

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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**ALINORM 07/30/33**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX ALIMENTARIUS COMMISSION**

Thirtieth Session

Rome, Italy, 2 - 7 July 2007

### **REPORT OF THE TWENTY-FOURTH SESSION OF THE CODEX COMMITTEE ON GENERAL PRINCIPLES**

Paris, France, 2 – 6 April 2007

Note: This document incorporates Circular Letter CL 2007/11-GP

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CX 4/10

CL 2007/11-GP  
April 2007

**TO:** - Codex Contact Points  
- Interested International Organizations

**FROM:** - Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00153 Rome, Italy

**SUBJECT:** Distribution of the Report of the 24th Session of the Codex Committee on General Principles (ALINORM 07/30/33)

## A. MATTERS FOR ADOPTION BY THE 30<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION

### Proposed Amendments to the Procedural Manual

1. Amendments to the text under the heading "Contaminants" in the *Format for Commodity Standards* (para. 13, Appendix VII).
2. Amendments to section 6, paragraph 1 of the "Principles Concerning the Participation of International Non-Governmental Organizations in the Work of The Codex Alimentarius Commission" (para. 26, Appendix VII).
3. Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues (para 34, Appendix II).
4. Proposed Draft Risk Management Methodologies, including Risk Assessment Policies in the Committee on Residues of Veterinary Drugs in Foods (para. 39, Appendices III/IV).
5. Amendment of the Principles for the Establishment or Selection of Codex Sampling Procedures (para. 42, Appendix V).
6. Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives (GSFA) (para. 46, Appendix VI).
7. Amendment to harmonise the text concerning the membership of the Coordinating Committee for Europe with that of the other Coordinating Committees (para. 114, Appendix VII).
8. Amendments to the Rules of Procedure on the responsibilities of Coordinators and the respective roles in the Executive Committee of the Regional Coordinators and the Members elected on a geographical basis (para. 114, Appendix X).
9. Amendments to the Guide to the Procedure for the Revision and Amendment of Codex Standards and Arrangements for the Amendments of Codex Standards Elaborated by Codex Committees which have been adjourned *sine die* (para. 142, Appendix XI).
10. Amendments to the General Principles of the Codex Alimentarius (para. 146, Appendix XII).

Governments and international organizations wishing to submit comments on the above amendments should do so in writing, preferably by E-mail to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: [codex@fao.org](mailto:codex@fao.org), fax : +39 06 57054593) **before 30 May 2007.**

### **Proposed Draft Text at Step 5/8 of the Procedure**

The Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments at Step 5 with a recommendation to omit Steps 6 and 7 and to adopt them at Step 8 (para 89, Appendix VIII)

Governments and international organizations wishing to submit comments on the Proposed Draft Working Principles should do so in writing, preferably by E-mail to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: [codex@fao.org](mailto:codex@fao.org), fax : +39 06 57054593) **before 30 May 2007.**

### **Recommendations for Endorsement**

The following recommendations are submitted for endorsement to the Commission (para. 107):

- a) Codex should encourage member countries to further implement the provisions in existing CCFICS texts related to the “*subsequent export of food, whether imported or produced domestically, that had been found to be unsafe or unsuitable*”;
- b) Codex should encourage FAO, WHO and other international organizations to give priority to providing technical assistance to member countries with insufficient capacity for establishing and implementing food import and export control systems;
- c) Codex should encourage those member countries with insufficient control systems to give priority in their capacity building/technical assistance needs assessments to the issue of import control systems.

## **B. REQUEST FOR COMMENTS AND INFORMATION**

### **Proposed Draft Text at Step 3 of the Procedure**

Proposed Draft Revised Code of Ethics for International Trade in Food (para 106, Appendix IX)

Governments and international organizations wishing to submit comments on the Proposed Draft Revised Code amendments should do so in writing, preferably by E-mail to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (Email: [codex@fao.org](mailto:codex@fao.org), fax : +39 06 57054593) **before 30 November 2007.**

## SUMMARY AND CONCLUSIONS

The summary and conclusions of the 24<sup>th</sup> Session of the Codex Committee on General Principles are as follows:

### **Matters for adoption by the Commission:**

The Committee agreed to forward to the Commission:

- the proposed amendments to the text under the heading “Contaminants” in the *Format for Commodity Standards* (para. 13, Appendix VII);
- the proposed amendments to section 6, paragraph 1 of the “Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission” (para. 26, Appendix VII);
- the Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues (para. 34, Appendix II);
- the Proposed Draft Risk Management Methodologies, including Risk Assessment Policies in the Committee on Residues of Veterinary Drugs in Foods (para. 39, Appendices III/IV);
- the Proposed Amendment of the Principles for the Establishment or Selection of Codex Sampling Procedures (para. 42, Appendix V);
- the Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the GSFA (para. 46, Appendix VI);
- the Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments for adoption at Step 5 with a recommendation to omit Steps 6 and 7 and adoption at Step 8 (para. 89, Appendix VIII);
- the proposed recommendations from the CCFICS related to the Code of Ethics (para 107);
- the proposed amendments to harmonise the text concerning the membership of the Coordinating Committee for Europe with that of the other Coordinating Committees (para. 114, Appendix VII);
- the proposed amendments to the Rules of Procedure on the responsibilities of Coordinators and the respective roles in the Executive Committee of the Regional Coordinators and the Members elected on a geographical basis (para. 114, Appendix X);
- the proposed amendments to the Guide to the Procedure for the Revision and Amendment of Codex Standards and Arrangements for the Amendments of Codex Standards Elaborated by Codex Committees which have been adjourned *sine die* (para. 142, Appendix XI);
- the proposed Amendments to the General Principles of the Codex Alimentarius (para. 146, Appendix XII).

### **Other matters of interest to the Commission:**

The Committee:

- agreed that there was no consensus to reinsert the Guide to the Consideration of Standards at Step 8 in the Procedural Manual and agreed to inform the Commission that it confirmed its earlier decision and did not wish to reconsider this question further;
- agreed that all Coordinating Committees be invited to discuss institutional and other implications of changing their terms of reference, at their next session and that those Coordinating Committees wishing to practice the adoption of regional positions should continue to do so under their current terms of reference and to report back to the 25<sup>th</sup> session of the CCGP on their experiences (para. 22);
- decided to circulate the Proposed Draft Code of Ethics for International Trade in Food for comments at Step 3 (para 106, Appendix IX);
- the Committee agreed to forward the content of the discussion on proposed draft amendments to the procedures for elaboration of Codex standards and related texts to the Commission for further advice (paras 116-130).

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## INTRODUCTION

1. The Codex Committee on General Principles held its Twenty-fourth Session in Paris, France, from 2 to 6 April 2007 at the kind invitation of the Government of the French Republic. The Session was chaired by Professor Michel Thibier, Science and Technology Counsellor, Embassy of France in Australia. The session was attended by 201 delegates representing 71 member countries, one Member Organization (European Community), and 15 international organizations. A full list of participants, including the Secretariat, is attached as Appendix I.

2. The session was opened by Mr. Guillaume Cerutti, Director-General of Competition Policy, Consumers Affairs and Fraud Control, who welcomed the participants on behalf of the French Government. Mr. Cerutti recalled that two key-subjects would be discussed during the session: the establishment of principles of risk analysis for food safety intended for governments, and the revision of the *Code of Ethics for the International Trade in Food*. He expressed the hope that the Committee could finalize work on these topics, which had started several years ago, during this session. He congratulated the Working Group on Risk Analysis on its success in reconciling the various concerns expressed. He emphasized that safe food was a basic right for everybody, and noted that many countries had difficulties in implementing effective import controls. He encouraged delegates to review the *Code of Ethics for the International Trade in Food* in order to define guiding principles that could lead to more balanced relationships in the food trade. Mr. Cerutti closed by wishing the delegates all success in their work.

## ADOPTION OF THE AGENDA (Agenda Item 1)<sup>1</sup>

3. The Delegation of Brazil proposed to remove Provisional Agenda Item 9 and its document CX/GP 07/24/9 from the Agenda because the document had been available only recently and it had been impossible to develop a national position on the item. The delegation requested clarifications from the Secretariat concerning the rules for the distribution of documents. The Codex Secretariat explained that according to the Procedural Manual, Section II, *Guidelines to Host Governments of Codex Committees and International Task Forces*: “Papers for a session should be sent by the chairperson of the Codex Committee concerned at least two months before the opening of the session...”. The Secretariat explained further that due to the high workload of the Codex Secretariat it was not always possible to respect this deadline as had been the case for several other documents for this session. Following the information from the Secretariat that the document was mainly for information and consultation and not for decision the Committee agreed to leave the item on the Agenda. The Delegation of Brazil reserved its position on this decision.

4. The Committee adopted the Proposed Agenda as proposed in document CX/GP 07/24/1 as the Agenda for the session. The Committee took note of the declaration of division of competence between the European Community and its Member States according to Rule II.5 of the Rules of Procedure (CRD 1).

## MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 2(a))<sup>2</sup>

### Decisions of the 29<sup>th</sup> Session of the Commission on the Work of the Committee

5. The Committee noted the decisions of the 29<sup>th</sup> Session of the Commission as presented in the working document for information.

### Matters Referred by the 29<sup>th</sup> Session of the Commission

#### Amendments to the General Principles of the Codex Alimentarius<sup>3</sup>

6. The Committee noted that this issue would be discussed under Agenda Item 7.

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<sup>1</sup> CX/GP 07/24/1 and CRD 1 (European Community)

<sup>2</sup> CX/GP 06/23/2 and Add.1, CAC29-LIM 12, CRD 6 (Comments from Malaysia), CRD 8 (comments from the European Community)

<sup>3</sup> ALINORM 06/29/41, paras. 24-25

Guide to the Consideration of Standards at Step 8 of the Procedure of the Elaboration of Codex Standards including Consideration of any Statement Relating to Economic Impact<sup>4</sup>

7. The Committee recalled that the 29<sup>th</sup> Session of the Commission had agreed to delete the Guide to the Consideration of Standards at Step 8 from the Procedural Manual and transfer relevant sections to the main text of the Elaboration Procedures and elsewhere in the Procedural Manual. The comments of Malaysia and India, supported by several delegations, to the effect that the provisions of the Guide should be reinserted, were referred to this Committee.

8. The Delegation of Malaysia stressed the importance of the provisions included in the Guide in order to ensure that Codex work was not affected by the adoption of inadequately addressed amendments and to allow sufficient time to consider these amendments; to allow members to raise matters of substantive nature at Step 8 in the Commission; and to allow consideration of the implication of a draft standard for a member's economic interests. The Delegation reiterated its position expressed at the Commission that the Guide should be reinserted as a whole. The position was supported by the Delegations of India, Thailand and Egypt.

9. Several delegations questioned the need to reinsert these provisions as they considered that they were covered in other sections of the Manual and had been deleted to avoid duplication.

10. As regards the possibility to raise substantial issues at Step 8, some delegations pointed out that these matters should be raised in the subsidiary body concerned during the elaboration procedure.

11. In reply to a question, the Secretariat recalled that the working document presented to the last session of the Committee (CX/GP 06/23/6 Part II) included detailed proposals on the transfer of the provisions in the Guide to other sections, or clarified how they were already addressed in the Manual, and noted that the Committee had taken its decision to delete the Guide on that basis.

12. The Committee agreed that there was no consensus to reinsert the Guide in the Procedural Manual and agreed to inform the Commission that it confirmed its earlier decision and did not wish to reconsider this question further.

Codex General Standard for Contaminants and Toxins in Foods (GSCTF)<sup>5</sup>

13. The Committee endorsed the standard wording proposed by the CCFAC concerning a specific reference to the GSCTF in the sections on contaminants of Codex commodity standards, for inclusion in the Procedural Manual and to forward to the 30<sup>th</sup> Session of the Commission the proposal to amend the text under the heading "Contaminants" in the *Format for Commodity Standards* as indicated in Appendix VII.

**Matters Referred by the 28<sup>th</sup> Session of the Commission**

Terms of reference of the FAO/WHO Coordinating Committees

14. The Committee recalled that at its last session it had discussed in detail the proposal of the Coordinating Committee for Latin America and the Caribbean (CCLAC) to amend its mandate to include an additional bullet point "To promote the adoption of regional positions on strategic subjects". The Committee had decided to recommend to the CCLAC to practice the adoption of regional positions as appropriate while keeping their terms of reference unchanged and to report back its experience to this session. All other Coordinating Committees had been invited to discuss the possible inclusion of the sentence proposed by the CCLAC into their terms of reference and its possible implications and report their views to this session.<sup>6</sup>

15. The Committee noted that at their sessions held in 2006/2007 three of the Coordinating Committees (CCNASWP, CCEURO and CCAFRICA) generally agreed that the current terms of reference should be unchanged because they were considered broad enough. They also agreed that the terms of reference of all Coordinating Committees should be kept harmonized. Within CCASIA and CCNEA there were diverging opinions on this issue while CCLAC supported the proposed amendment. The Committee noted further that the CCLAC and the CCEURO had gained some experience in adopting regional positions on certain issues at their last session.

