codex alimentarius commission



FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS WORLD HEALTH ORGANIZATION



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Agenda Item 2

CX/PR 05/37/2 February 2005 Revised

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty seventh Session The Hague, The Netherlands, 18 – 23 April 2005

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES

PART 1 27th SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Geneva, Switzerland, 28 June – 3 July 2004)¹

AMENDMENTS TO THE PROCEDURAL MANUAL²

1. As the quorum specified in Rule V.6 of the Rules of Procedure was not constituted, the Commission was unable to adopt the following proposed amendments and agreed that their consideration should be deferred to its next session.

- Proposed Amendments concerning the enlargement of the Executive Committee, the functions of the Executive Committee and matters related to budget and expenses
- Proposed Amendments to Rules VIII.5 Observers

2. The Commission adopted the following proposals to amend other sections of the Procedural Manual.

- Amendments to the Procedures for the Elaboration of Codex Standards and Related Texts
- Criteria for the Appointment of Chairpersons
- Guidelines to Host Governments of Codex Committees and *ad hoc* Intergovernmental Task Forces
- Guidelines on the Conduct of Meetings of Codex Committees and *ad hoc* Intergovernmental Task Forces
- Guidelines to Chairpersons of Codex Committees and *ad hoc* Intergovernmental Task Forces
- Matters related to Methods of Analysis and Sampling

¹ Full report of the 27th Session of the Commission is available from: <u>http://www.codexalimentarius.net</u>

² ALINORM 04/27/41, paras 9-20

- General Criteria for the Selection of Single Laboratory Validated Methods of Analysis Principle
- Amendments to the Analytical terminology for Codex Use
- Definitions of Risk Analysis Terms related to Food Safety (*Food Safety Objective (FSO, Performance Objective (PO and Performance Criterion (PC)*), on an interim basis, for inclusion in the Procedural Manual with the understanding that the Committee on General Principles would reconsider these definitions if required in the light of the advice of the **Committee on Pesticide Residues**, the Committee on Food Additives and Contaminants, the Committee on Residues of Veterinary Drugs in Foods, the Committee on Meat Hygiene, and the Committee on Food Import and Export Inspection and Certification Systems.
- 3. The adopted amendments will be included in the 14th Edition of the Procedural Manual.

4. The Committee is therefore **invited to consider** how the above definitions are applicable in the area of pesticide residues from its point of view (see Appendix to this paper).

STRATEGIC PLANNING OF THE CODEX ALIMENTARIUS COMMISSION³

5. The Commission endorsed the decision of the 53^{rd} Session of the Executive Committee to discontinue the elaboration of the Medium-Term Plan, with the understanding that its elements would be used as a basis for a list of programmes/activities to be incorporated into the new Strategic Plan 2008-2013. In the absence of a Medium-Term Plan, the Commission agreed that the Executive Committee would exercise its critical review functions, closely coordinate work between different Codex Committees and monitor the progress of standards development in accordance with the current Strategic Framework and the *Criteria for the Establishment of Work Priorities*.

6. The Commission agreed to initiate the preparation of a new Strategic Plan for the period 2008-2013, and recommended that:

- The Executive Committee, at its next session, discuss the structure and format for a new Strategic Plan covering a six-year period of 2008-2013 as well as the ways to further proceed with the development of the Strategic Plan;
- The Strategic Plan state strategic objectives and priorities of the Commission and incorporate a list of programme areas/planned activities with a clearly defined timetable for each of the activities;
- After requesting the views of Regional Coordinating Committees, the draft Plan be submitted to the Commission for adoption by 2007; and
- The Strategic Plan, once adopted, be renewed every two years on a rolling basis.

