codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/FICS 99/2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS
Seventh Session
Melbourne, Australia, 22-26 February 1999

MATTERS REFERRED FROM CODEX COMMITTEES

DRAFT GUIDELINES FOR THE DEVELOPMENT OF EQUIVALENCE AGREEMENTS REGARDING FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

1. The 45th Session of the Executive Committee (June 1998) adopted the proposed draft Guidelines at Step 5 (ALINORM 99/3, para. 29 and Appendix 4) on the basis of a text forwarded by the 6th CCFICS (ALINORM 99/30, paras. 10-33 and Appendix II). Comments submitted at Step 6 in response to CL 1998/20-FICS are summarized in document CX/FICS 99/3.

Note: This subject is scheduled for discussion by the Committee under agenda item 3.

PROPOSED DRAFT GUIDELINES/RECOMMENDATIONS FOR FOOD IMPORT CONTROL SYSTEMS

2. The 45th Session of the Executive Committee (June 1998) approved the elaboration of the proposed draft Guidelines/Recommendations as new work, with the understanding that careful attention should be given to the nature of the output of the work, especially as to the status of the final text (ALINORM 99/3, para. 26 and Appendix 3).

Note: This subject is scheduled for discussion by the Committee under agenda item 4.

PROPOSE DRAFT GUIDELINES AND CRITERIA FOR OFFICIAL CERTIFICATE FORMATS AND RULES RELATING TO THE PRODUCTION AND ISSUANCE OF CERTIFICATES

3. The 45th Session of the Executive Committee (June 1998) approved the elaboration of the proposed draft Guidelines and Criteria as new work (ALINORM 99/3, para. 26 and Appendix 3).

4. The 23rd Session (June 1998) of the Codex Committee on Fish and Fishery Products (CCFFP) noted (ALINORM 99/18, para. 101) that in light of the ongoing work in the CCFICS concerning this subject, it was suggested that the CCFFP continue its work on the title and scope of the model certificate and keep the CCFICS informed of its progress. The Committee agreed that work on a model certificate should proceed and delegations were invited to send their comments on the issues discussed by Norway, with a view to the preparation of a draft model certificate by Canada and Norway for further consideration.

Note: This subject is scheduled for discussion by the Committee under agenda item 5.

DISCUSSION PAPER ON ISSUES RELATING TO THE JUDGEMENT OF EQUIVALENCE

5. The 45th Session of the Executive Committee (June 1998) discussed in depth the matter of Judgement of Equivalence in relation to the Terms of Reference of the CCFICS and the overall work programme of the Commission. The Executive Committee was of the opinion that the matter was a priority for the work of the Commission, and invited the Codex Secretariat to arrange for a revision of the basic paper (ALINORM 99/3, paras. 35-36).

6. On the basis of the above advice of the CCEXEC that this matter should first be discussed by the CCFICS, the 13th Session of the Codex Committee on General Principles (September 1998) deleted Item 4.3 (Food Safety Objectives) of its Provisional Agenda (ALINORM 99/33, para. 4).

7. In discussing Recommendations for the Management of Microbiological Hazards for Foods in International Trade, the 31st Session (October 1998) of the Codex Committee on Food Hygiene (ALINORM 99/13A, para. 81) had an extensive discussion as to the meaning of "Food Safety Objectives" and how they should be incorporated in the document. It was proposed to include FSO into the section on Risk Management Principles. The Observer from the European Community, supported by other delegations, emphasized that this concept was not clearly defined and no internationally accepted definition existed at this stage. It was pointed out that the work of other Codex Committees (CCFICS and CCGP) on this issue should be taken into account. Confusion should be avoided between principles and tools, as Food Safety Objectives represented one of the important risk management tools. Some delegations stressed the need to separate principles and tools. The Delegation of the United States, while generally supporting the development of the document, pointed out that risk management was the responsibility of individual countries and the inclusion of FSO was premature until this concept had been clearly defined.