<sup>4</sup> ALINORM 06/29/41, paras. 22-23; CAC29-LIM 12

<sup>5</sup> ALINORM 06/29/41, para. 194

<sup>6</sup> ALINORM 06/29/33, paras. 6-18



16. The Delegation of Argentina reiterated the importance of the proposed amendment in order to ensure transparency within the Executive Committee. In its opinion the function of Coordinators to advise of the views of countries and organizations in their respective regions on matters under discussion could only be fulfilled transparently on the basis of regional positions established in the Coordinating Committees. It also argued that through development of regional positions in the Coordinating Committees developing countries that did not have the resources to attend many other Codex Committees could contribute more efficiently to the work of Codex. This view was supported by other countries of the CCLAC region.

17. A number of other delegations, including Germany, speaking on behalf of the Member States of the European Community, stated that in their opinion the proposed addition to the terms of reference was not necessary as such a function was already covered in the present terms of reference of Coordinating Committees but that if one Committee changed its terms of reference, consistency should prevail and the change be made to the terms of reference of all Coordinating Committees.

18. The Representative of the Legal Counsel of WHO confirmed the statement made at the last session by the Representative of the Legal Counsel of FAO that there were no problems in principle in having different terms of reference for different Coordinating Committees as long as they were consistent with Codex procedures and if the Commission so decides. She also confirmed that regional conferences in FAO and regional committees in WHO, had the same terms of reference and that the consistency in the terms of reference was desirable also for the FAO/WHO Coordinating Committees.

19. Several delegations asked questions concerning the legal implications of only one Coordinating Committee changing its terms of reference: How should Codex Committee Chairs deal with regional positions from only one region? Could other Coordinating Committees still formulate regional positions if they considered their terms of reference broad enough?

20. The Chairperson of the Commission expressed his concern that the goal of the Codex Alimentarius Commission to develop internationally harmonized standards could be jeopardized through regional strategic decisions which could lead to a fragmentation among the members of the Commission.

21. The Delegation of Chile stated that the need for amending the terms of reference had also come out of insecurity on how much liberty a region had for including strategic subjects on the agenda of Coordinating Committees. The Codex Secretariat clarified that according to the *Guidelines for Committees*, provisional agendas were prepared by the Secretary, Codex Alimentarius Commission in consultation with the Chairperson of the Committee. The provisional agenda of all Coordinating Committees must include items referred by the Commission but also could include any particular items regarding problems arising from food control, food safety and food regulatory systems relevant to the region, in consultation with the Regional offices of FAO and WHO as encouraged by the 28<sup>th</sup> Session of the Commission.

22. As there was no consensus on recommending to the Commission that the CCLAC change its terms of reference to include the proposed sentence nor that all Coordinating Committees change their terms of reference in the same way, the Committee agreed that all Coordinating Committees be invited to discuss this matter, including institutional and other implications, at their next session and that those Coordinating Committees wishing to practice the adoption of regional positions should continue to do so under their current terms of reference and to report back to the CCGP on their experiences.

### **Matters referred by other Committees**

#### Review of observer status with the Codex Alimentarius Commission (Executive Committee)<sup>7</sup>

23. The Committee recalled that the Executive Committee at its 58<sup>th</sup> Session was of the opinion that current and future policy and rules on how to deal with the issue of double representation should be applied to existing and prospective observers equally. In this context the Executive Committee discussed the issue of how to review the status of existing observers, provided for in section 6 of the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*. In particular it was noted that a number of observers had been admitted before the adoption of the first version of the Principles by the Commission. The question was raised whether the first paragraph of section 6 of the Principles was to be interpreted to the effect that those observers were virtually “un-

<sup>7</sup> ALINORM 06/29/3A, paras. 106-108

reviewable” because the paragraph made reference to the “criteria that applied at the time it was granted observer status”. The clarification of the scope of this paragraph would allow the Secretariat to fully implement the provisions of section 4 of the Principles. The Executive Committee recommended that the Committee on General Principles be invited to clarify the intent and scope of section 6, paragraph 1 of the Principles.

24. The Codex Secretariat informed the Committee that subsequent to the 58<sup>th</sup> Session of the Executive Committee the Legal Services of FAO and WHO were consulted on how to address the problem identified by the Executive Committee. It was suggested that the problem could be solved by deleting in section 6, paragraph 1 of the Principles the phrase: “that applied at the time it was granted observer status” to the effect that sections 3 and 4 of the Principles apply to all observers.

25. Several delegations mentioned the need to treat existing observers and new applicants equally and there was general agreement on this proposal. Concerns were expressed as to the high workload for the Secretariat resulting from having to review a large number of present observers. The Codex Secretariat informed the Committee that it would most probably proceed with the review in an incremental manner so that the review would not constitute an excessive burden on the Secretariat.

26. The Committee agreed to recommend to the Commission to amend section 6, paragraph 1 of the “*Principles Concerning the Participation of International Non-Governmental Organizations in the Work of The Codex Alimentarius Commission*” as proposed by the Secretariat (see Appendix VII).

#### Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues

27. The Delegation of Malaysia, referring to its written comments in CRD 6, stressed the need to ensure consistency between the documents describing risk analysis policies throughout Codex, and noted that there were some discrepancies between the documents under consideration for pesticide and veterinary drugs residues and the recently adopted Risk Analysis Principles Applied by the CCFAC. The Delegation though supporting the endorsement and adoption of these documents proposed that the Commission for the three committees concerned (Pesticide Residues, Food Additives and Contaminants in Foods) review their risk analysis principles in order to ensure consistency with those applied by the CCRVDF, which followed a more logical sequence, and proposed some specific amendments for consideration at the present session.

28. Some other delegations supported the endorsement and adoption of these documents in view of their importance and in order to complete the work on risk analysis policies and principles initiated at the request of the Commission, with the understanding that they could all be revised once they had been adopted, especially to ensure consistency.

29. It was also noted that the Draft Strategic Plan 2008-2013 for adoption by the 30<sup>th</sup> Session of the Commission included the review of the consistency of risk analysis principles elaborated by the relevant Codex Committees (Goal 2.1).

30. The Committee therefore agreed that it would not consider substantial changes at this stage but would seek to improve the clarity of the text where needed. It was further agreed that following the adoption of the texts under consideration, all adopted risk analysis policies should be reviewed by the Committee especially as regards their consistency with the general *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*.

31. The Delegation of Malaysia proposed some amendments to paragraph 15 to make it consistent with the approach taken to risk analysis for additives and contaminants. Some other delegations did not support this change as they noted that this paragraph should only reflect the criteria applied in the framework of the CCPR for the prioritization of compounds and the Committee retained the current text.

32. The Delegations of Argentina and Chile expressed their concern with the practice of withdrawing MRLs when they were not supported by the industry although the compounds concerned were still used by member countries and no specific safety issues had been identified, especially as it was likely to reduce the availability of pesticides that could be used by developing countries.

33. The Committee agreed to make a number of editorial amendments, such as the correction or deletion of references to Codex documents, whether adopted or under discussion; deletion of the reference to “CXL” in addition to the official term “MRL”; and clarification of advancement to Step 5/8. It was also agreed that in the Annex, paragraphs 5 and 6 would use the text of the adopted *Criteria for Prioritization*.

34. The Committee endorsed the document with the above amendments, as presented in Appendix II, and agreed that this text and all other similar texts would be reviewed together once they had been adopted by the Commission.

Proposed Draft Risk Management Methodologies, including Risk Assessment Policies in the Committee on Residues of Veterinary Drugs in Foods

35. In addition to the general discussion presented above and to some editorial changes, the Committee made some specific amendments to the text, as follows.

36. The Committee agreed that the title of section 3.1.2 should refer only to the establishment of the priority list, and not to the identification of a food safety problem since a veterinary drug could be placed on the priority list even if no actual food safety problem had been identified.

37. In paragraph 14, the Committee agreed to clarify that the protection of confidential information was addressed in Article 39 of the WTO TRIPS Agreement, section 7. Protection of Undisclosed Information.

38. The Delegation of Argentina expressed its reservation on this decision as Article 39 of TRIPS was of a broader nature and went beyond the scope of the provisions applicable in the framework of the CCRVDF. Therefore this reference might affect the rights of countries to present information in the CCRVDF.

39. The Committee endorsed the Proposed Draft Risk Management Methodologies, with the amendments mentioned above, as presented in Appendices III and IV.

Committee on Methods of Analysis and Sampling

40. The Committee recalled that, following approval as new work by the 29<sup>th</sup> Session of the Commission, the CCMAS had finalized a Proposed Amendment of the Principles for the Establishment or Selection of Codex Sampling Procedures that took into account the adoption of the General Guidelines on Sampling in 2004.

41. The Delegation of Germany, speaking on behalf of the Member States of the European Community present at the session, while supporting the adoption of the text, pointed out that in general, the principles for sampling and methods of analysis on which guidance in Codex was based were dated and that in future these would need to be revisited to take into account new work such as sampling uncertainty. The Committee noted that this issue had also been noted by the CCMAS.

42. The Committee endorsed the text as proposed and as presented in Appendix V.

Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the GSFA (Committee on Food Additives and Contaminants)

43. The Committee noted that although this text was related to the establishment of provisions for additives, it was more relevant to the Elaboration Procedures than to the section on risk analysis in the Procedural Manual and agreed that it should be included in that section when adopted. The reference to the Committee on Food Additives and Contaminants was replaced with the Committee on Food Additives throughout the text. The Committee also agreed to several editorial changes and corrections, including the diagram in the French version.

44. In reply to a question concerning “intake assessment”, it was noted that this term was used in the Preamble of the General Standard for Food Additives in relation to the data on intake assessment which could be provided by member countries, whereas exposure assessment was one of the steps of risk assessment carried out by JECFA, and the text was therefore retained as currently drafted.

45. The Delegation of the United States proposed to defer consideration of the provisions concerning the use of food additives in standardized foods, as the interaction between the Committee on Food Additives and Commodity Committees was currently under consideration in that Committee, and new proposals might be put forward by the next session of the CCFA. The Committee however agreed to endorse the document as proposed at this stage, and to draw the attention of the CCFA to the fact that these provisions might need to be reconsidered depending on the outcome of the discussion on this matter at the forthcoming session of CCFA.

46. The Committee endorsed the Proposed Procedure, as presented in Appendix VI.

**PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY (Agenda Item 3)<sup>8</sup>**

47. The Committee recalled that its last session had agreed to return the Proposed Draft Working Principles to Step 2 for consideration by a physical working group co-chaired by Canada and Norway and hosted by the European Community.

48. The Co-Chair of the working group, Mr Paul Mayers (Canada) recalled that the tasks assigned to the working group were to discuss and articulate the rationale for guidance for governments related to the application of risk analysis by governments; to describe the output that Codex may require to respond of this rationale; and to draft, for further discussion, some simple and horizontal principles on the implementation of risk analysis by governments. The working group had agreed to develop simple principles rather than detailed guidelines and to build on the agreed text of the *Working Principles for Risk Analysis for Application within the Framework of Codex Alimentarius*, retaining the principles and elements that were relevant for application by governments, and adding other provisions where necessary. All components of risk analysis had been discussed extensively and the working group had agreed on the revised Proposed Draft Principles presented in Appendix III to the working document, which was circulated for comments at Step 3.

49. The Committee expressed its thanks to Mr Paul Mayers, Ms Bodil Blaker (Co-Chair, Norway) and the participants in the working group for their excellent work to address complex issues and thereby facilitating the consideration of this important subject in the Committee.

50. Many delegations expressed their general support of the approach taken by the working group and of the revised working principles and stressed the importance of providing guidance on risk analysis to governments at the earliest possible opportunity. The Committee noted that a number of detailed comments had been made and agreed that the terminology should be harmonized, especially in the French and Spanish versions with current Codex texts in the area of risk analysis. The Committee considered the document section by section and made the following amendments and comments.

**General Aspects**

51. The Representative of FAO recalled that guidance to governments was provided in the FAO/WHO Food Safety Risk Analysis - A Guide for National Authorities, which had also been presented to the participants in the working group.

52. In paragraph 2 concerning the objective of risk analysis, the Committee agreed with the proposal from several delegations to refer to “human health protection” for clarification purposes. Throughout the document the Committee agreed that the terminology should be harmonized with the terminology used in the adopted *Working Principles*, as far as possible. Following a proposal to refer to the dual mandate of Codex, the Committee recalled that while considerations related to fair trade practices appeared in relevant sections of the document where appropriate, the overall objective of risk analysis was the protection of human health and the current text sentence was retained.

53. The Committee noted a proposal to refer to “international trade” instead of trade in paragraph 3, however it was agreed that the current text was clear enough and consistent with other Codex texts. The Committee also confirmed that the term “non discriminatory” was wide enough to cover all situations and there was no need to add other terms such as “non discretionary” as regards the application of risk analysis.

54. The Committee had an extensive discussion on paragraph 12, especially on the first sentence “Precaution is an inherent element of risk analysis”.

55. Some delegations expressed the view that the first sentence was unclear, not in line with the main content of the paragraph and should be deleted since the approach to addressing uncertainty in risk analysis was explained in the third and fourth sentences. Some delegations proposed to retain only the last sentence of paragraph 12.