ACTION PLAN FOR CODEX-WIDE DEVELOPMENT AND APPLICATION OF RISK ANALYSIS PRINCIPLES AND GUIDELINES 4

7. The Commission noted that several Committees had developed or were in the process of developing guidance on risk analysis in their respective areas, for inclusion in the Procedural Manual. The Commission endorsed the recommendations of the 53^{rd} Session of the Executive Committee and decided to:

a) request each relevant Codex Committee, when developing or completing specific guidelines on risk analysis, to review and document the mechanism it uses to identify and prioritise proposals for new work, particularly in the light of needs for and availability of scientific advice;

³ ALINORM 04/27/41, paras 120-126

⁴ ALINORM 04/27/41, paras 124-126

- b) request the Committee on General Principles, when examining specific guidelines submitted by other Committees, to ensure as much consistency as possible between the guideline texts;
- c) request the Committee on General Principles to continue the revision of the Criteria for the Establishment of Work Priorities, especially from the viewpoint of the need for clear prioritisation of requests for scientific advice; and
- d) monitor the progress of all the work mentioned above and take into account its outcome in the development of the next Strategic Plan.

8. The Commission recalled that the Committee on General Principles was considering the revision of the Criteria for the Establishment of Work Priorities, while the Executive Committee was developing new criteria for the prioritization of requests for scientific advice within Codex.

REVIEW OF THE MANDATES OF CODEX COMMITTEES AND TASK FORCES⁵

- 9. The Commission adopted the following Terms of Reference of the Review:
 - a) With the objective of reducing the number of Codex meetings while also keeping them short and focused, the review should concentrate on:
 - adequacy of the current structure of general subject committees to meet member countries' needs in a flexible and timely manner;
 - adequacy of the current structure of commodity committees to meet member countries' needs in a flexible and timely manner;
 - areas of overlap and areas where coverage of the subject matter is inadequate, taking into consideration the needs that were not covered or new issues that may arise in the future; and
 - relationship between all committees and task forces, particularly the relations between commodity and general subject committees (task forces);
 - b) Based on a detailed study of the points above and inputs received from various sources, recommendations should be formulated for consideration by the Commission. These may include proposals for revision of the existing committee mandates with a view to rationalisation, proposals for redistribution of tasks and responsibilities between committees, and proposals to split or merge committees.
 - c) The recommendations to the Commission should also take into account the ability of all members of the Commission to participate in the standards development process, including the sustainability of the subsidiary body structures and their work programmes, especially in the light of the holding of annual sessions of the Commission and the operation of the FAO/WHO Trust Fund for Enhanced Participation in Codex.

10. The Commission agreed that the recruitment of a small team of consultants (three or four) would be initiated after the Commission and that the time frame presented in document ALINORM 04/27/10C would be followed in order that recommendations be submitted to the 28th Session of the Commission. The Commission agreed that a Circular Letter would be sent to all Codex Members to ask for their views on the review of the mandates of Committees and Task Forces. The review will also include Regional Coordinating Committees.

⁵ ALINORM 04/27/41 paras 132-136

FAO/WHO PROJECT AND TRUST FUND FOR ENHANCED PARTICIPATION IN CODEX⁶

11. The Commission generally supported the use of the Trust Fund for projects other than for travelling to Codex sessions. It was however stressed that participation in training activities on Codex should not be the primary focus of the Trust Fund, but should rather covered by the Regular Programme and extra-budgetary resources of FAO and WHO as part of their capacity building activities.

12. The Commission requested that the criteria used in the distribution of funds should be kept under review. Further consideration should be given to ensuring adequate regional representation and the effectiveness of the participation of the beneficiary countries in Codex work.

Relations between the Codex Alimentarius Commission and Other International ${\rm Organizations}^7$

13. In accordance with Article 6 of the *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, the Secretariat reported to the Commission on the cooperation with NGOs, as presented in ALINORM 04/27/10E and LIM 7.

Relation between Codex and ISO

14. The Commission recalled that the 53rd Session of the Executive Committee had agreed that the Codex Secretariat establish preliminary contact with the International Organization for Standardization (ISO) to obtain information on the current status of food safety work within ISO.

15. The Commission agreed that the Secretariat should maintain its contacts with ISO and report to the Executive Committee and the Commission on ISO activities of relevance to Codex work.

