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codex alimentarius commission





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Agenda Item 10

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-sixth Session, FAO Headquarters, Rome (Italy), 30 June-7 July 2003

JOINT FAO/WHO EVALUATION OF THE CODEX ALIMENTARIUS AND OTHER FAO AND WHO WORK ON FOOD STANDARDS

Addendum 3: Improved Processes for Standards Management

1. INTRODUCTION

- The function of ensuring much tighter management of standards development was regarded by the Evaluation Team and Expert Panel as especially important for the effectiveness of Codex and this paper will recommend that improved Standards Management in Codex should be allocated the highest priority for followup to the Evaluation. Several specific recommendations were made to improve the Codex processes for standards management, including Recommendations 11, 12, 18, 20, 23 and 24. There are other recommendations and suggestions included in the Evaluation Report, particularly in the narratives leading to the individual recommendations, and these have also been taken into account in the preparation of this paper.
- The Commission, when it adopted its Strategic Framework 2003-2007, committed itself to provide strategic oversight, direction and cross coordination of the work programmes of all subsidiary bodies; and to initiate new work and adopt standards and related texts against defined time frames. The recommendations in the Evaluation Report are entirely consistent with this strategic objective.
- 3. The Evaluation report proposed the establishment of a Standards Management Committee to undertake these tasks, but the report also indicates that such tasks could be carried out by the Executive Board or Executive Committee. It is clear from the Evaluation Report that it is the functions themselves that are important and not the establishment of a Standards Management Committee or other structure, or even changes in Codex Nevertheless, procedural changes could enhance the standards management process and are therefore covered in this paper to the extent necessary.
- At the 25th (Extraordinary) Session of the Codex Alimentarius Commission many delegations expressed their concern with the recommendation to establish a Standards Management Committee, as this was not likely to increase the transparency, efficiency or inclusiveness of the process and would entail significant additional

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costs¹. Written comments are, however, mixed on this matter. Nevertheless, the written comments all tend to agree that the management of standards development in Codex needs to be improved, whether or not this responsibility lies with a Standards Management Committee, the Executive Committee or an Executive Board. This paper will provide options on this matter as it is clear that the responsibility for standards management must lie with a recognized body.

5. The Evaluation Report also considers the question of *consensus* in relation to the standards management process and means of assessing whether or not a consensus exists. This paper will not discuss the definition or meaning of consensus (See the paper on Procedures, ALINORM 03/26/11: Add. 4 in this regard), but will discuss some aspects of the processes used to attain consensus, as this is critical to the standards management process.

2. STRATEGIES FOR STANDARDS MANAGEMENT

- 6. This section will cover paragraphs 96-100 of the Evaluation Report with Recommendations 11 and 12. The standards management process envisaged in the Evaluation² includes advice to the Commission on strategic planning of standards development and:
 - proposal of priorities for standard revision and setting;
 - examining the proposals of the Codex committees for development/revision of standards and the required supporting work to provide the independent risk assessment;
 - advice on establishment and dissolution of committees and decision on initial task force establishment, including *ad hoc* cross-committee task forces (in areas where work falls within several committee mandates);
 - monitoring progress in developing standards and advising if corrective action should be taken or work suspended due to lack of progress;
 - assisting in identifying standard setting needs of developing countries; and
 - examining proposed standards from Codex committees and passing them on for adoption by CAC or returning them for further development by committees.
- 7. To a greater or lesser degree, procedures exist within the current Codex framework on all of these matters, but either they are not exercised or there is no unified approach that could be called "strategic management" or "standards management". Decisions are mostly taken on an *ad hoc* basis as proposals or problems relating to the development of standards are brought to the attention of the Commission or the Executive Committee.³ Despite a commitment to allocating a higher priority to standards for consumer health protection (food safety), this is not incorporated into a strategic planning process.
- 8. The Secretariat makes the following proposals and options for the consideration of the Commission:

Strategic Planning of Standards Development

9. The Commission should institute a mechanism of strategic planning for the development of standards over a six-year period. The strategic plan should establish broadly stated priorities and criteria against which individual proposals for standards (and revision of standards) can be evaluated. The strategic plan should be

ALINORM 03/25/5, para. 18.

Evaluation Report: para. 96.