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<sup>8</sup> CX/GP 07/24/3, CX/GP 07/24/3-Add.1 (comments of Australia, Colombia, Costa Rica, Japan, Norway, Panama, CRN, 49P), CX/GP 07/24/3-Add.2 (comments of European Community, Kenya, Mali, New Zealand, Paraguay, Peru, Consumers International), CRD 3 (comments of the Republic of Korea), CRD 4 (comments of the United States), CRD 5 (comments of the Philippines), CRD 8 (comments of the European Community), CRD 9 (comments of Mexico)

56. Other delegations and observers pointed out that the term “precaution” did not refer exclusively to risk management but was a general aspect of risk analysis directly related to the uncertainty in scientific information which was clearly explained in the remainder of the paragraph, and recalled that a similar statement appeared in the adopted *Working Principles*.

57. The Delegation of Argentina supported by other delegations expressed the view that the similar statement in the risk analysis principles applied in Codex should be read in conjunction with the decision of the Commission in this regard, but that in order to be retained in a document intended for governments it should be stressed that the statement was for exceptional use in situations where there is a risk for health but where there is no sufficient scientific evidence; the obligation to collect the necessary evidence to conclude the risk assessment in a reasonable time frame should also be stressed.

58. The Representative of WHO recalled that precaution was applied in the framework of risk analysis and that WHO applied precaution in its approach to emergency assessment and response under INFOSAN and will do so under the International Health Regulations (IHR) (2005), which will enter into force in June 2007, and include public health emergencies related to food.

59. The Representative of WTO noted that the text under consideration reflected a well known fact of risk analysis and did not affect or contradict the provisions of the SPS Agreement, which were legally binding for WTO members.

60. After some discussion the Committee agreed to retain the current text of paragraph 12. The Delegation of Malaysia expressed its reservation on this decision

61. In paragraph 13, the Committee deleted the reference to an “output” from international organizations, as it was considered that the results of expert FAO/WHO committees were covered by the terms “relevant guidance and information”.

62. Several delegations proposed to delete the specific reference to OIE and IPPC as the objective of risk analysis in Codex was to address human health and the scope of these organizations was different and therefore only guidance from Codex, FAO and WHO should be considered as related to food safety risk analysis. These delegations however supported a general reference to other relevant organizations.

63. Other delegations and the Representative of FAO stressed the importance of the food chain approach, especially as regards primary production and animal production and therefore supported the reference to the work of OIE and IPPC, taking into account in particular the cooperation between Codex and OIE as regards food safety for products of animal origin. It was also pointed out that Codex, OIE and IPPC were referred to under the SPS Agreement and that it was essential to take into account the whole range of relevant international recommendations and apply risk analysis consistently across the board within the national framework.

64. The delegation of Brazil expressed the opinion that it was important to maintain the reference to the expert groups as it appears on the document prepared by the working group. The Codex Secretariat informed the Committee that the reference to expert groups was not necessary because these groups belong to the activities of FAO and WHO, the experts being nominated by the Directors General of FAO and WHO.

65. After some further discussion, the text of paragraph 13 was amended to clarify that only risk analysis activities “pertaining to human health protection” were concerned in order to avoid any confusion, and that they were “conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.”

### **Risk Assessment Policy**

66. The Delegation of India proposed to insert additional text concerning the feasibility of establishing risk assessment policy. The Committee recalled that these issues had been discussed in the working group, that the difficulties had been recognized, especially for developing countries, and that some flexibility should exist, but that the establishment of a risk assessment policy was an essential component of risk analysis, and the current text was therefore retained.

### **Risk Assessment**

67. The Committee noted the proposal of the Delegation of Cameroon to amend paragraph 18 to read “the objective of risk assessment should be specified, in conformity with the risk assessment policy”. However the Committee retained the current text as its purpose was to ensure that the risk assessment should be fit for its purpose and that the risk assessment policy was addressed in the above section.

68. In paragraph 19, the Committee agreed to refer to “the scope and purpose of the risk assessment”, as there was no need to use the term “particular” to qualify risk assessment.

69. The Committee discussed paragraph 20 concerning the question of conflict of interest. The Delegation of the Republic of Korea and other delegations proposed to amend the text to avoid repetition and group the provisions addressing governments and non government experts. One delegation reported that government risk assessors were generally part of a panel constituted to provide scientific advice over a certain period of time and were not submitted to a new selection process every time they had to provide scientific advice, while non government experts had to be selected through a case-by-case selection process involving declaration of interest. After some discussion, it was agreed to rearrange the text to group the provisions for both government and non government experts. It was also clarified that the purpose was to avoid any conflict of interest “that may compromise the integrity of the assessment”. The Committee specified that public information on the experts was “subject to national considerations”, as it was recognized that procedures and common practice may vary from one country to another.

### **Risk Management**

70. The Committee agreed to delete the reference to “recommendations” that was used in the context of Codex but was not appropriate in relation to the action taken by governments.

71. The Delegation of Argentina, supported by several delegations, proposed to replace the term “decision” with “sanitary measure” in order to ensure consistency with the provisions of the SPS Agreement in paragraph 28 and throughout the text. The Delegation of the European Community, supported by other delegations expressed the view that the use of “sanitary measure” might be justified in some cases but the term “decision” was used in a broader context in several sections and should not be systematically replaced.

72. After some discussion, the Committee agreed to refer to “National government decisions on risk management, including sanitary measures taken”.

73. The Committee considered some proposals to amend the second sentence of the paragraph on “unjustified differences in the level of consumer health protection”. The Delegation of New Zealand proposed to replace this wording with “technically unjustified differences in food safety controls to address similar risks”. Other delegations proposed to retain the current text. The Committee noted that it was difficult to define the level of consumer health protection and agreed to refer to “the measures selected”.

74. In paragraph 30, the Delegation of the United States proposed that the decisions should be “rationally related” to the assessed risk, rather than “proportional”, which was not included in the previously adopted principles and may be interpreted as a strict mathematical relationship between the risk management measure and the level of risk.

75. The Delegation of Malaysia expressed its concern with the term “proportional” and proposed to delete the phrase “and should be proportional to the assessed risk”.

76. After some discussion, the Committee agreed to the proposal from the Delegation of the European Community to replace “proportional” with “proportionate”, as it did not imply the establishment of a precise mathematical relationship. The Delegation of the United States noted its continuing concern and its preference for the deletion of the term. The Delegation of Malaysia expressed its reservation on this decision.

77. The Committee agreed to amend the last sentence to reflect that national governments should base their sanitary measures on Codex standards and related texts where available, as proposed by several delegations in order to emphasise the importance of Codex texts in the framework of the SPS Agreement.

78. The Delegation of Argentina proposed to move the last sentence of paragraph 30 to the section on general aspects. After some discussion, the Committee however decided to retain the sentence in paragraph 30 as the sentence mainly referred to risk management.

79. In paragraph 34, the Committee noted the proposal from the Delegation of Cameroon to refer to an “informed decision” on the management of risk but retained the current text.

80. In paragraph 36, the Delegation of the United States proposed to delete the end of the sentence or alternatively, to insert a footnote to provide guidance on “no more trade restrictive than necessary”: “A measure is no more trade restrictive than necessary unless there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of consumer health protection and is significantly less restrictive to trade”.

81. Some delegations supported the current text, which is the same as in the adopted *Working Principles*, as it was important to ensure that risk management measures did not result in unjustified barriers to trade. Other delegations proposed to delete the phrase “and select measures that are no more trade-restrictive than necessary”. After an exchange of views, the Committee agreed to retain the current text of paragraph 36. The Delegations of Cameroon and the United States reserved their position on this decision.

82. The Delegation of India, supported by some delegations and one observer, proposed to insert additional provisions in paragraph 36 to reflect the importance of cost effectiveness and technical feasibility when considering risk management options. It was however noted that these aspects were specifically covered in paragraph 32 of the same section, and no change was made to the text in this respect.

83. The Delegation of Argentina, supported by some delegations and one observer, proposed to insert provisions for conflict of interest applying to risk managers that would be similar to those applied to risk assessors. The Delegation of Tunisia pointed out that such provisions were relevant in the case of risk assessment as individual experts may have personal interests, but not in the case of risk management which was carried out as part of a governmental regulatory system.

84. The Delegation of Canada recalled that the question had been discussed in the working group, where it had been recognised that provisions applicable to risk assessment were intended to ensure the integrity of the risk assessment, while risk management took into account a range of information in addition to scientific information. In addition, transparency was specifically addressed in the risk management section and therefore it had been agreed that there was no need for “conflict of interest” provisions in this section. The Committee agreed to retain the text of paragraph 36.

### **Risk Communication**

85. The Committee agreed to retain the section as currently drafted.

### **Implementation**

86. The Committee discussed the title and place of this section. The Delegation of New Zealand, supported by other delegations, proposed to change the title of the section to “application” or “other aspects” as the section had been discussed in the context of the application of the principles, not the implementation of measures. Some delegations proposed to refer to capacity building in the title as this was considered in paragraphs 42 and 43. Several delegations pointed out that the aspects covered by the section were not limited to capacity building in risk analysis but were rather of a general nature. The Delegation of Cameroon pointed out that the section covering application dealt with the international aspects of these working principles and recalled that they were meant for national governments.

87. The Committee therefore agreed to transfer paragraphs 42 and 43 at the end of the General Aspects section. As it was recognised that the footnote to the section title provided useful clarification but was not a principle in itself, it was agreed to transfer it to paragraph 4.

### **Further Steps**

88. The Committee recognised that considerable progress had been made and discussed the proposal of the Chair to advance the text to the Commission for final adoption. Several delegations supported the advancement of the text to Step 5 as they had no objection in principle to its content but pointed out that substantial changes had been made and that they needed more time to consider it in depth at the national level before supporting its advancement to Step 8. Other delegations supported its advancement to Step 8 in view of its importance for governments of guidance on risk analysis.

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

89. The Committee advanced the Proposed Draft Working Principles for adoption by the 30<sup>th</sup> Session of the Codex Alimentarius Commission at Step 5 with a recommendation to omit Steps 6 and 7 and to adopt them at Step 8 (see Appendix VIII).

90. The Delegations of Argentina, India, Malaysia and Thailand expressed their reservation on this decision.

91. Following a question of the Delegation of Cameroon on how member governments could report to the Commission on the application of the *Working Principles* following their adoption, the Representative of FAO indicated that FAO and WHO would report to the Commission on capacity building activities in risk analysis, and proposed that the report of countries on the application of risk analysis at the national level should be considered in the framework of Coordinating Committees, possibly as a specific item.

**PROPOSED DRAFT REVISED CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS**  
**(Agenda item 4)<sup>9</sup>**

92. The Secretariat recalled the history of the Code of Ethics for International Trade in Food (CAC/RCP 20-1979), which had been revised once in 1985. Since then events such as the creation of the World Trade Organization and the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) had taken place and the Secretariat had alerted the Committee on the need to revise the Code and the task had been given to the Committee on General Principles. However, in recent sessions of the Committee there was no consensus on whether the present code should be revised or how it should be revised.

93. The 22<sup>nd</sup> Session of the Committee on General Principles agreed to ask the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) to consider whether it could provide recommendations to address the question of “the subsequent export of food, whether imported or produced domestically, that had been found to be unsafe or unsuitable or otherwise did not meet the safety standards of the exporting country”, within its terms of reference, and also consider whether further guidance could be provided to remedy the problems faced by countries with insufficient capacity to conduct import food control. The Committee thus suspended consideration of the Proposed Draft Code of Ethics, currently at Steps 3/4 until the present session, pending the reply from the CCFICS.<sup>10</sup>

94. The Delegation of Australia as host country to the CCFICS reported on the discussion that had taken place at the 15<sup>th</sup> Session of the CCFICS on the basis of the results of an electronic working group<sup>11</sup>. The CCFICS had generally agreed that if new work was required it should fall within the CCFICS mandate and supported a recommendation on the need to ask members to identify the specific provisions that may need to be amended or added and to submit specific proposals for new work. The CCFICS also endorsed the three recommendations of the working group and forwarded them to the 24<sup>th</sup> Session of the Committee on General Principles. The CCFICS could however not reach consensus concerning the establishment of a general principle along the following line “*A country should not export or re-export food to a country if this food is generally recognized dangerous, unfit for human consumption, adulterated, or misleading to the consumers*”.

95. The Chairperson stressed the importance of making progress with the revision of the Code in the Committee on General Principles as this work was explicitly referred to in its terms of reference. He said further that the reputation of Codex was at stake and the Committee might be seen as inefficient if it was not able to update the Code, recalling that the current revision work should be completed by 2009. He suggested forming an in-session working group with the specific objective of drafting a few simple principles that could form a basis for further work by the Committee.

96. Several members and one observer did not support the establishment of a working group. In their view, any new or revised text would only reiterate what was already stated in other Codex documents as well as texts of other organizations. While recognizing that there was a problem with export of unsafe food, they were of the opinion that this was mainly due to insufficient import controls and incomplete food standards of importing countries and that that the issue could be addressed more efficiently by capacity building and by assisting developing countries in strengthening their infrastructure and improving their food control systems. It was mentioned that the CCFICS had recommended a similar way forward and that the CCLAC had expressed a position against further work on the Code based on the arguments above mentioned.

