THE CODEX ALIMENTARIUS COMMISSION (Section J)

New Work to be undertaken by Existing Subsidiary Bodies

1. *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 Medium-Term Plan of Work, any specific relevant strategic project currently being undertaken by the Commission and the prospect of completing the work within a reasonable period of time. It should also assess the proposal against the criteria set out in paragraph 4, below.*

¹⁵ Proposed new text is presented in *italics*.

2. *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.*

New Work which may Require the Establishment of a New Subsidiary Body

3. *When a Member wishes to propose the elaboration of a standard, code of practice or related text in an area not covered by the terms of reference of any existing subsidiary body, it should accompany its proposal with a written statement to the Commission referring to the Commission's Medium-Term Objectives and containing, as far as practicable, the information required by the appropriate section of paragraph 4, below.*

RELATIONS BETWEEN COMMODITY COMMITTEES AND GENERAL SUBJECT COMMITTEES (SECTION K)

Food Additives and Contaminants

- 1) Third paragraph (p. 114)
- 2) In preparing working papers for the Codex Committee on Food Additives, the Secretariat should make a report to the Committee concerning the endorsement of provisions for food additives (including processing aids), *on the basis of the General Principles for the Use of Food Additives. Provisions for food additives should indicate the INS number, the ADI, technological justification, proposed level, and whether the additive was previously endorsed (or temporarily endorsed)*
- 3) Sections (i), (ii) and (iii) (pages 114-115): deleted and integrated into the General Principles for the Use of Food Additives.
- 2) First paragraph p.115 "When commodity standards are sent to governments for comments at Step 3, they should contain a statement that the provisions "in respect of food additives *and contaminants* are subject to endorsement by the Codex Committee on Food Additives *and to incorporation into the General Standard for Food Additives or the General Standard for Contaminants and Toxins in Food*
- 1) Second paragraph and Sections (i) to (v) on page 114-115: delete and replace with
- 2) *When establishing provisions for food additives, Codex committees should follow the General Principles for the Use of Food Additives and the Preamble of the General Standard for Food Additives. Full explanation should be provided for any departure from the above recommendations*
- 3) *When an active commodity committee exists, proposals for the use of additives in any commodity standard under consideration should be prepared by the committee concerned, and forwarded to the CCFAC for endorsement. When the CCFAC decides not to endorse specific additives provisions (use of the additive, or level in the end-product), the reason should be clearly stated. The section under consideration should be referred back to the Committee concerned if further information is needed, or for information if the CCFAC decides to amend the provision.*
- 4) *When no active commodity committee exists, proposals for new additive provisions or amendment of existing provisions, should be forwarded directly by member countries to the CCFAC.*