> **Note:** This subject is scheduled for discussion by the Committee under agenda item 6 (also see CL 1998/24 – FICS for details).

REPORT ON MATTERS RELATING TO THE APPLICATION OF THE WTO SPS AND TBT AGREEMENTS

8. The 45th CCEXEC (June 1998) was informed (ALINORM 99/3, paras. 41-44) that the 22nd session of the Commission requested the Secretariat to write to the chair of the WTO Committee on the Application of Sanitary and Phytosanitary Measures in order to obtain clarification on how the Committee would "differentiate standards, guidelines and other recommendations" in relation to the SPS Agreement. The response of the Chair of the SPS Committee is provided *verbatim* in the working paper (CX/EXEC 98/45/9).

9. The Executive Committee noted the following features in the reply:

- the SPS Committee cannot formally interpret the provisions of the SPS Agreement;
- the Agreement does not differentiate between the terms "standards', "guidelines" or "recommendations";
- there is no legal obligation on WTO Members to apply any of these Codex texts;
- how a text would be applied depended on its substantive content rather than on the category of the text;
- Regional standards are not included in the definition of "international standards" used in the Agreement, but may be applied within a given Region.

10. The Executive Committee also noted that the above points seem to be consistent with the rulings of the Appellate Body in relation to the Panel reports concerning EC Measures Concerning Meat and

Meat Products (Hormones)[1]. It also noted that the SPS Committee was of the view that the work of Codex should not be constrained by this question.

11. The Executive Committee agreed that:

- the reply of the SPS Committee should be brought to the attention of all Codex Committees;
- the reply by the SPS Committee seemed to conclude the correspondence on this matter;
- the work of Codex should move forward without concern arising from misunderstandings or misinterpretations as to how Codex standards and related texts might be used;
- the guidance given by the 22nd Session of the Commission in relation to the status of Codex advisory texts should continue to be adhered to;
- the Committee on General Principles should examine the possibility of developing a set of appropriate preambular statements explaining the intent of different types of Codex texts.

REVIEW OF THE CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOODS

12. The 13th Session of the Codex Committee on General Principles (September 1998) recalled (ALINORM 99/33, paras. 84-90) that a Circular Letter (CL 1998/2-GP) had been sent to seek the views of member countries on the opportunity of revising the Code in view of the need to update a number of references, especially as a result of the conclusion of the WTO Agreements and the work of the Committee on Food Import and Export Inspection and Certification Systems.

13. The Committee generally agreed that the Code of Ethics was still needed to provide general guidance for the conduct of international trade, although several texts already covered the issues relating to import/export.

14. The Delegation of Austria, expressing the views within the European Union, stressed the importance of ethical aspects, suggesting that the title of the Code should be amended to reflect more precisely its broadened purpose (viz. “Ethical and General Principles”). It was proposed that the revised text should include the following elements: other legitimate factors; problems related to rejection of consignments on safety grounds; nutrition and health claims; and the status of Codex texts. It was also proposed to introduce a general requirement to limit chemical substances to a reasonable minimum.

15. Other delegations, while supporting the revision of the current text, expressed their objection to the inclusion of new elements such as ”other factors”, as the Code should focus on ethical issues; in addition, questions concerning the limits for chemical substances in food should be addressed in the framework of the discussion on risk analysis in the CCGP and in other concerned committees.

16. Several delegations supported the inclusion in the Code of a statement on special and differential treatment for developing countries. It was proposed that the Code should be self-standing and would include all of the pertinent provisions coming from other Committees.

17. The Committee agreed that coordination with other concerned committees would be exercised where necessary, especially as regards inspection and certification and food safety matters. As regards health claims, it was recalled that the Committee on Food Labelling was currently elaborating guidelines

[1] WTO Document AB-1997-4, World Trade Organization, Geneva.

in this area, and was generally responsible for such matters, in coordination with the Committee on Nutrition and Foods for Special Dietary Uses.