97. Several other members and one observer were in favor of establishing a working group to revise the Code. They felt that the group could concentrate on ethical principles that went to the heart of the Codex objective to ensure safe, sound and wholesome food for all consumers. These principles should not reiterate what other texts already stated but should aim to define moral responsibilities in international trade in order to protect the most vulnerable consumers from sub-standard imports. Some members gave an account of experiences with unsafe imported food consignments. It was mentioned that the CCEURO and the CCAFRICA had expressed a position in favor of further work on the Code.

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<sup>9</sup> CX/GP 07/24/4, CX/GP 07/24/2 (Positions of CCEURO and CCLAC), CRD 2 (comments of Kenya), CRD 5 (comments of the Philippines), CRD 8 (comments of the European Community), CRD 10 (comments of Thailand), CRD 12 (Report of the Working Group consisting of Canada, Cameroon, China, Denmark, European Community, France, Germany, Ghana, Italy, Japan, Kenya, Morocco, the Netherlands, Norway, Switzerland, United Kingdom, United States, Zambia, WHO and Consumers International).

<sup>10</sup> ALINORM 05/28/33A, paras 55-73, ALINORM 06/29/33, paras 78-87

<sup>11</sup> ALINORM 07/30/30, paras. 60-67



98. Some delegations stressed that while capacity building to improve food control in developing countries was critical it would take some time to bring all countries' infrastructure to a satisfying level and a lot of resources were needed. In the meantime a strong Code of Ethics could help to protect importing countries from unsafe food consignments.

99. The Representative of the WTO noted that the WTO Agreements did not oblige governments to take measures to protect consumers from unsafe food or deceptive practices, but gave them the right to restrict trade when necessary for these purposes. Governments could only protect consumers in their own country from unsafe food. She provided information on the Standards and Trade Development Facility (STDF), referred to in the CCFICS report. She also mentioned that the SPS Committee discussed at each session the problems faced by developing countries in the context of special and differential treatment and technical assistance and that it would be useful if Codex delegates participated in SPS Committee sessions to report on their experiences and call for technical assistance needed. The Codex Secretariat could also report the discussion on this issue in the Committee on General Principles at the SPS Committee.

100. The Committee agreed to the proposal made by the Chairperson (see para 92) and decided to establish an in-session working group, to work in English, with the terms of reference: "to consider whether the revision of the current Code could focus on a small set of core principles, set down in Article 4 of the adopted text". After its meeting during the present session the French Secretariat of the CCGP reported on the results to the plenary (CRD 12). The Working Group had taken as a starting point a non-paper prepared by the United States which consisted of an extract of the existing Code.

101. Several members including the Delegation of Morocco speaking as Coordinator for Africa and one observer stated that while the resulting text in CRD 12 was not yet sufficient it could serve as an excellent starting point for further discussions. A number of potential deficiencies and ways for improvement were mentioned by these delegations as follows:

- Article 4 is not precise enough to protect developing countries from unacceptable practices;
- A statement on responsibilities of exporters should be included;
- The text should have a preamble and should keep some principles already in the code that are still useful today (such as statements on most vulnerable groups and breastfeeding);
- The terminology of article 3.2 should be modernized to reflect contemporary concepts such as hazard and risk;
- Implementation issues need to be resolved;
- The work of the World Food Programme on this issue should be looked at and complemented by Codex;
- The problems arising from transit countries should be included;

102. Several delegations including the Delegation of Argentina and other Delegations from Latin America and the Caribbean were of the opinion that the text proposed by the working group would not help to avoid existing problems in trade with the export of sub-standard food products. They stressed that governments should be committed to prevent exports of sub-standard food products but reiterated their opinion that all relevant rules for this already existed in international guidelines and agreements including the present Code of Ethics but that it was the implementation of these rules that did not work. They supported the way forward suggested by the CCFICS and discontinue revision work in the Committee on General Principles.

103. In reply to some statements it was clarified that the proposed text from the working group as well as the existing Code not only applied to food trade but also to concessional and food aid transactions.

104. The Representative of FAO was of the opinion that both a Code of Ethics and efforts in capacity building were needed. He stressed that the Code should not be seen as protecting consumers only in developing countries but in all countries as even a good import control system could not prevent some shipments containing sub-standard food from entering the country. He further indicated that while FAO and WHO had invested extensively in capacity building in food safety over the last decades this was a huge task and it would take many more years to achieve satisfactory results and that in this context a Code of Ethics could help achieving consumer protection globally. He felt that the text proposed by the working group was a good start but should have a preamble that could make reference to the UN Resolution on Consumer Protection and the FAO Guidelines on the Realization of the Right to Food.

105. The Representative of the WHO while also welcoming the continuation of work on a Code of Ethics in Codex stated that a preamble to the text could make reference to the International Health Regulations and the INFOSAN network.

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

106. The Committee decided to circulate the text developed by the working group for comments at Step 3. The Proposed Draft Code of Ethics for international Trade in Food is reproduced in Appendix IX.

107. The Committee also decided to forward the recommendation from the CCFICS to the Commission for endorsement, with a minor amendment, as follows:

- a) Codex should encourage member countries to further implement the provisions in existing CCFICS texts related to the “*subsequent export of food, whether imported or produced domestically, that had been found to be unsafe or unsuitable*”;
- b) Codex should encourage FAO, WHO and other international organizations to give priority to providing technical assistance to member countries with insufficient capacity for establishing and implementing food import and export control systems;
- c) Codex should encourage those member countries with insufficient control systems to give priority in their capacity building/technical assistance needs assessments to the issue of import control systems.

**RESPECTIVE ROLES OF THE REGIONAL COORDINATORS AND THE MEMBERS OF THE EXECUTIVE COMMITTEE ELECTED ON A GEOGRAPHIC BASIS (Agenda Item 5)<sup>12</sup>**

108. The Committee recalled that at its last session, it had agreed to request the Secretariat to prepare an amendment to the Rules of Procedure clarifying the responsibilities of Coordinators to host and designate the Chairperson of the concerned Coordinating Committee. These responsibilities continued to be discharged by the Coordinators but had been deleted from the Rules of Procedure when the Coordinators ceased to be individuals to become Members.

109. The Committee agreed to recommend that the Commission adopt the amendments to Rules IV and XI of the Rules of Procedure contained in document CX/GP 07/24/5 Part I, with the understanding that these amendments would not change the current functions of Coordinators but would clarify them within Rule IV. The Committee also agreed to amend the French version of the current paragraph 3 (i) of Rule IV to align it with the provision in the other language versions. These amendments are set out in Appendix X to this report.

110. The Delegation of Germany, speaking on behalf of the member countries of the European Community present at the session and referring to their comment in CRD 8, proposed an amendment to the specific text governing the membership of the Coordinating Committee for Europe which established a direct link between the Chairperson of the Coordinating Committee and the Coordinator. The current wording was inappropriate since Coordinators had ceased to be individuals. The Committee agreed to recommend to the Commission to harmonise the text concerning the membership of the Coordinating Committee for Europe with that of the other Coordinating Committees. The proposed amendment is included in Appendix VII to this report.

111. The Committee recalled that at its last session the respective roles of the Coordinators and the Members elected on a geographic basis were discussed on the basis of a detailed paper presented by the Legal Offices of FAO and WHO. At that session of the Committee, many delegations concurred with the view that the roles of the Coordinators and the members elected on a geographic basis should be differentiated, and a number of delegations shared a position whereby the members elected on a geographic basis were expected to act within the Executive Committee in the overall interest of the Commission as a whole, while the primary role of the Coordinators was to present the opinions of their respective regions on matters under discussion within the Executive Committee.

112. In the meantime, the Coordinating Committees were invited to examine this issue at their latest session. The discussion held in the Coordinating Committees appeared to reflect a strong consensus whereby it was considered desirable that the respective roles of the Coordinators and the members elected on a

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<sup>12</sup> CX/GP 07/24/5 (Part I and Part II), CRD 5 (comments of the Philippines), CRD 6 (comments of Malaysia), CRD 8 (comments of the European Community), CRD 10 (comments of Thailand)

geographic basis in the Executive Committee be set out in the Procedural Manual. In this respect the Delegation of Cameroon informed the Committee that CCAFRICA following its 2007 session began experimenting to distribute tasks within the Committee by making the Coordinator its spokesperson on matters pertaining to the region in the Executive Committee and the Commission.

113. In reply to the questions raised by some delegations, the Representative of the Legal Counsel of WHO expressed the view that the members elected on a geographic basis were expected to act within the Executive Committee in the interest of the Commission as a whole while the Coordinators were to represent the interest of concerned region or group of countries, confirming the observation presented to the last session of the Committee by the Legal Offices of FAO and WHO. The Committee also noted that the role of the members of the Executive Committee elected on a geographic basis, as articulated above, was comparable to the roles of the countries elected to serve on the governing bodies with restricted membership of FAO and WHO.

114. After some discussion, the Committee reaffirmed the view that the members elected on a geographic basis were expected to act within the Executive Committee in the interest of the Commission as a whole, while the primary role of the Coordinators was to present the opinions of their respective regions on matters under discussion within the Executive Committee. The Committee agreed to recommend to the Commission to insert a new sentence in Rule V paragraph 1 of the Rules of Procedure to clarify the role of the members elected on a geographic basis, as proposed in paragraph 16 of document CX/GP 07/24/5 Part II. The proposed amendment to Rule V paragraph 1 of the Rules of Procedure is set out in Appendix X to this report.

115. As regards the decision of the Eighteenth Session of the Commission allowing the representatives of members of the Executive Committee elected on a geographic basis, but not the Coordinators, to be accompanied by not more than two advisors from the same specified geographic location, delegations who spoke on this matter expressed their general satisfaction with the current arrangement. The Committee noted that it was the prerogative of the members of the Executive Committee elected on a geographic basis to designate their advisors and that it was open to these members to choose their advisors from the countries belonging to a sub-region different from that the members belonged to.

#### **PROPOSED DRAFT AMENDMENTS TO THE PROCEDURES FOR ELABORATION OF CODEX STANDARDS AND RELATED TEXTS (Agenda Item 6(a))<sup>13</sup>**

116. The Committee recalled that the 27<sup>th</sup> Session of the Commission<sup>14</sup> had referred a number of comments from India on the Procedures for Elaboration of Codex Standards and Related Texts to the CCGP which at its 22<sup>nd</sup> Session agreed that the Delegation of India would prepare a discussion paper providing the objectives and rationale for the proposed changes to the Elaboration Procedure for consideration by the next session of the Committee, as a separate Agenda Item<sup>15</sup>. At its 23<sup>rd</sup> Session the CCGP briefly discussed the paper but considered that it was yet premature to request approval of the Commission to initiate new work on these subjects and agreed that the discussion of the issue be continued at its present session. The Chairman confirmed that at the present session the CCGP was not asked to take a decision on the content of the discussion paper but to recommend to the Commission whether or not to start new work on these issues.

117. The Delegation of India recalled that the three main issues addressed in the paper were: (i) Reference to decisions taken by consensus in the Elaboration Procedure, including a definition of that term; (ii) Elaboration of provisions on how to take into account the situation of developing countries within the Critical Review; (iii) Scope of the Critical Review including the basis of the decision to entrust work to a Committee other than the one to which it had originally been entrusted.

118. Concerning item (i) many delegations supported work on a definition of consensus, some supported the concept and others also the wording suggested by India. These delegations stated that the definition of consensus was important to facilitate reaching consensus in Codex meetings, as the practical application of this concept had raised many doubts.

119. Many other delegations, while being open to a discussion on this question, were of the opinion that arriving at a definition that would help the work of Codex would be difficult and that care should be taken to avoid describing the qualitative concept in quantitative terms. They also felt that the terms used in the

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<sup>13</sup> CX/GP 06/23/6 Part-I, CAC29-LIM 12, CRD 8 (comments of the European Community)

<sup>14</sup> ALINORM 04/27/5

<sup>15</sup> ALINORM 05/28/33A (paras 8-16)

definition proposed by India might create new problems because they also needed to be defined in order to make the definition applicable.

120. Some delegations made reference to the decision at the 21<sup>st</sup> Session of the Committee that no new work should be undertaken on a definition of “consensus”, until more experience had been gained in the application of the *Measures to Facilitate Consensus*.<sup>16</sup> They were of the opinion that this decision was still valid and more time was needed before revisiting the issue.

121. Other delegations were of the opinion that the concept of a “spirit of compromise” in order to find consensus was already well established in Codex and an explicit definition of consensus might be detrimental to the present situation.

122. The Delegation of Argentina noted that during the discussion all those delegations that intervened in favor of a definition of consensus came from developing countries and all those who intervened against it came from developed countries.

123. Concerning item (ii) on the need to take into account the situation of developing countries the Delegation of India presented proposals for inclusion into paragraphs 1 and 3 of the critical review. They recalled also that provisions for Special and Differential Treatment were laid down in Article 10 of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) which are currently under discussion in the SPS Committee.

124. Some delegations supported the proposals of India as proposed especially the proposal concerning “economic impact on developing countries”.

125. Several other delegations were of the opinion that the special needs of developing countries had already been addressed in recent amendments of the Procedural Manual concerning the Critical Review, the *Guidelines for Codex Committees and ad hoc Intergovernmental Task Forces*, the *Criteria for the Establishment of Work Priorities*, the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, as well as the *General Decisions of the Commission*.