CONSIDERATION OF DRAFT STANDARDS AND RELATED TEXTS

16. The Commission adopted various standards and other texts elaborated by the Codex Committees and Task Forces. A complete list of these texts and details of their consideration could be found in ALINORM 04/27/41, Appendices III and IV and paras 32-86. The Commission made the following observations on the text submitted by the Committee:

DECISIONS RELATED TO THE COMMITTEE ON PESTICIDE RESIDUES 8

Draft Maximum Residue Limits for Pesticides at Step 8 and Step 5/8

17. The Commission noted that the MRL for carbaryl (08) for sorghum forage (dry) should be 50 mg/kg instead of 5 mg/kg and that the MRL for fenaminphos (85) for banana should be marked with an asterisk to indicate that this MRL is at or about the limit of determination. With these amendments, the Commission **adopted** the draft MRLs and proposed draft MRLs at Step 8 and Step 5/8 as proposed.

Proposed Draft Maximum Residue Limits for Pesticides at Step 5⁹

18. The Commission adopted the Proposed Draft MRLs at Step 5 as proposed.

CONSIDERATION ON PROPOSALS FOR THE ELABORATION OF NEW STANDARDS AND RELATED TEXTS

19. The Commission approved the elaboration of new standards and related texts as summarized in ALINORM 04/27/41, Appendix VI and paras 88-102. In relation to the CCPR, the Commission approved the new work on the 1) Priority List for the Establishment of MRLs for Certain Pesticides and 2) Limited Revision of the Codex Classification of Foods and Animal Feeds.

⁶ ALINORM 04/27/41, paras 188-196

⁷ ALINORM 04/41, paras 181-187

⁸ ALINORM 04/27/24, Appendices II and III.

⁹ ALINORM 04/27/24, Appendix IV.

Risk Analysis¹⁰

20. Following the request from the CCFH to clarify the appropriateness of their approach in the area of risk analysis, the Commission **endorsed** the view of the 54th Session of the Executive Committee¹¹ that the past and ongoing work by the Committee on Food Hygiene on the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL-30, 1999) and the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management addressing issues relevant to both member governments and to the Codex was consistent with the Commission's expectations.

21. The Commission noted that the decisions of the Committee on Food Import and Export Inspection and Certification Systems, Committee on Meat Hygiene, **Committee on Pesticide Residues**, Committee on General Principles, and Committee on Milk and Milk Products regarding the need for developing specific guidelines on risk analysis.

Antimicrobial Resistance

54th Session of the CCEXEC¹²

22. The Executive Committee noted that the Committee on Food Hygiene supported the establishment of a Codex/OIE Task Force to develop broad risk management options for antimicrobial resistance related to non-human use of antimicrobials. The Executive Committee also noted that the 20th Session of the Committee on General Principles did not support the establishment of joint standards with other intergovernmental organizations.

23. The Executive Committee was informed that the Committee on Pesticide Residues and the ad hoc Intergovernmental Task Force on Animal Feeding did not propose specific actions as follow-up to the outcome of the two expert workshops on antimicrobial resistance convened by FAO, OIE and WHO. The Executive Committee also noted that the Committee on Residues of Veterinary Drugs in Food had initiated the elaboration of a Code of Practice for the containment of antimicrobial resistance and its forthcoming session would consider the proposed draft Code at Step 4.

24. The Representative of WHO recalled that the two FAO/OIE/WHO workshops had been convened at the request of the 48th session of the Executive Committee and urged the Executive Committee to invite the Commission to take necessary actions, in cooperation with the OIE, to address the issues regarding the terminology, risk assessment policy and risk management options for the containment of antimicrobial resistance. The Coordinator for Asia also stated that a project document for this issue would be introduced by the Delegation of the Republic of Korea during the 27th Session of the Commission, and supported the view of the Representative of WHO.

25. The Representative of FAO stated that Codex should carefully evaluate the need for and implications of joint OIE/Codex standards and should explore ways to make better use of its current subsidiary bodies to address the issue before taking further steps towards establishing a joint task force.

26. While noting that antimicrobial resistance is an important matter to be addressed by Codex, the Executive Committee was of the view that there are several possible options for the Commission to deal with this matter, including the establishment of a Codex task force with active participation of the OIE, or the use of existing Codex subsidiary bodies such as the Committee on Food Hygiene, the Committee on Residues of Veterinary Drugs in Foods and the Task Force on Animal Feeding. The Committee noted that OIE would participate in the 27th Session of the Commission and present its views during the session.