18. The Committee agreed to propose to the Commission the revision of the Code as new work, following which a revised draft would be prepared by the Secretariat and circulated for comments prior to the 15th Session of the Committee.

MATTERS ARISING FROM THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

19. At the 21st Session (May 1998) of the Codex Coordinating Committee for Europe (ALINORM 99/19, paras. 66-67), the Delegation of the United Kingdom informed the Committee of the views of the countries in the European Union concerning the work of CCFICS. The Committee had been created with the understanding that it would carry out specific tasks and reexamine the need for its work to continue. The time had come to examine the question of whether the CCFICS had now completed its work assignments. Some delegations expressed their appreciation for the work carried out so far by CCFICS while expressing their concerns as to the possibility that it extend its work to areas beyond those specified in its terms of reference. If that was the case careful consideration should be given to the task assigned to the Committee, especially on the question of equivalence applied to Codex standards.

20. The Delegation of Norway pointed out that the work of CCFICS was not initially scheduled to be discussed by the Committee and that it could not take a position on such issues; further information should be provided by countries in the EU as to their specific concerns. It was however noted that the position of the EU countries was presented for information purposes only.

CRITERIA FOR EVALUATING ACCEPTABLE METHODS OF ANALYSIS FOR CODEX PURPOSES

21. At the 22nd Session (November 1998) of the Codex Committee on Methods of Analysis and Sampling (ALINORM 99/23, paras. 29-31), the Delegation of France presented Annex IV of the referenced paper (CX/MAS 98/5) and recalled that at the last Session the Delegations of the United States and France had expressed concerns that how to deal with trade dispute situations had not been fully addressed in CX/MAS 97/3. The Delegation explained that the annex included all possible trade dispute situations envisaged. The settlement procedure started with the comparison of the results of the export laboratory and import laboratory. If no agreement was reached in this phase, the two laboratories should first agree to the method to be used for new analysis. If no agreement was yet obtained after the second analysis they should take new samples according to the procedure specified in the annex. Further settlement would involve an arbitrating laboratory. The Delegation also mentioned other conditions such as quality assurance of the laboratory and archives of samples.

22. Many delegations highly appreciated the annex for its illustration of all possible scenarios. However, the Delegation of the United States was of the opinion that within its governmental system, it would not be possible to delegate authority to third parties.

31. Recognizing that the Codex Committee on Food Import and Export Inspection and Certification System is the Committee which deals with horizontal issues regarding food import and export, the Committee agreed to refer Annex IV of CX/MAS 98/5 to that Committee.

> **Note:** Annex IV of CX/MAS 98/5 is attached to this paper for consideration by the Committee.

DISPUTE SETTLEMENT PROCEDURE

When the same product is analysed by two laboratories and the results differ, there are two possible reasons:

- One relates to the facilities, methods and interpretation of results of the laboratories conducting the analyses.
- The other relates to the samples themselves, which might be different; in this case, the representativeness of the samples analysed should be checked.

1 - SETTLEMENT PROCEDURE FOR INTER-LABORATORY DISPUTES

1.1 - ***The export laboratory and import laboratory compare*** their results, analytical methods, expression of results, recovery factors, and all conditions likely to influence the analysis results.

- If one laboratory recognises the validity of the other laboratory's results (agreement on conformity or agreement on nonconformity): ⇒ The inter-laboratory analytical dispute is settled.
- If the laboratories cannot reach agreement: ⇒ Phase **1.2**

1.2 - The laboratories undertake new analyses.

Preliminary: The two laboratories agree on the most appropriate analytical method.
The results obtained will be compared to those from the initial analyses:

1.2.1 - If each laboratory has kept a sample: The two samples are exchanged and analysed according to a specific method.

1.2.2 - If only the export laboratory sample is available: It is divided between the two laboratories and analysed by both.

1.2.3 - If only the import laboratory sample is available: It is divided between the two laboratories and analysed by both.