126. Other delegations, while expressing support in principle for the concerns of India, were of the opinion that the requirements would be difficult to fulfill by a drafter of a project document because the information might not be easily found and the provisions might thus lead to slowing down the work of Codex. It was suggested that in order to overcome these difficulties, the concerns of India could be taken into account at a later stage of standard development when a proposed draft was presented for comments to all countries and it was clearer what risk management options existed and the economic impact could be calculated.

127. Some delegations requested more information on the background of the second proposal concerning cultural and/or traditional practices and it was mentioned that such practices existed in all countries regardless of their state of development. It was mentioned that some of these issues may be related to the protection of intellectual property rights such as Geographic Indications.

128. The Delegation of India explained that this proposal had been made in order to bring in a human perspective into the otherwise science-oriented standards development process.

129. Concerning item (iii) responding to the proposal to eliminate the Critical Review at Step 8 of the Elaboration Procedure, the Codex Secretariat explained that the critical review at Step 8 mainly allowed the Secretariat through the Executive Committee to make some editorial and other adjustments to the final draft texts and that the elimination of this review would not save any time. Concerning the proposal to add an obligation for the Executive Committee to consult the Committee previously entrusted with a task before proposing that it be undertaken by a different Committee, the Codex Secretariat explained that fulfilling this obligation could be difficult and time consuming because Committees met at different intervals.

## **Conclusion**

130. The Committee thanked India for the preparation of the discussion paper. The Committee agreed to forward the content of the discussion to the Commission for further advice.

## **REVIEW OF THE PROCEDURES FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS**

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<sup>16</sup> ALINORM 05/28/33, para. 10

**Guide to the Procedure for the Revision and Amendment of Codex Standards and Arrangements for the Amendments of Codex Standards Elaborated by Codex Committees which have been adjourned *sine die* (Agenda Item 6b)<sup>17</sup>**

131. The Committee recalled that its last session had agreed to delete the Guide to the Consideration of Standards at Step 8 as its provisions had been transferred to other sections of the Procedural Manual, to merge the two above texts and to consider how to address amendments and revisions in a more systematic manner.

132. The Secretariat indicated that a proposal for merging the two guides had been prepared, with a number of provisions intended to clarify the nature of amendments and revisions and how to proceed in each case; the procedure to be followed according to the status of the statutory body that developed the standard; how to apply the Elaboration Procedure in each case; and how to allow for some flexibility in order to make the process as efficient as possible.

133. The Committee had an extensive discussion on the proposed definitions in paragraphs 3 and 4. Several delegations considered that it was necessary to have a clearer definition of the term “revision” by using concrete examples or if this was not possible to delete the definition as the proposed text was likely to create confusion and might create additional constraints to the work of Committees. These delegations pointed out that it might be difficult to determine whether a proposal for change to a Codex text should be considered as an editorial or a substantive change.

134. The Committee noted the clarification from the Secretariat that the distinction between “amendment” and “revision” was introduced only for the purpose of this Guide, based on the request from delegations at its last session. The actual process for amendment/revision work would not substantively change from the current arrangements, while certain flexibility was built in the Proposed Guide to facilitate and accelerate, in some cases, the work of the Commission.

135. It was pointed out that the Commission would in any case decide whether the amendment proposed was substantive or otherwise and on the procedure that should be followed in each case.

136. The Committee had an exchange of views on the reference to “other texts of general applicability” in the third indent of the definition of “amendment” as some delegations questioned whether this was similar to “related texts”. The Secretariat indicated that this was intended to cover texts such as the General Principles of Food Hygiene or the General Standard for the Labelling of Prepackaged Foods, which applied to all foods, and the Committee agreed to mention these texts as examples for clarification purposes.

137. The Delegation of Mexico, speaking as the host country of the Committee on Fresh Fruits and Vegetables, expressed the view that following the request from that Committee, consideration should be given to the application of a simplified procedure for minor amendments to Codex standards, such as inclusion of new varieties.

138. The Delegation of Colombia, referring to paragraph 3 of annex 1 of the working document concerning the finalization of the methods of analysis and sampling, mentioned that in some cases the updating of a method of analysis and sampling in a Codex text could be considered as substantive rather than editorial. For this reason the Delegation did not agree to treat these in the same way as editorial amendments. The Delegation noted that the current text in the Procedural Manual in the Spanish version did not refer to “updating” but only to “finalization” of the process of elaboration of methods of analysis.

139. The Delegation of Malaysia, referring to its written comments, proposed a number of changes to paragraph 4, transferring the provisions applicable to adjourned committees to paragraph 6; applying the deadline for a proposal for amendment or revision to all subsidiary bodies; and reflecting in the last sentence to reflect that only the Commission could take a decision concerning the need for a project document or otherwise to support new work.

140. The Committee however decided to retain the provisions in the working document, noting that for active subsidiary bodies the standard provisions of the Elaboration Procedures applied and that the Executive Committee should also be able to judge the need for a project document thus allowing for some flexibility and more timely decisions within the Commission.

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<sup>17</sup> CX/GP 07/24/6-Part II, CRD 5 (comments of the Philippines) CRD 6 (comments of Malaysia), CRD 8 (comments of the European Community), CRD 13 (comments of Indonesia)

141. In paragraph 5, the Committee agreed to include the advancement of standards to Step 8 with the omission of Steps 6 and 7 in order to expedite the development of standards when consensus existed in the subsidiary body concerned and the Commission.

142. The Committee agreed to advance the proposed amendments, with modifications as agreed, to the Commission for adoption and inclusion in the Procedural Manual (see Appendix XI).

#### **REVIEW OF THE GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS (Agenda Item 7)<sup>18</sup>**

143. The Committee recalled that its last session had agreed to forward the proposed amendment to the General Principles of the Codex Alimentarius to the Commission for adoption. At the 29th Session of the Commission, the Delegation of Malaysia expressed its concern with the deletion of the provisions concerning advisory texts in the General Principles. The Commission agreed to return the proposed amendment to the Committee on General Principles for further consideration, taking into account the comments presented at the present session.

144. The Delegation of Malaysia, referring to its written comments, proposed to insert in the proposed revised General Principles some phrases to clarify what the “related texts” actually were and that these texts were of an “advisory nature”.

145. The Committee recalled that the 22<sup>nd</sup> Session of the Commission had decided that in view of confusion created by the use of the term “advisory” and as the term could not be defined satisfactorily and the SPS and TBT Agreements did 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”. The Committee therefore agreed that it was not appropriate to re-instate references to “advisory” texts, and agreed, upon the proposal from the Delegation of China to add a footnote to the term “related texts” to clarify that these include codes of practice, guidelines and other recommendations.

#### ***Status of the General Principles of the Codex Alimentarius***

146. The Committee agreed to forward the proposed revised General Principles of the Codex Alimentarius, as agreed at its last session with the addition of a footnote agreed on at its current session, to the Commission for adoption (see Appendix XII).

#### **PROPOSED NEW DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY: CLARIFYING THE NATURE OF RISK BASED STANDARDS (Agenda Item 8)<sup>19</sup>**

147. The Committee recalled that its last session had considered a discussion paper prepared by the Delegation of New Zealand concerning the use of the term risk based, following the consideration of risk analysis definitions developed by the Committee on Meat Hygiene. Following the general discussion, the Committee had agreed that the Delegation of New Zealand, in cooperation with the United Kingdom, would prepare a revised paper for consideration by the next session, and that informal consultations on this subject would be held in conjunction with the meeting of the working group on the Proposed Draft Working Principles for Risk Analysis for Food Safety.

148. The Delegation of New Zealand recalled that this issue arose from discussions related to microbiological risk analysis, but that it was also relevant for risk analysis as a whole. In the area of food hygiene, three approaches could be taken to the development of standards: they could be based on good hygienic practice (GHP), on HACCP, or on risk assessment. It appeared that several Codex standards and related texts that had been elaborated on the basis of the GHP or HACCP had considerable value in the control of food risks as they were “fit for purpose” although they did not result from a formal risk assessment, and in the future they would continue to be used.

149. The Delegation pointed out that there were several ways to gain scientific knowledge to develop “risk based” standards that do not necessarily involve resource intensive quantitative risk assessment modelling. The Delegation pointed out that there was no intention to establish a hierarchy of Codex texts on the basis of the approach taken in their development, since all Codex standards should be “fit for purpose”. The Committee was further informed that the workshop held in conjunction with the working group

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<sup>18</sup> CX/GP 07/24/7, CRD 6 (comments of Malaysia), CRD 8 (comments of the European Community), CRD 10 (comments of Thailand)

<sup>19</sup> CX/GP 07/24/8, CRD 7 (comments of Nigeria), CRD 8 ( comments of the European Community) and CRD 11 (comments of Brazil)

mentioned above had facilitated better understanding of the concepts highlighted in the discussion paper. In conclusion, the Delegation of New Zealand proposed that the Committee consider undertaking new work on an explanatory text on “risk-based” standards so as to guide Codex in future application of risk analysis and to prevent unnecessary hurdles when developing standards that should be “fit for purpose”.

150. The Delegation of the United Kingdom, recalling that there was no intention to reconsider the current approach to risk analysis within Codex and in relation to WTO, indicated that any qualification of standards as “risk based” should be consistent with the current Codex provisions concerning risk analysis, and highlighted the importance of providing explanations and practical guidance in this area.

151. The Delegation of Argentina welcomed further discussion of these issues and proposed that the Committee consider the relationship between the concept of “risk-based” standards and the Codex principles for risk analysis that had been finalized at the current session and other current texts in this area; in addition, the legal implications in relation to the provisions of the SPS Agreement would require further consideration.

152. The Delegation of Brazil drew the attention of the Committee to its written comments in CRD 11 and the Committee agreed that all the written comments submitted to the present session would be taken into account when redrafting the discussion paper.

153. The Delegation of Japan noted that the term “risk-based” was used in three Codex texts, the Code of Hygienic Practice for Meat; the Code of Practice for Good Animal Feeding; and the Guidelines for Food Import Control Systems, and pointed out that the Committee would need to consider how to relate these existing provisions to any future work on “risk-based” standards.

154. The Committee expressed its appreciation to the Delegations of New Zealand and the United Kingdom for this important document exploring new concepts, and agreed that these delegations would revise the document for consideration by the next session, taking into account the above discussion, and any contribution that other interested members might wish to make.

155. The Representative of FAO welcomed the consideration of general risk analysis issues in the Committee. Recently, as a result of the consideration of methylmercury in fish in the Committee on Fish and Fishery Products and the Committee on Food Contaminants, and in response to a specific request of the latter, FAO and WHO were in the process of organizing an expert consultation on risk and benefits of fish consumption, which would take into account not only risks from contamination but also nutritional benefits. This represented one of the new approaches to food safety risk analysis.

## **CONSIDERATION OF THE STRUCTURE AND PRESENTATION OF THE PROCEDURAL MANUAL (Agenda Item 9)<sup>20</sup>**

156. The Committee recalled that its last session had made some general recommendations on the content and restructuring of the Manual and agreed that the Secretariat should prepare a revised paper in that perspective. In the meantime some changes had been made to the Manual following the adoption of new texts, especially in the area of risk analysis. The Commission had also made some related recommendations such as the transfer of the Analytical Terminology to a separate Guideline and the deletion of the year of revision or amendment in the reference to Codex texts.

157. The Secretariat indicated that the document had been rewritten on the basis of the recommendations of the last session of the Committee concerning the presentation of the Manual in two parts to make a clear distinction between procedures and other texts of general application on one hand, and texts applying to a specific area of work or a Committee. The discussion paper presented an outline of the Manual according to this approach and suggested new reordering of each section as a basis for discussion. The question of the decisions of the Commission in the Appendix also required some further consideration.

158. The Secretariat indicated that the second part could include the texts on risk analysis and the provisions applying to a specific area of work, which had been adopted by the Commission but were currently included in other publications or in working documents. In particular, the Secretariat drew the attention of the Committee to the MRL Periodic Review Procedure, and recalled that since the present session had finalised the Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues and the Criteria for Prioritization had been adopted by the Commission, there may be a need to reconsider the relevance of this text.

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159. The Delegation of the Netherlands, speaking as the former host country of the CCPR, recalled that the MRL Periodic Review Procedure had been adopted in 1997 and had provided very useful guidance to the CCPR in its systematic review of MRLs, and noted that the finalisation of new texts concerning risk analysis and prioritization justified its review in the framework of the CCPR. The Committee agreed to recommend that the CCPR review the MRL Periodic Review Procedure in the light of more recent documents related to MRL setting process and consider the relevance of this procedure to be published in the Procedural Manual.

160. Several delegations welcomed the revised paper as it provided an opportunity to exchange views on the presentation and contents of the Manual in order to make it more useful and user-friendly.

161. The Delegation of Colombia expressed the view that the terms of reference of Coordinating Committee should be grouped together and that the list of past sessions of committees should be deleted from the Manual in order to leave more space for substantial provisions. The Committee noted that this had been discussed at the last session but that different views had been expressed in this regard.

162. Another delegation expressed the view that the second part should be as inclusive as possible as all relevant texts, especially those that were difficult to locate, should be presented in the Manual. The Delegation pointed out that, while the organisation of the Manual was generally appropriate, it was difficult to find specific items and therefore proposed to include an index, which was also supported by several delegations.