¹⁰ ALINORM 04/27/13, paras 70-71.

¹¹ ALINORM 04/27/4, para. 63.

¹² ALINORM 04/27/4, paras 68-73.

27. The Executive Committee agreed that before deciding on the procedure to follow the Commission should develop a clear and common understanding of what should be achieved by Codex in regard to the question of antimicrobial resistance related to non-human use of antimicrobials. The Executive Committee further agreed that it would be useful to prepare a Circular Letter to request the views of Members and Observer on what is expected as future achievements by Codex in this area.

27th Session of the CAC¹³

28. The Representative of WHO informed the Commission that the two FAO/WHO/OIE workshops had been convened, at the request of the 48th Session of the Executive Committee¹⁴, in order to advice the Commission on possible directions to be taken on this issue. He stressed the need to address the matters regarding the terminology, risk assessment policy and risk management options for the containment of antimicrobial resistance.

29. The Representative of the OIE drew the attention of the Commission to the fact that the OIE had already adopted sections on the containment of antimicrobial resistance in the OIE Code and indicated that the OIE would support recommendations of the second Workshop held in Oslo. The Representative pointed out that in principle the OIE would accept the proposal to establish a Joint *ad hoc* Task Force on antimicrobial resistance, to operate on the procedures to be agreed upon by the two bodies, with specific terms of reference in accordance with the outcome of the Oslo Workshop: to define risk assessment policy to be used by JEMRA; to develop risk management options; to consolidate existing texts in this area; and to develop guidance for the use of antimicrobials in animal production.

30. The Commission noted the willingness of the Delegation of the Republic of Korea to host an *ad hoc* Task Force on Antimicrobial resistance, if such a Task Force was to be established in future.

31. Many delegations supported the recommendation by the 54th Session of the Executive Committee as the way to proceed on this matter¹⁵.

32. The Commission noted that there was a unanimous support for the cooperation with the OIE, but that financial implications and impact on country participation, especially for developing countries should be carefully considered before taking a final decision towards establishing a new Task Force is taken. The Commission also noted the kind offer of the OIE that the cost for joint activities could be shared between the organizations.

33. The Commission agreed that there were several possible options for the Commission to deal with this matter, including the establishment of a Codex task force with active participation of the OIE, or the use of existing Codex subsidiary bodies such as the Committee on Food Hygiene, the Committee on Residues of Veterinary Drugs in Foods and the Task Force on Animal Feeding.

34. The Commission further agreed that before deciding on the procedural mechanisms to further work, there should be a clear and common understanding of what should be achieved by Codex in regard to the question of antimicrobial resistance related to non-human use of antimicrobials.

35. In order to facilitate the discussion, the Commission **requested** Secretariat to prepare, as soon as possible, a Circular Letter which would include two questions:

- a) What should be achieved by Codex to address the issue of antimicrobial resistance related to non-human use of microbials (e.g. risk assessment principles, risk management options);
- b) What mechanisms should be used by Codex to achieve the above outcome?
- 36. The Circular Letter would also contain the following information:

¹³ ALINORM 04/27/41, paras 210-219.

¹⁴ ALINORM 01/4, paras 36-37.

¹⁵ ALINORM 04/27/4, paras 68-73.

- the outline of ongoing work on this matter in relevant Codex Committees, their Terms of Reference in relation to their work on antimicrobial resistance; and
- the executive summary prepared by FAO and WHO from the two Workshops.

37. The Commission **agreed** that the comments received in reply to the Circular Letter would be considered at the 55^{th} Session of the Executive Committee with the understanding that it would provide the advice to the next session of the Commission.

38. The Representative of the OIE stated that the OIE Working Group on Animal Production Food Safety would continue its work on microbial resistance, while waiting for further decisions by Codex.

39. Conference Room Document will be issued in order to update the Committee on Pesticide Residues with the decisions taken by the 55^{th} Session of the Executive Committee on the above subject matter.