It should be noted that prior to 1993, the Executive Committee played no direct role in standards development. The 20th Session of the Commission, when it adopted the Uniform Procedures for the Elaboration of Codex Standards and Related Texts, delegated to the Executive Committee the responsibility for approving new work and the adoption of draft standards at the intermediate Step 5 of the Procedure. However, neither the Commission nor the Executive Committee have actively undertaken strategic planning for standards development; active monitoring of the standards under development; active identification of the standard setting needs of developing countries; or routine examination of draft standards for consistency and legal coherence prior to their submission to the Commission for adoption, with the exception of the process of "endorsement" of selected provisions by the "General Subject Committees".

renewed every two years on a rolling basis. The strategic plan should assist in identifying standard setting needs of developing countries.

Proposal No.13 - Strategic planning

10. A strategic plan for Standards Development should be submitted to the 27th Session of the Commission (2004) and subsequently at two-yearly intervals on a rolling basis.

Option 13.1 – Secretariat

11. The Secretariat should submit a draft Strategic Plan for consideration by the Executive Committee and subsequently by the Commission.

Option 13.2 – Sub-Committee of the Executive Committee

12. The Sub-Committee on Programming, Budget and Planning of the Executive Committee should submit a draft Strategic Plan for consideration by the Executive Committee and subsequently by the Commission.

Standards Management – Procedures for Implementation and Monitoring (Critical Review)

- 13. This proposal describes the establishment of a critical review process to implement and monitor the strategic plan for standards development. The Secretariat wishes to provide only two options under this proposal, based on the standards management functions described paragraph 96 of the Evaluation Report. The difference between the two options is the streamlining of the endorsement process, thereby saving time and effort in this area. If the Commission decides to establish a process of strategic planning, as described above, the standards management process will need to concentrate on a critical review, at regular intervals, of the status of all standards in the process of elaboration as well as proposals for new standards or revisions of existing standards.
- 14. The "Criteria for the Establishment of Work Priorities" will need to be revised as a consequence of this, and other proposals presented in this paper (See ALINORM 03/26/11: Add.4 on Procedures). The revised criteria should provide explicit judgment tools for assessing work proposals against priorities.

Proposal No.14: - Critical review of proposals to undertake work

- 15. A critical review process should ensure that draft standards submitted to the Commission for adoption meet the strategic priorities of the Commission and can be developed within a reasonable period, taking into account the requirements of scientific expert advice. The critical review should therefore include:
 - examination of proposals for development/revision of standards, taking into account the strategic priorities of the Commission and the required supporting work of independent risk assessment;
 - identifying the standard setting needs of developing countries;
 - advice on establishment and dissolution of committees and task forces, including *ad hoc* cross-committee task forces (in areas where work falls within several committee mandates); and
 - assessment of the need for expert scientific advice and the availability of such advice from FAO, WHO or other relevant expert bodies.
- 16. Each major standard⁴ or revision of a major standard approved for development should have a small project document on purposes of the standard, why it was important, the main aspects to be covered and the time-line envisaged for the work. Monitoring can then take place against the time line revised as necessary and revisions in the coverage of the standard etc. would need to be specifically endorsed.

The term "major standard" excludes individual maximum residue limits for pesticides or veterinary drugs, or the maintenance of standards and texts as the General Standard on Food Additives, International numbering System, etc

Proposal No.15: - Monitoring progress of standards development

- 17. The critical review process should also ensure that progress of the development of standards is consistent with the envisaged time frame, that draft standards submitted to the Commission for adoption have been fully considered at Committee level, and that they are technically and legally sound. This should therefore include:
 - monitoring of progress in developing standards and advising if corrective action should be taken or work suspended due to lack of progress;
 - examining proposed standards from Codex committees for coherence with basic texts and other international legal instruments⁵; technical consistency with General Standards and similar texts⁶; format and presentation; conformity with major decisions of the Commission⁷; and lingual consistency; before they are submitted to the Commission for adoption.