The delegation of Cameroon was in favour of the re-organisation of the manual into two volumes as well as the creation of an index and also supported the idea that the second volume should be as exhaustive as possible from the beginning in order to avoid having to re-issue it too frequently.

163. Another delegation drew the attention of the Committee to issues of cost when deciding whether to publish the Manual in one or two volumes, and noted that this would depend on how frequently each of the provisions was likely to be amended. The delegation proposed to retain the section on the Uniform System of Reference for information purpose, as it was not available elsewhere at the moment, as well as the Core Functions of Contact Points as this provide useful guidance to governments, especially those that initiated Codex work at the national level.

164. Several delegations preferred to retain all provisions in the Manual in a single volume for practical and budgetary reasons, even if they were grouped in two parts as mentioned above.

165. The Secretariat thanked the delegations for their constructive contribution and indicated that it would take their proposals and comments into account when preparing future editions, including the inclusion of an index in order to facilitate its use. The Secretariat also informed the Committee that the website was kept under continuous review in order to provide as much useful information as possible, and to assist users in finding specific references and other information.

#### **DATE AND PLACE OF THE NEXT SESSION (Agenda Item 10)**

166. The Committee was informed that its 25<sup>th</sup> Session was tentatively scheduled to be held in Paris in April 2009, the final arrangements subject to confirmation by the Host Country and the Codex Secretariat.



## SUMMARY STATUS OF WORK

Subject Matter	Step	Action by	Reference in ALINORM 07/30/33
Amendments to the text under the heading “Contaminants” in the <i>Format for Commodity Standards</i>		Governments 30 <sup>th</sup> CAC	para. 13, Appendix VII
Amendments to section 6, paragraph 1 of the “Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission”		Governments 30 <sup>th</sup> CAC	para. 26, Appendix VII
Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues		Governments 30 <sup>th</sup> CAC	para. 34, Appendix II
Proposed Draft Risk Management Methodologies, including Risk Assessment Policies in the Committee on Residues of Veterinary Drugs in Foods		Governments 30 <sup>th</sup> CAC	para. 39, Appendix III/IV
Amendment of the Principles for the Establishment or Selection of Codex Sampling Procedures		Governments 30 <sup>th</sup> CAC	para. 42, Appendix V
Proposed Procedure for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives		Governments 30 <sup>th</sup> CAC	para. 46, Appendix VI
Amendment to harmonize the text concerning the membership of the Coordinating Committee for Europe with that of the other Coordinating Committees		Governments 30 <sup>th</sup> CAC	para. 114, Appendix VII
Amendments to the Rules of Procedure on the responsibilities of Coordinators and the respective roles in the Executive Committee of the Regional Coordinators and the Members elected on a geographical basis		Governments 30 <sup>th</sup> CAC	para. 114, Appendix X
Amendments to the Guide to the Procedure for the Revision and Amendment of Codex Standards and Arrangements for the Amendments of Codex Standards Elaborated by Codex Committees which have been adjourned <i>sine die</i>		Governments 30 <sup>th</sup> CAC	para. 142, Appendix XI
Amendments to the General Principles of the Codex Alimentarius		Governments 30 <sup>th</sup> CAC	para. 146, Appendix XII
Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments	5/8	Governments 30 <sup>th</sup> CAC	para. 89, Appendix VIII
Proposed Draft Revised Code of Ethics for International Trade in Food	3	Governments 25 <sup>th</sup> CCGP	para. 106, Appendix IX
Recommendations from the CCFICS related to the Codex of Ethics		30 <sup>th</sup> CAC	para. 107

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## **DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES**

Advanced for adoption at Step 8

### **SCOPE**

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

### **ROLES OF CCPR AND JMPR IN RISK ANALYSIS**

#### **INTERACTION BETWEEN CCPR AND JMPR**

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.
3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.
4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.
5. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members<sup>1</sup>.
6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.
7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR.

#### **ROLE OF CCPR**

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.
9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.
10. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.
11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.
12. CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

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<sup>1</sup> Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.
14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.
15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:
  - CCPR's Terms of Reference;
  - JMPR's Terms of Reference;
  - The Codex Alimentarius Commission's Strategic Plan;
  - The Criteria for the Establishment of Work Priorities;
  - The Criteria for Inclusion of Compounds on the Priority List;
  - The Criteria for Selecting Food Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
  - The Criteria for Evaluation of New Chemicals;
  - The Criteria for Prioritization Process of Compounds for Evaluation by JMPR
  - A commitment to provide the necessary data for the evaluation in time.
16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.
17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.
18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

#### **ROLE OF JMPR**

19. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.
20. This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.
21. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.
22. JMPR provides CCPR 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 CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.
23. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

24. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.
25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.
26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

## **ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR**

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

### **ESTABLISHMENT OF MRLs/EMRLs**

#### **Procedure for Proposing Pesticides for Codex Priority Lists**

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR<sup>2</sup>.

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date when the chemical was nominated for evaluation;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or

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<sup>2</sup> Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual



- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years or
- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

### **MRLs for Commodities of Animal Origin**

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

### **MRLs for Processed or Ready-to-eat Foods or Feeds**

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

### **MRLs for spices**

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

### **MRLs for fat-soluble pesticides**

13. If a pesticide is determined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”.
- In the absence of useful information on the distribution of residues in muscle and fat, residues with  $\log P_{ow} > 3$  are likely to be “fat soluble”

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

### **Establishment of MRLs**

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised)(1997)<sup>3</sup>. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

21. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

#### **Utilization of Steps 5/8 for elaboration of MRLs**

##### *22. Preconditions for utilization of Step 5/8 Procedure*

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

##### *23. Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8)*

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session.
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8.

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<sup>3</sup> Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

### **Establishment of EMRLs**

24. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses have been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data<sup>4</sup>.

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

### **Periodic Review Procedure**

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

### **Deleting Codex MRLs**

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs can be deleted.

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing MRLs at the following session (t=0+1 year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

### **MRLs AND METHODS OF ANALYSIS**

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

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<sup>4</sup> Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

**PROPOSED DRAFT**  
**RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES**  
**OF VETERINARY DRUGS IN FOODS**

(for inclusion in the Codex Procedural Manual)

**1. PURPOSE – SCOPE**

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods.

**2. PARTIES INVOLVED**

2. The *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius* has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

3. According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

- (a) to determine priorities for the consideration of residues of veterinary drugs in foods;
- (b) to recommend maximum residue limits (MRLs) for such veterinary drugs;
- (c) to develop codes of practice as may be required;
- (d) to consider whether available methods of sampling and analysis for the determination of veterinary drug residues in foods.

4. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs.

5. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

6. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

7. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation where possible.

**3. RISK MANAGEMENT IN CCRVDF**

8. Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken.

9. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for 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*<sup>5</sup>.

### **3.1 PRELIMINARY RISK MANAGEMENT ACTIVITIES**

10. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;
- Identification of a food safety problem;
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

#### **3.1.1 RISK ASSESSMENT POLICY FOR THE CONDUCT OF THE RISK ASSESSMENT**

11. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in *Risk Assessment Policy for the Setting of MRLs in Food*, established by the Codex Alimentarius Commission.

#### **3.1.2 ESTABLISHMENT OF PRIORITY LIST**

12. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.

13. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

- A Member has proposed the compound for evaluation;
- A Member has established good veterinary practices with regard to the compound;
- The compound has the potential to cause public health and/or international trade problems;
- It is available as a commercial product; and
- There is a commitment that a dossier will be made available.

14. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

#### **3.1.3 ESTABLISHMENT OF A PRELIMINARY RISK PROFILE**

15. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

16. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

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<sup>5</sup> *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*, Codex Procedural Manual Appendix

### 3.1.4 RANKING OF THE HAZARD FOR RISK ASSESSMENT AND RISK MANAGEMENT PRIORITY

17. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues such as temporary Acceptable Daily Intakes (ADIs) and/or MRLs. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

18. Prior to development of MRLs for new veterinary drugs not previously evaluated by JECFA, a proposal for this work shall be sent to the Codex Alimentarius Commission with a request for approval as new work in accordance with the *Procedures for the Elaboration of Codex Standards and Related Texts*.

### 3.1.5 COMMISSIONING OF THE RISK ASSESSMENT

19. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information.

### 3.1.6 CONSIDERATION OF THE RESULT OF THE RISK ASSESSMENT

20. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations<sup>6</sup>. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

22. The JECFA assessment reports related to the concerned veterinary drugs should be made available in sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

23. JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options.

24. The CCRVDF may ask JECFA any additional explanation.

25. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

### 3.2 EVALUATION OF RISK MANAGEMENT OPTIONS

26. The CCRVDF shall proceed with a critical evaluation of the JECFA proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12<sup>th</sup> session of the CCRVDF<sup>7</sup> and subsequent amendments made by this Committee.

27. The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question.

28. Particular attention should be given to availability of analytical methods used for residue detection.

<sup>6</sup> Definition of “Codex maximum limit for residues of veterinary drugs”, Codex Procedural Manual.

<sup>7</sup> ALINORM 01/31 paragraph 11.

### **3.3 MONITORING AND REVIEW OF THE DECISIONS TAKEN**

29. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the *Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993).

30. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs.

31. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

### **4. RISK COMMUNICATION IN THE CONTEXT OF RISK MANAGEMENT**

32. In accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCRVDF, in cooperation with JECFA, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

33. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

**TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX  
COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**ADMINISTRATIVE INFORMATION**

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names
5. Names and addresses of basic producers

**PURPOSE, SCOPE AND RATIONALE**

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

**RISK PROFILE ELEMENTS**

8. Justification for use
9. Veterinary use pattern
10. Commodities for which Codex MRLs are required

**RISK ASSESSMENT NEEDS AND QUESTIONS FOR THE RISK ASSESSORS**

11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework
12. Specific request to risk assessors

**AVAILABLE INFORMATION<sup>8</sup>**

13. Countries where the veterinary drugs is registered
14. National/Regional MRLs or any other applicable tolerances
15. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

**TIMETABLE**

16. Date when data could be submitted to JECFA

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<sup>8</sup> When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a veterinary drug for the establishment of an ADI and MRLs, published by JECFA.



**PROPOSED DRAFT**  
**RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR**  
**RESIDUES OF VETERINARY DRUGS IN FOODS**

(for inclusion in the Codex Procedural Manual)

**Role of JECFA**

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.
2. This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
  - (a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs).
  - (b) JECFA should take into account all available scientific data to establish its risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.
  - (c) Constraints, uncertainties and assumptions that have an impact on the risk assessment need be clearly communicated by JECFA.
  - (d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific group of populations of potentially enhanced vulnerability (e.g. children).
  - (e) Risk assessment should be based on realistic exposure scenarios.
  - (f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.
  - (g) MRLs, that are compatible with the ADI, should be set for all species based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

**Data Protection**

3. Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data is to be considered as confidential. The procedure includes a formal consultation with the sponsor.

**Expression of risk assessment results in terms of MRLs**

4. MRLs have to be established for target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice.

5. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the control of the safety of carcasses moving in international trade.

6. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

## APPENDIX V

**PROPOSED AMENDMENT TO THE PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION  
OF CODEX SAMPLING PROCEDURES**

**PURPOSE OF CODEX METHODS OF SAMPLING**

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

**METHODS OF SAMPLING**

*Types of Sampling Plans and Procedures*

**(a) Sampling Plans for Commodity Defects:**

Such plans ~~These~~ are normally applied to visual defects (e.g. loss of colour, ~~mis-graded for~~ misgrading of size, etc.) and extraneous matter. They ~~are will~~ normally ~~be~~ attributes plans, and plans such as those included in Section 3.1 and 4.2 of the ~~FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL 6.5) General Guidelines on Sampling (CAC/GL 50-2004)~~ (hereinafter referred to as "General Guidelines") may be applied.

**(b) Sampling Plans for Net Contents:**

~~These~~ Such plans are sampling plans those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

**(c) Sampling Plans for Compositional Criteria:**

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

**(d) Specific Sampling Plans for Health-related Properties:**

Such plans are ~~generally~~ normally applied to heterogeneous conditions, e.g., in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

***General Instructions for the Selection of Methods of Sampling***

~~(a) Official methods of sampling as elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such methods, when attracted to Codex standards, may be revised using Codex recommended sampling terms (to be elaborated).~~

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(bc) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

- (i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the

standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

- (ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(ed) Instructions on the procedure for the taking of samples should indicate the following:

- (i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;
- (ii) the size and the number of individual items forming the sample taken from the lot or consignment;
- (iii) the administrative measures for taking and handling the sample.

(de) The sampling protocol may include the following information:

- (i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;
- (ii) the procedures to be adopted in cases of dispute.

## **GENERAL CONSIDERATIONS**

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

**APPENDIX VI****Procedures for Consideration of the Entry and Review of Food Additive Provisions in the General Standard for Food Additives**

(for inclusion in the Codex Procedural Manual)

**SCOPE**

The Codex General Standard for Food Additives is intended to include food additive provisions for standardised and non-standardised foods in the Codex Alimentarius.

The following text describes the data and information that should be submitted to the Codex Committee on Food Additives when requesting the Committee to initiate work to add or revise food additive provisions in the Codex General Standard for Food Additives. The decisions required to establish acceptance or rejection of new proposals are also elaborated.