Analysis may also be carried out in a single laboratory in the presence of a representative from the second laboratory.

- If the analysis results of the exporting country are confirmed: agreement on conformity
- If the analysis results of the importing country are confirmed: agreement on non-conformity
- If the sample's representativeness can be challenged ⇒ Phase **2**.
- If the laboratories cannot reach agreement ⇒ Phase **2**.

2. PROCEDURE FOR SETTLEMENT THROUGH FURTHER SAMPLING AND ANALYSIS

In this phase, no account is taken of the initial analyses.

Depending on the parties' choice:

- ***The parties together take from the consignment a representative sampling consisting of three samples***. One sample is sent to each of the laboratories for analysis using the common method upon which they have decided.
  If the results obtained are identical ⇒ The analytical dispute is settled.
  If the results are different ⇒ The third sample is sent to a third laboratory chosen by the parties by mutual consent or designated by the judicial authorities of the importing country. This laboratory must use the same method. Its results will be binding. ⇒ The analytical dispute is settled.

- ***The parties together take a representative sampling consisting of <u>a single sample</u>*** and send it to one of the laboratories, which will conduct an analysis in the presence of a representative from the second laboratory. The results obtained will be binding. ⇒ The analytical dispute is settled.

Settling disputes

The result of the first analysis (that of the export laboratory) is assumed always to be in conformity. This is shown as C below, while a non-conforming result is shown as NC.

Export lab.	Import lab.			
C	C	No procedure	⇒	Agreement on C (for the record)
C	NC	Comparison of results		
1-1				
		⇒⇒⇒⇒ C established ⇒⇒⇒⇒⇒	⇒	Agreement on C
		⇒⇒⇒⇒ NC established ⇒⇒⇒⇒⇒	⇒	Agreement on NC
		⇒⇒⇒⇒ Disagreement Comparison of analyses as in **§ 1-2-1; § 1-2-2; § 1-2-3**		

1-2

1-2-1		**Agree on analytical method and exchange export laboratory sample and import laboratory sample**	**Account is taken of first two analyses which gave different results**
Export lab.	Import lab.		
C → C	*NC* → C	Import laboratory error for first result	Agreement on C
C → NC	*NC* → C	Samples different	Resample and proceed as in § 2
C → C	*NC* → NC	Disagreement between laboratories	Resample and proceed as in § 2
C → NC	*NC* → NC	Export laboratory error for first result	Agreement on NC

1-2-2		**Agree on analytical method and divide export laboratory sample**	**Account is taken of first two analyses which gave different results**
Export lab.	Import lab.		
C → C	*NC* → C	Import laboratory sample different	Agreement on C
C →	*NC* →	Disagreement between laboratories	Resample and proceed as in § 2

C	NC		
C → NC	*NC* → C	Export laboratory fails to confirm its first result, Import laboratory has analysed another sample	Resample and proceed as in § 2
C → NC	*NC* → NC	Export laboratory error for first result	Agreement on NC
1-2-3		**Agree on analytical method and divide import laboratory sample (most likely case)**	**Account is taken of first two analyses which gave different results**
Export lab.	Import lab.		
C → NC	*NC* → NC	Export laboratory sample different	Agreement on NC
C → C	*NC* → NC	Disagreement between laboratories	Resample and proceed as in § 2
C → NC	*NC* → C	Import laboratory fails to confirm its first result Export laboratory has analysed another sample	Resample and proceed as in § 2
C → C	*NC* → C	Import laboratory error for first result	Agreement on C
2		**Further sampling and analysis**	**Final procedure**
Export lab.	Import lab.	Before analysing official samples both laboratories must agree on analytical method to be used	No account is taken of first two analyses which gave different results
C	C		Agreement on C
NC	NC		Agreement on NC
C	NC	Arbitrating laboratory ⇒⇒ C	Agreement on C
NC	C	Arbitrating laboratory ⇒⇒ NC	Agreement on NC