Standards Management – Responsibility

- 18. From the comments made by "many delegations" at the 25th Session of the Commission, the response to the Evaluation questionnaire, and the written comments in reply to Codex Circular Letter CL 2003/8-CAC, it is clear that there is little support for the establishment of a Standards Management Committee as described in the Evaluation Report. In the reply to the Circular Letter, only two countries support the proposal and most of the countries that have commented propose that the function of standards management be entrusted to the Executive Committee. The Secretariat notes the FAO Management Response in which there is support "in principle" for the establishment of such a Committee.
- 19. The Secretariat therefore submits three options for the consideration of the Commission, while recognizing that little support has been expressed for either the first or third of these options.

Proposal No.16 - Responsibility for Standards Management

Option 16.1 – Standards Management Committee

- 20. Should the Commission wish to establish a Standards Management Committee, it may wish to consider the following membership for the Committee:
 - Twenty Members elected on a regional basis (three from each region except North America (2)); and
 - Five Chairpersons of Codex Committees/Task Forces established under Rule IX.1.(b) appointed on a rotating basis.
- 21. The Committee should be established under Rule IX.1(a) and meet on an annual basis, not less than six weeks before the commencement of any Commission session and should report to each Commission session. The Committee should elect its own Chairperson. The Committee should have the power to invite Chairpersons of Committees/Task Forces, not members of the Committee to attend its sessions. The Committee should be open to participation of international intergovernmental and non-governmental organizations as observers.
- 22. The functions of the Committee would be to undertake the critical reviews of new work and the monitoring of progress in standards development as described above.

Option 16.2 – Executive Committee

23. As noted above, most of the countries commenting in response to Codex Circular Letter CL 2003/8-CAC, expressed a preference for this work to be undertaken by the Executive Committee. This could be done immediately, and without changes to the mandate of the Executive Committee as currently described in the

See paragraph 131 of the Evaluation Report.

Including the General Standards or Codes for Food Additives, Food Labelling, Food Hygiene, and the endorsement of methods of analysis and sampling in accordance with the criteria established by the Commission.

For example, the Working Principles of Risk Analysis.

Rules of Procedure⁸, but in the longer term it would probably be preferable to amend Rule III.2 so as to refer explicitly to a standards management function for the Executive Committee (see also the paper on Review of the Functions of the Executive Committee, ALINORM 03/26/11: Add. 2). Under this option, the Executive Committee would undertake the critical reviews of new work and the monitoring of progress in standards development as described above and report its findings to the Commission.

Option 16.3 – Executive Board

24. Same as Option 16.2 in the case that the Commission decides to establish an Executive Board in place of the Executive Committee (see the paper on Review of the Functions of the Executive Committee, ALINORM 03/26/11: Add. 2).

Standards Management - Procedures

- 25. The Evaluation Report makes a firm recommendation based on the responses of 77% of country respondents and 86% of observers (including consumers) in favour of all work being time-bound (Paragraph 117 and Recommendation 18). Most of the comments received in response to Codex Circular Letter CL 2003/8-CAC support this view, with the qualification that where necessary additional time should be allowed in order to achieve a consensus.
- 26. The Evaluation Report also recommends that the current 8-step Procedure be simplified to a 5-step procedure, but notes that there is less support for this proposal that for the proposal for work being time-bound (Paragraphs 130-131 and Recommendation 23). Most of the comments received from governments note that Committees already have the option of using the accelerated procedure, or advancing the standard by the omission of steps. The Secretariat notes, however, that the current 8-step Procedure is the norm and use of the accelerated procedure is rare and that recommendations to omit Step 5 and 6 represent only a small proportion of standards submitted to the Commission (with the possible exception of MRLs). There is also the fact that decisions to omit steps or use the accelerated procedure are subject to a higher level of decision-making than the normal process (two-thirds majority in the place of a simple majority). The Evaluation report in this matter encourages Committees to submit standards to the Commission for adoption as soon as consensus is reached and not be bound formally by the need to invoke additional steps after consensus is reached. It has also not escaped the notice of the Secretariat that the current elaboration procedures have been prolonged by the use of a process of developing "discussion papers", adding several additional steps to the procedure before the official decision to commence work on a standard is taken at Step 1. This process, which is contrary to objectives of the Evaluation, should be brought into the process of standards management.
- 27. The Evaluation Report strongly recommends that there should be much more work between sessions with use of facilitators to consult among members and to develop re-drafts for further consideration by committees (Paragraphs 121-125 and Recommendation 20). The Report notes that this would be a major departure from the present way of working. The emphasis should shift from developing standards in committee sessions to developing standards between sessions following a consultative process with the members that also fully considers written comments. The use of facilitators and electronic working groups has the potential to foster an inclusive process of consultation for developing countries whereas the greater use of between-session working group meetings could have the reverse effect. Recommendation 20 provides greater inclusiveness by enhancing the intersession consultation processes including, where appropriate, the organization of local workshops; providing that written comments should be fully taken into account; that where between-session working groups are used they should be electronic, not generally physical meetings which are not inclusive in possible participation; and that greater use should be made of knowledgeable NGOs in preliminary standard development.
- 28. Comments on Recommendation 20 are uniformly negative with respect to the proposal to make greater use of knowledgeable NGOs in preliminary standard development. Reactions to the other proposals range from very strong support (especially in relation to the consideration of written comments) to cautious (the use of