Provisions for the use of processing aids (e.g., most enzyme preparations, clarifying and filtering aids, extraction solvents) are not included in the General Standard for Food Additives.

**INITIATION OF WORK****Revision**

The food additive provisions of the General Standard for Food Additives may be revised by the Committee on Food Additives after requests submitted by Codex Committees, Codex members, or the Codex Alimentarius Commission. Information to support amendment of the General Standard for Food Additives shall be provided by the proposing body. Supporting information provided to the Committee on Food Additives should include, as appropriate:

- Specifications for the food additive;
- A summary of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) safety evaluation of the food additive;
- The food categories or sub-categories in which the additive is intended to be used;
- An indication of the technological need / justification for the additive, referencing one or more of the General Principles for the Use of Food Additives of the GSFA (Section 3);
- Maximum use levels for the food additive in the specified food categories:
  - For additives with a numerical Acceptable Daily Intake (ADI), a numerical maximum use level for each specified use although for certain cases, a level of GMP may be appropriate;
  - For additives with an ADI Not Specified or Not Limited, a recommendation to list the additive in Table 3 accompanied by additional proposals for inclusion in Tables 1 and 2 for use in the food categories listed in the Annex to Table 3, as appropriate;
  - For additives with an “acceptable” ADI, either a numerical maximum use level for the acceptable level of treatment of a food or a level of GMP, consistent with the JECFA evaluation.
- A justification of the maximum use levels from a technological point-of-view; and an indication, by means of the procedure indicated in Annex A of the General Standard for Food Additives or an exposure assessment, that this level meets the safety requirements enumerated in Section 3.1 of the General Standard for Food Additives.
- A reasoned statement that consumers will not be misled by the use of the additive.

The Committee on Food Additives shall consider all amendments to the General Standard for Food Additives proposed by Codex Committees, Codex members, or the Codex Alimentarius Commission.

## Review

The food additive provisions for the General Standard for Food Additives shall be reviewed by the Committee on Food Additives on a regular basis and revised as necessary in light of revisions of the risk assessment by JECFA or of changing technological need and justification for use.

- If JECFA changes an ADI to a Temporary ADI, the food additive provisions of the General Standard for Food Additives may remain unchanged until the ADI has been withdrawn or the full status has been restored by JECFA.
- If JECFA withdraws an ADI the food additive provisions of the General Standard for Food Additives shall be amended by removing all provision for the use of the additive.

The following additional guidance is provided regarding the information to be submitted:

- Identity of the food additive
  - Food additives shall have been evaluated by JECFA and either assigned a full numerical or non-numerical (“not specified” or “not limited”) ADI, or deemed to be acceptable for a particular use.
  - Food additives shall have been assigned an International Numbering System number.
- Functional effect of the food additive
  - The functional class list used in *Class Names and the International Numbering System* (CAC/GL 36-1989) should be used.
- Proposed use of the food additive
  - The appropriate food categories from the food category system (Annex B of the General Standard for Food Additives) and maximum use levels should be specified.
  - With regard to the acceptable maximum use level:
    - A numerical use level should be provided for a food additive assigned a numerical ADI. However, in some cases, reporting the use level as good manufacturing practice (“GMP”) may be appropriate.
    - For a food additive assigned a non-numerical (“not specified” or “not limited”) ADI that is listed in Table 3 of the General Standard for Food Additives, a numerical or good manufacturing practice (“GMP”) use level should be provided for any request to list the additive in a food category in the Annex to Table 3.
    - For some food additives, the ADI has been reported on a specific basis (e.g., “as phosphorus” for phosphates; “as benzoic acid” for benzoates). For consistency, the maximum use level for these additives should be reported on the same basis as the ADI.
- Justification for the use and technological need of the food additive
  - Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives should be included.
- Safe use of the food additive
  - An intake assessment of the proposed use of the food additive, in accordance with Section 3.1 of the Preamble of the General Standard for Food Additives, should be included as appropriate.
- Justification that the use does not mislead the consumer
  - A reasoned statement that consumers will not be misled by the use of the additive should be provided.

**DOES THE FOOD ADDITIVE USE MEET THE CRITERIA OF SECTION 3.2 OF THE PREAMBLE OF THE GENERAL STANDARD FOR FOOD ADDITIVES?**

Section 3.2 of the Preamble of the General Standard for Food Additives establishes the criteria for justifying the use of a food additive. Adherence to these criteria is necessary for the inclusion of the food additive in the General Standard for Food Additives. If the use of the additive does not meet these criteria, it is not considered further and the work is discontinued. If the information provided to justify the use of the additive is inadequate for the Codex Committee on Food Additives to reach a decision, further information on the use and technological justification and need for the food additive will be requested for consideration at the Committee's next session. If this information is not provided by the next session, work on the provision is discontinued.

**IS THE FOOD ADDITIVE USED IN STANDARDIZED FOOD?**

The Codex Committee on Food Additives, asks the relevant Codex commodity committee to consider the functional classes of additives, additives, and their technological justification for the commodity and to refer back this information by the next available session.. In light of this information, the Codex Committee on Food Additives recommends appropriate conditions of use based on proposals of the commodity committee.

In certain cases, however, it may be appropriate for the Codex commodity committee to develop a list of food additives with associated functional classes and acceptable maximum use levels that would be forwarded to the Codex Committee on Food Additives for endorsement and, ultimately, incorporation into the General Standard for Food Additives. The development of such food additive lists should be consistent with the principles used in the development of the General Standard for Food Additives. However, the development of food additive lists in commodity standards should be restricted as much as possible. For example, an additive may be listed in a commodity standard if it is needed to achieve a technical effect that is not achievable by the use of other additives of the same functional class. Additives may also be listed in a commodity standard if there is a need, based on a safety assessment, to limit the use of the additive. Justification for such exceptions should be provided by the Codex commodity committees to the Codex Committee on Food Additives for consideration.

If the Codex commodity committee has been adjourned, the Codex Committee on Food Additives may revise the food additive provisions in commodity standards under the purview of the adjourned committee, as necessary.

The Codex Committee on Food Additives would consider any proposed revision in light of the principles of technological justification for the use of additives as indicated in Section 3.2 of the Preamble of the General Standard for Food Additives. These revisions, once adopted by the Commission, would be incorporated into the General Standard for Food Additives.

**HAS A NON-NUMERICAL (“NOT SPECIFIED” OR “NOT LIMITED”) ADI BEEN ASSIGNED?**

Yes - Non-Numerical (“Not Specified” or “Not Limited”) ADI:

Food additives assigned a non-numerical ADI are proposed for inclusion in Table 3 of the General Standard for Food Additives. Requests for the use of these additives in the food categories listed in the Annex to Table 3 are made by proposing provisions for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under “**Consideration of Conditions of Use in the Specific Food Categories,**” below.

No - Numerical ADI or Acceptable for Limited Use:

Food additives assigned a numerical ADI or evaluated to be acceptable for one or more particular uses are proposed for inclusion in Tables 1 and 2 of the General Standard for Food Additives. These proposals are considered by the Codex Committee on Food Additives according to the criteria described under “**Consideration of Conditions of Use in the Specific Food Categories,**” below.

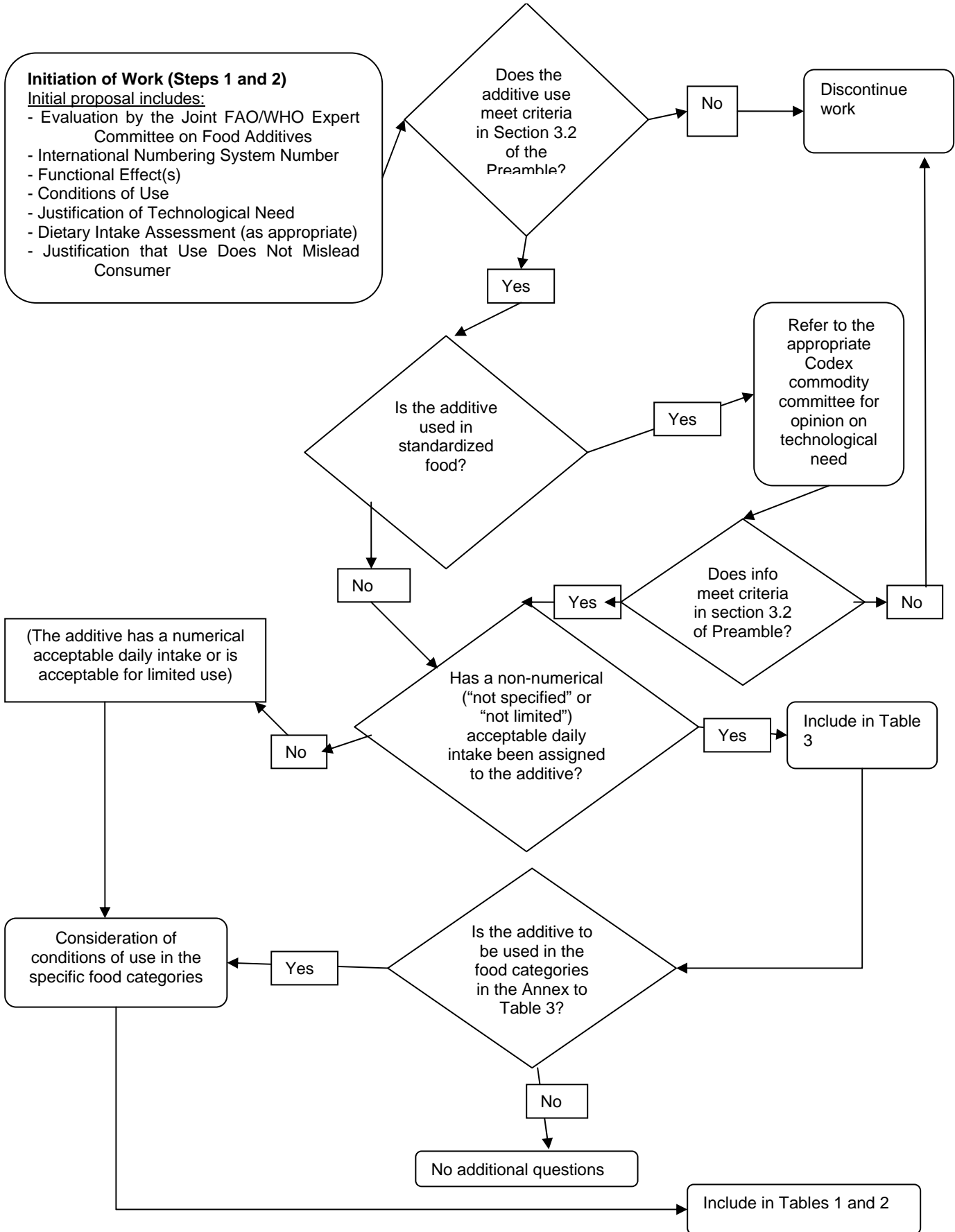
**CONSIDERATION OF CONDITIONS OF USE IN THE SPECIFIC FOOD CATEGORIES**

The Codex Committee on Food Additives identifies and recommends appropriate food categories and use levels for inclusion in Tables 1 and 2 of the General Standard for Food Additives. For this purpose, the Committee will consider the following general principles for the inclusion of a food additive provision in Tables 1 and 2 of the General Standard for Food Additives:

1. Food additives that share a numerical group ADI will be considered as a group without further restrictions on the use of individual additives in that group. However, in some cases, restrictions on the use of individual additives in that group could be appropriate (e.g., because of public health concerns).
2. Food additives that have multiple functional classes will be considered without further restrictions to their functional class.
3. In general, a numerical use level for a proposed use of a food additive in a food category is given preference over a use level reported as good manufacturing practice (“GMP”). However, exceptions, as noted under “**Initiation of Work,**” shall also be taken into account by the Codex Committee on Food Additives on a case-by-case basis.
4. When establishing the acceptable maximum level of use for an additive in a specified food category, the Codex Committee on Food Additives considers the technological justification for the proposed level and the exposure assessment in accordance with Sections 3.1 and 3.2 of the Preamble of the General Standard for Food Additives. If more than one maximum use level is proposed, and the Committee cannot reach consensus on the appropriate maximum use level, the delegations supporting and the delegations opposing the proposed maximum use level should provide additional justification for their proposed levels to address any specific concerns raised by the Committee, by the next available session, to the Codex Committee on Food Additives, for consideration in its next session. Proposals lacking justification will no longer be considered, and the proposed level for which justification has been provided will be forwarded for adoption.
5. To resolve questions related to dietary exposure of food additives, the Codex Committee on Food Additives may request JECFA to perform exposure assessments for the additives based on the acceptable maximum use levels under consideration by the Codex Committee on Food Additives.
6. Acceptable maximum use levels are established as described in the previous sections and the food additive provisions are entered in the General Standard for Food Additives. Each use level represents the highest acceptable maximum use level in the broadest food category for which the use is technologically justified. To the extent possible, the hierarchical structure of the food category system will be used to simplify the listing of the food additive provisions in Tables 1 and 2 of the General Standard of Food Additives. In this regard:
  - If the new use of a food additive is for a broader food category and at a maximum use level that is higher than or equal to those in the sub-categories of the broad food category that are already listed in the General Standard for Food Additives, then the new use in the broader food category supersedes the already-listed provisions. These provisions are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
  - If the new use of a food additive is for a broader food category and at a lower maximum use level than for the sub-categories of the broad food category that already exist in the General Standard for Food Additives, then the provisions listed in the General Standard for Food Additives are determined according to the hierarchy of the food category system. The highest maximum use level in each food sub-category, whether from an existing provision or from the new use in the broader food category, is entered into the General Standard for Food Additives. Any existing provisions that are superseded by the new use are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the proposed use at Step 8 (if adopted provision at Step 8).
  - If the new use of a food additive, together with the already-listed provisions in the General Standard for Food Additives, represents use in all of the sub-categories of a broader food category at the same maximum use level, then the use in the broader food category will be listed in the General Standard for Food Additives. The already-listed provisions in the sub-categories are discontinued (if proposed draft or draft provisions), or revoked upon adoption of the provision in the broader food category at Step 8 (if adopted provision at Step 8).