A. Progress Report Related to Scientific Advice¹⁶

40. The Representative of FAO presented a progress report of the FAO/WHO Consultative Process on Provision of Scientific Advice, including the outcome of the FAO/WHO Workshop held in January 2004 and the comments on the Workshop report received from governments and non-governmental organizations. The Representative indicated the practical steps taken by FAO and WHO to implement the recommendations of the Workshop, including:

- the establishment of an FAO/WHO internal task force to review management options and improve communication with stakeholders;
- the preparation of a procedural manual as a compilation of principles and procedures followed by FAO and WHO in the provision of scientific advice with a view to increasing transparency;
- the preparation of in-depth analysis to address procedures for the selection of experts and the openness of meetings, and for the use of data; and
- the organization of a workshop to explore new approaches to enhance developing countries' capacities to generate data needed and to participate more effectively in expert meetings.

41. The Representative of FAO indicated that the final step of the consultative process would be implemented in the form of an expert consultation or an intergovernmental meeting to prepare feasible recommendations to FAO and WHO, once the analysis of the workshop recommendations has been completed and necessary resources mobilised.

199. The Commission **noted** the advance being made and **expressed their appreciation** to FAO and WHO for their efforts to improve the scientific advice provided to the Commission.

42. B. Requests for Scientific Advice from Codex Subsidiary Bodies.

43. The Representative of WHO, also speaking on behalf of FAO, stressed the need for the Commission to prioritize the requests for scientific advice coming from Codex subsidiary bodies as the current budget of FAO and WHO available for the provision of scientific advice would not allow for a timely response to all these requests and drew the attention of the Commission to the fact that the 53rd Session of the Executive Committee had reviewed the Codex requests to FAO and WHO on scientific advice and indicated issues requiring further discussion in the Commission¹⁷. The Executive Committee

¹⁶ INF 3; INF 3A.

¹⁷ ALINORM 04/27/3, paras 55-75.

had also considered a preliminary set of criteria to establish priorities but postponed further discussion to a later session¹⁸.

44. The Representative of WHO highlighted the need to secure adequate funding both from Regular Budgets and from extra budgetary sources so that the provision of scientific advice be made in a more sustainable manner.

45. The Commission **expressed its appreciation** to FAO and WHO for their continuous effort to provide the scientific advice to Codex subsidiary bodies in an optimal way.

46. The Commission **agreed** that Codex requests No 6 (functional foods), No.7 (active chlorine) and No.16 (transport of fats and oils in bulk) for scientific advice in Annex I of the working document should not be considered as cancelled but be retained.

47. Some delegations proposed to give a higher priority to the Codex request No.6 from the 13th Session of the Coordinating Committee for Asia, to evaluate the safety and regulatory issues related to functional foods, given their importance to developing countries. Other delegations indicated that the Committee on Nutrition and Foods for Special Dietary Uses gave priority to the evaluation of upper limits of vitamins and minerals and that there was no international definition of functional food and no work was being undertaken by the Codex in this area and that from a legal point of view functional foods could be considered as common foods or foods for special dietary uses.

48. The Commission noted that the Committee on Food Additives and Contaminants and the Committee on Food Hygiene were preparing the draft Terms of Reference for the proposed expert consultation on safety of active chlorine used in and on foods.

49. In relation to the request regarding the evaluation of the safety of acceptable previous cargoes, the Commission confirmed its earlier request to FAO and WHO to convene an expert consultation, preferably before the next Session of the Committee on Fats and Oils. The Delegation of the United States stated that future work by the Committee on Fats and Oils should concentrate on criteria but not on the list.

50. The Commission **agreed** that priority for the provision of scientific advice should be given to requests coming from Codex subsidiary bodies rather than from Member governments and that the work plan of Codex shall take into account the availability of relevant scientific advice. The Commission noted the view that priority should also be given to the concerns of developing countries, the decisions of the Commission and prioritised requests by Codex subsidiary bodies.

51. The Commission **noted** that in the absence of Codex criteria for setting priorities for the provision of scientific advice, FAO and WHO would continue planning expert meetings and consultations considering the following criteria:

a) clear scope of the advice requested;

- b) urgency of the advice requested,
- c) availability of required data or commitment of countries to provide such data; and

d) availability of financial resources.

¹⁸ ALINORM 04/27/3, paras 76-83.

Appendix

Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.