Rule III.2 – "The Executive Committee shall, between sessions of the Commission, act on behalf of the Commission as its executive organ [...] and help implement the programme as approved by the Commission".

facilitators). Most countries that have commented on the question of working groups support the shift from physical meetings to electronic methods of working.

29. Taking these considerations into account, the Secretariat proposes the following proposals.

Proposal No.17: - Time-bound decision-making

- 30. At the time of deciding to undertake new work on a standard (including preparation of so-called "discussion papers"), the Commission shall indicate the time frame for the work to be carried out, normally not more than five years from the date of the decision. At the end of this time frame, the body responsible for standards management shall automatically review the status of the work and report its findings to the Commission. The body responsible for standards management may propose an extension of the time frame; cancellation of work; or propose that the work be undertaken by a Committee other than the one to which it was originally entrusted.
- 31. This option can be implemented immediately, but the in the longer term should be incorporated explicitly into the Procedures for the Elaboration of Codex Standards and Related Texts (See also the paper on Procedures, ALINORM 03/26/11: Add. 4).

Proposal No.18: - Simplified procedures for standards development

- 32. The current Uniform and Accelerated Procedures for the Elaboration of Codex Standards and Related Texts should be revised to encourage Committees to submit standards to the Commission as soon as consensus on them is reached. This could be achieved by:
 - Removing the qualification of two-thirds majority when deciding on an accelerated procedure or the omission of steps;
 - Re-drafting the Elaboration Procedures to provide for a normal 5-Step procedure and an extended 8-step procedure, the latter being subject to endorsement by the body responsible for standards management and subsequent approval by the Commission.
- 33. The first part of this proposal could be implemented immediately but will require an amendment to the Procedures for the Elaboration of Codex Standards and Related Texts (See also the paper on Procedures, ALINORM 03/26/11: Add. 4). The second part of the proposal would require a full re-drafting of the relevant text.

Proposal No. 19: – Use of facilitators

- 34. At any time in the process of elaboration of standards, a Codex Committee or the body responsible for standards management, should have the ability to appoint a facilitator to help parties to reach consensus. The role of the facilitator would be to consult among members and to develop re-drafts for further consideration by committees. A main part of the function of facilitators would be to understand dissenting views, including all written comments, and facilitate the development of consensus. This could have very positive benefits both in terms of ensuring greater inclusiveness and in speeding up work, provided facilitators have the clear function of consulting members widely. Facilitators should report to the Committee entrusted with development of the draft standard. The facilitator's report should explicitly show how the written comments received on draft standards have been addressed.
- 35. This proposal could be implemented immediately, without changes to the Procedures for the Elaboration of Codex Standards and Related Texts in the Procedural Manual, but in the longer term it would be preferable to amend these Procedures especially to define the role of facilitators. In the interim, the Secretariat suggests that facilitators could be appointed on an experimental basis (see also the paper on Procedures, ALINORM 03/26/11: Add. 4).

Proposal No.20: – Establishment of electronic working groups

36. Codex Committees, when deciding to undertake work between sessions, should give the first priority to the establishment of electronic working groups to be coordinated by the Host Government Secretariat. Such working groups should be open to all members of the Commission and interested international organizations as observers providing comments. The terms of reference and the expected output of the Working Group should be

explicitly stated. Such working groups should be disbanded once their specific task has been achieved. See also the paper on Procedures (ALINORM 03/26/11: Add. 4) concerning rules for the establishment and operation of working groups.