**Diagram of procedure for consideration of the entry and review of food additives in the Codex General Standard for Food Additives**



## OTHER AMENDMENTS TO THE PROCEDURAL MANUAL

A. *Amendments to the Principles Concerning the Participation of International Non-Governmental Organizations in the Work of The Codex Alimentarius Commission*

Sections 1-5 [no change]

## 6. Review of "Observer Status"

The Directors-General may terminate observer status if an Organization no longer meets the criteria in sections 3 and 4 above ~~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. [...]

B. *Amendments to the Format for Codex Commodity Standards**Contaminants*~~Pesticide Residues:~~

~~This section should include, by reference, any levels for pesticide residues that have been established by the Codex Alimentarius Commission for the product concerned.~~

~~Other Contaminants:~~

~~In addition, this section should contain the names of other contaminants and where appropriate the maximum level permitted in the food, and the text to appear in the standard may take the following form:~~

~~*“The following provisions in respect of contaminants, other than pesticide residues, are subject to endorsement [have been endorsed] by the Codex Committee on Contaminants in Foods.”*~~

~~Then should follow a tabulation, viz.:~~

~~*“Name of contaminant, maximum level (in percentage or mg/kg).”*~~

This section should include the following statement:

*“The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC.”*

C. *Amendments to Section VI, FAO/WHO Coordinating Committee for Europe (CX-706)**Membership:*

Membership of the This Committee is open to all Member Nations Governments and Associate Members of FAO and/or WHO which are members of the Codex Alimentarius Commission, within the geographic location area of Europe, including Israel, Turkey and the Russian Federation ~~and its Chairperson is, ex officio, the Coordinator for Europe.~~

*Terms of reference:* [no change]

## APPENDIX VIII

**Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments  
(At Step 5/8 the Procedure)**

**SCOPE**

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

**GENERAL ASPECTS**

2. The overall objective of risk analysis applied to food safety is to ensure human health protection.

3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.

4. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.<sup>9</sup>

5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

6. Risk analysis should be:

- \* applied consistently;
- \* open, transparent and documented; and
- \* evaluated and reviewed as appropriate in the light of newly generated scientific data.

7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission<sup>10</sup>, each component being integral to the overall risk analysis.

8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties<sup>11</sup>.

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

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

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

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and

<sup>9</sup> It is recognized that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.

<sup>10</sup> See *Definitions of Risk Analysis Terms Related to Food Safety*, Procedural Manual.

<sup>11</sup> For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”).

variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.

14. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.

15. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

### **RISK ASSESSMENT POLICY**

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

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

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

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

### **RISK ASSESSMENT**

20. Each risk assessment should be fit for its intended purpose.

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

22. Experts, involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

23. Risk assessment should incorporate the four steps of risk assessment, i.e., hazard identification, hazard characterization, exposure assessment and risk characterization.

24. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

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

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
27. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.
28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.
29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

### ***RISK MANAGEMENT***

30. National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.
31. Risk management should follow a structured approach including preliminary risk management activities<sup>12</sup>, evaluation of risk management options, implementation, monitoring and review of the decision taken.
32. The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles<sup>13</sup> as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available.
33. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
34. Risk management should take into account the economic consequences and the feasibility of risk management options.
35. The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.
36. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

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<sup>12</sup> For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

<sup>13</sup> See *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*, Procedural Manual.

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

38. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary.

### **RISK COMMUNICATION**

40. Risk communication should:

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

41. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

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

43. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).

**APPENDIX IX****PROPOSED DRAFT CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD****(AT STEP 3)****ARTICLE 1 - OBJECTIVE**

1.1 The objective of this Code is to establish principles for the ethical conduct of international trade in food, thereby protecting the health of the consumers and ensuring fair practices in the food trade.

**ARTICLE 2 - SCOPE**

2.1 This Code applies to all food introduced into international trade<sup>14</sup>

2.2 This Code establishes principles of ethical conduct to be applied by all those concerned with international trade in food.

**ARTICLE 3 - PRINCIPLES**

3.1 International trade in food should be conducted on the principle that all consumers are entitled to safe, sound and wholesome food and to protection from unfair trade practices.

3.2 No food (including re-exported food) should be in international trade which<sup>15</sup>:

- a) has in or upon it any substance in an amount which renders it poisonous, harmful or otherwise injurious to health; or
- b) consists in whole or in part of any filthy, putrid, rotten, decomposed or diseased substance or foreign matter, or is otherwise unfit for human consumption; or
- c) is adulterated; or
- d) is labelled or presented in a manner that is false, misleading or deceptive; or
- e) is prepared, packaged, stored, transported or marketed under unsanitary conditions.

**ARTICLE 4 – REQUIREMENTS FOR FOOD IN INTERNATIONAL TRADE**

Food that is traded internationally should conform:

- a) to the requirements of Codex Alimentarius Commission's relevant standards and related texts; or
- b) to such food legislation as may be in force in the exporting and/or importing country; food standards and safety requirements of importing countries should be transparent and available to exporting countries; or
- c) to the provisions contained, regarding food, in bilateral or multilateral agreements signed by the exporting country and the importing country; or
- d) in the absence of such provisions, to such standards and requirements as may be agreed upon, taking into account the provisions of Codex Standards and related texts wherever possible.

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<sup>14</sup> It is understood that the principles of this code should also apply, *mutatis mutandi*, to concessional and food aid transactions.

<sup>15</sup> The provisions of Article 3.2 do not prevent the export of raw or semi processed foods which are not edible as such in order to be further processed, re-processed or reconditioned in the importing country for the purpose of human consumption.

## AMENDMENTS TO THE RULES OF PROCEDURE

### Rule IV Coordinators

1.-2. [no change]

3. The functions of the Coordinators shall be:

- (i) to appoint the Chairperson of the Coordinating Committee where such committee has been set up under Rule XI.1(b)(ii) for the region or group of countries concerned.
- ~~(i)~~(ii) to assist and coordinate the work of the Codex Committees set up under Rule XI.1(b)(i) in their region or group of countries in the preparation of draft standards, guidelines and other recommendations for submission to the Commission;
- ~~(ii)~~(iii) to assist the Executive Committee and the Commission, as required, by advising them of the views of countries and recognized regional intergovernmental and non-government organizations in their respective regions on matters under discussion or of interest;

### Rule IV (paragraph 3 (i) renumbered 3 (ii) as above)

[FRENCH]

aider aux travaux des comités du Codex créés pour leur région ou groupe de pays en vertu de l'Article XI.1b)i) et les coordonner,  ~~dans leur région ou groupe de pays~~ en ce qui concerne la préparation de projets de normes, de lignes directrices et autres recommandations à soumettre à la Commission;

### Rule V Executive Committee

1. The Executive Committee shall consist of the Chairperson and the Vice-Chairpersons of the Commission, and the Coordinators appointed on the basis of Rule IV 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. Not more than one delegate from any one country shall be a member of the Executive Committee. Members elected on a geographic basis shall hold office from the end of the session of the Commission at which they were elected until the end of the second succeeding regular session and shall be eligible for re-election if they have not served for more than two years in their current term, but after having served two consecutive terms shall be ineligible to hold such office for the next succeeding term. Members elected on a geographic basis are expected to act within the Executive Committee in the interest of the Commission as a whole.

2.-7. [no change]

### Rule XI Subsidiary Bodies

1.-9. [no change]

10. The Members who shall be responsible for appointing Chairpersons of subsidiary bodies established under Rule XI.1(b)(i) ~~and Rule XI.1(b)(ii)~~ shall be designated at each session by the Commission and shall be eligible for re-designation. All other officers of subsidiary bodies shall be elected by the body concerned and shall be eligible for re-election.

11. [no change]



## APPENDIX XI

### Guide to the Procedure for the Amendment and Revision of Codex Standards and Related Texts

1. The procedure for amending or revising a Codex standard is laid down in paragraph 8 of the Introduction to the Procedure for the Elaboration of Codex Standards and Related Texts. This Guide provides more detailed guidance on the existing procedure for the amendment and revision of Codex standards and related text.
2. When the Commission has decided to amend or revise a standard, the unrevised standard will remain the applicable Codex standard until the amendment to the standard or the revised standard has been adopted by the Commission.
3. For the purpose of this Guide:

**Amendment** means any addition, change or deletion of text or numerical values in a Codex standard or related text, which may be editorial or substantive, and concerns one or a limited number of articles in the Codex text. In particular, amendments of an editorial nature may include but are not limited to:

- correction of an error;
- insertion of an explanatory footnote; and
- updating of references consequential to the adoption, amendment or revision of Codex standards and other texts of general applicability (e.g. revision of the General Principles of Food Hygiene, General Standard for the Labelling of Prepackaged Foods), including the provisions in the Procedural Manual.

Finalization or updating of methods of analysis and sampling as well as alignment of provisions, for consistency, to those in similar standards or related texts adopted by the Commission may be handled by the Commission in the same manner as amendments of an editorial nature, as far as the procedure described in this Guide is concerned.

**Revision** means any changes to a Codex standard or related text other than those covered under “amendment” as defined above.

The Commission has the final authority to determine whether a proposal made constitutes an amendment or a revision, and whether an amendment proposed is of an editorial or substantive nature.

4. Proposals for the amendment or revision of Codex standards and related texts should be submitted to the Commission by the subsidiary body concerned, by the Secretariat, or by a member of the Commission where the subsidiary body concerned is not in existence or has been adjourned *sine die*. In the latter case, proposals should be received by the Secretariat in good time (not less than three months) before the session of the Commission at which they are to be considered. The proposal should be accompanied by a project document (see Part 2 of the Elaboration Procedures) unless the Executive Committee or the Commission decides otherwise. However, if the amendment proposed is of an editorial nature, the preparation of a project document is not required.
5. Taking into account the outcome of the on-going critical review conducted by the Executive Committee, the Commission decides whether the amendment or revision of a standard is necessary. If the Commission decides in the affirmative, one of the following courses of action will be taken:
  - (i) In the case of an amendment of an editorial nature, it will be open to the Commission to adopt the amendment at Step 8 of the Uniform Procedure (see Part 3 of the Elaboration Procedures).

- (ii) In the case of an amendment proposed and agreed upon by a subsidiary body, it will also be open to the Commission to adopt the amendment at Step 5 or Step 5/8 of the Uniform Procedure (see Part 3 of the Elaboration Procedures).
- (iii) In other cases, the Commission will approve the proposal as new work and the approved new work will be referred to the appropriate subsidiary body, if such body is still in existence. If such body is not in existence, the Commission will determine how best to deal with the new work.

6. Where Codex subsidiary bodies have been abolished or dissolved, or Codex committees have been adjourned *sine die*, the Secretariat keeps under review all Codex standards and related texts elaborated by these bodies and determines the need for any amendments, in particular those arising from decisions of the Commission.

If the need for amendments of an editorial nature is identified then the Secretariat should prepare proposed amendments for consideration and adoption by the Commission. If the need for amendments of a substantive nature is identified, the Secretariat, in cooperation with the national secretariat of the adjourned Committee if applicable, should prepare a working paper containing the reasons for proposing amendments and the wording of such amendments as appropriate, and request comments from members of the Commission:

- (a) on the need to proceed with such an amendment and
- (b) on the proposed amendment itself.

If the majority of the replies received from members of the Commission is affirmative on both the need to amend the standard and the suitability of the proposed wording for the amendment or an alternative proposed wording, the proposal should be submitted to the Commission for consideration and adoption. In cases where replies do not appear to offer an uncontroversial solution then the Commission should be informed accordingly and it would be for the Commission to determine how best to proceed.

## APPENDIX XII

**PROPOSED AMENDMENTS TO  
THE GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS**

**Purpose of the Codex Alimentarius**

1. The Codex Alimentarius is a collection of internationally adopted food standards and related texts<sup>16</sup> presented in a uniform manner. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade. ~~The Codex Alimentarius also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures intended to assist in achieving the purposes of the Codex Alimentarius.~~ The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

**Scope of the Codex Alimentarius**

2. The Codex Alimentarius includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions in respect of food hygiene, food additives, ~~pesticide~~ residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification. ~~It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.~~

**Nature of Codex Standards**

3. Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

43. Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe sound, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the sections criteria listed therein.

**Revision of Codex Standards**

54. The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts using the same procedures as followed for the elaboration of a new standard. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

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<sup>16</sup> These include codes of practice, guidelines and other recommendations.