Proposal No.21: - Establishment of physical working groups

- 37. If Codex Committees decide to undertake work between sessions by means of physical working groups, such working groups should be representative of the membership of the Commission. It is therefore proposed that the membership of such working groups be limited to two or three members from each of the Commission's regions. Interested international organizations may be invited to participate as observers, provided that the number of observers does not exceed one half the number of countries participating as members. The composition of the working group should be explicitly defined, as should its terms of reference and the expected output. Such working groups should be disbanded once their specific task has been achieved.
- 38. The options concerning working groups could be implemented immediately, but in the longer term it would be preferable to amend the Guidelines for Codex Committees so as to clarify the role of working groups (see also the paper on Procedures, ALINORM 03/26/11: Add. 4).

Use of knowledgeable NGOs in preliminary standards development

39. In view of the responses from governments on this matters, the Secretariat does not wish to provide options in relation to this proposal. It should be noted, however, that the current Codex Procedures provide for this.

3. DECISION-MAKING FOR STANDARDS MANAGEMENT

- 40. This section will address some aspects of Codex working procedures as described in paragraphs 116-118, including Recommendation 18; paragraphs 130-137 including Recommendations 23 and 24; and Recommendation 21. It will deal only with aspects that are critical for the standards management process. For detailed proposals concerning Codex Procedures in general, see ALINORM 03/26/11: Add. 4.
- 41. An efficient and transparent process of standards management requires clear decision-making at all stages of this process and clear reporting of the decisions made.

Standards Management Decisions of the Commission

42. The Evaluation Report recommends that, at the adoption stage, the Commission should not amend the draft standard, but should make certain clear decisions regarding its status (Recommendation 23). Very few comments have been received on this recommendation and those that have been received are in support. On the other hand, the Commission as the final decision-making body must reserve to itself the right to decide on the content of a standard, but should use this authority carefully and sparingly. Two options are presented; both can be implemented immediately, but the in the longer term should be incorporated into the Procedures for the Elaboration of Codex Standards and Related Texts (See also the paper on Procedures, ALINORM 03/26/11: Add. 4).

Proposal No.22 - Adoption of Standards

Option 22.1 – Decision to adopt without amendment

- 43. At the adoption step, the Commission should not amend the standard but shall either:
 - adopt the standard;
 - refer the standard back to the Committee to explore certain changes; or
 - cancel or suspend work on the standard.
- 44. The decision taken shall be reported clearly in a manner that focuses on decisions and not on discussion.

Option 22.2 – Decision to adopt with amendment

- 45. At the adoption step, the Commission may decide to amend the standard in the light of written comments but shall limit such amendments to considerations that have not previously been raised in Committee and which are not of a nature affecting the technical content of the standard. Otherwise, the Commission shall either:
 - adopt the standard;
 - refer the standard back to the Committee to consider the proposed amendment(s); or
 - cancel or suspend work on the standard.
- 46. The decision taken shall be reported clearly in a manner that focuses on decisions and not on discussion.

Standards Management Decisions of Committees

- 47. The decision to forward a draft standard to the Commission for adoption is the most important decision taken by any Committee. For this reason, the decision should be clearly reported, with a focus on the decision itself, as well as any additional information that may assist in the critical review and information that will assist the Commission in deciding on the adoption of the standard. The Evaluation Report in Recommendation 24 also recommends that, as the norm, Committees should achieve consensus before passing standards on to the Commission for adoption. Both of these matters are taken up in detail in the paper on Procedures (ALINORM 03/26/11: Add. 4).
- 48. In view of the negative comments received, the Secretariat does not wish to make any proposals concerning postal balloting.

4. PRIORITY FOR STANDARDS MANAGEMENT

- 49. The Secretariat recommends that the Commission give the highest priority to the implementation of proposals directed towards standards management as these will provide the most immediate positive impact from the Evaluation, especially in the areas of:
 - greater speed in the standards development process;
 - increased inclusiveness of developing member countries in the Codex standard development process;
 and
 - greater usefulness of standards in terms of relevance to their needs and timeliness.
- 50. The fact that the critical operational changes can be undertaken without waiting to make formal changes to the Rules of Procedure or other procedural texts, enhances this priority.