

codex alimentarius commission



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Agenda Item 3(a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Thirteenth Session

Melbourne, Australia, 6 – 10 December 2004

PROPOSED DRAFT APPENDICES TO THE GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION

(N04-2004)

(Prepared by the United States with the assistance of Argentina, Australia, Canada, China, France,
India, Japan, New Zealand, Republic of Korea, Romania and South Africa)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 25 October 2004** to: Codex Australia, Australian Government Department of Agriculture Fisheries and Forestry GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

BACKGROUND

1. The 11th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems completed work on the *Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* (CAC/GL –/2003).¹ At this Session, during “Other Business and Future Work”, the Committee noted the comments of Consumers International that suggested the development of three appendices or references to the Guidelines dealing with: 1) documentation requirements for the submission of a request for a judgement of equivalence; 2) terms for on-site visits by importing country authorities to verify inspection and certification systems; and 3) technical assistance to be provided by importing countries to exporting developing countries. Other delegations also noted the need for further work in these areas².

¹ ALINORM 03/30A, paras 8-6 and Appendix II

² ALINORM 03/30A, para 55

2. The Codex Alimentarius Commission, at its 26th Session, adopted the Guidelines³. During the adoption, the Delegation of the Republic of Korea stated that Section 7 of the Guidelines dealing with *Procedure for the Determination of Equivalence* did not contain sufficient information to enable the implementation of the Guidelines and required further elaboration. Additionally, the Delegation of Peru stated that it considered that Section 4 dealing with the *General Principles for the Determination of Equivalence* was subjective and required further clarification.

3. CCFICS, at its 12th Session, recommended that new work be undertaken on “Proposed Draft Appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL - /2003)*”⁴ using an electronic drafting group led by the United States and assisted by Australia, Canada, China, France, India, Japan, New Zealand, Republic of Korea, Romania and South Africa. The Committee’s Project Document stated that the following main aspects would be covered in the proposed new work.

- a) Documentation requirements for submissions of requests for equivalence determinations;
- b) Terms for on-site visits by importing country authorities undertaking a determination of equivalence;
- c) Information relating to technical assistance to be provided by importing countries to exporting countries;
- d) Assessing which measures are to be the subject of an equivalence determination;
- e) Determining an “objective basis of comparison”; and
- f) More detail on the process of judging equivalence.

The Committee also agreed to respond to the concerns brought forward by the Republic of Korea and Peru at the 26th Session of the Codex Alimentarius Commission.

Considerations Relating to the Issues Brought Forward by the Republic of Korea and Peru⁵

4. As indicated above, the Delegation of the Republic of Korea stated that Section 7 of the Guidelines dealing with Section 7, *Procedure for the Determination of Equivalence*, did not contain sufficient information to enable the implementation of the Guidelines to the control of food trade and required further elaboration. It is suggested that the concerns of Korea can be addressed by elaborating the additional guidance presented in the Project Document (a –f above) as appendices to the *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems (CAC/GL - /2003)*.

5. The Delegation of Peru stated that it considered that Section 4 dealing with the *General Principles for the Determination of Equivalence* was subjective and required further clarification. With respect to implementing equivalence, the general principles include the selection of measures, objectively demonstrating that a measure(s) meets an ALOP, consistency in the application of risk assessment techniques, taking into account prior knowledge and past experience of a country’s exporting system, and providing technical assistance. The proposed work outlined in a-f above, including the aspects of documentation requirements, on-site visits, determining the objective basis of comparison, details on the process of judging equivalence and technical assistance should provide the additional information sought by Peru to clarify the Principles.

³ ALINORM 03/41, para. 63-65

⁴ ALINORM 04/27/30 para 88 (a)

⁵ ALINORM 03/41 para 64

Considerations Relating to the Proposed Areas of Work

6. CCFICS agreed to undertake the above noted six new work items but did not indicate whether the work would be taken as a whole or carried out in a step-wise prioritized fashion. Because the six items could represent a substantial level of effort and technical complexity, it is suggested that two or three of them be undertaken at a time. The order in which the items are presented below presents a suggested priority for undertaking the new work.

7. Both for assuring that the work covers the elements considered necessary by the Committee and to assist with the prioritization of the work, it is helpful to first consider the scope of each new work item before developing the detailed guidance. This “scoping exercise” is presented below for each of the six new work items.

8. It is useful to recall that the guidance developed will be appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* (CAC/GL - /2003). Hence, the information developed should be as succinct as possible.

9. Equivalence is discussed in CCFICS texts other than the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* (CAC/GL - /2003). In particular, other CCFICS incorporating reference to equivalence include the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999) and the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). As appropriate, cross-referencing of the information contained in these and other CCFICS documents should be made.

10. The following areas of work relate to the initial undertaking of a judgment of equivalence. It is recognized that a determination of equivalence must be maintained and/or may need to be re-verified, and the Committee is invited to consider whether this area should be incorporated into the proposed new work, and if so, the best means to accommodate this need.

Content Outlines for New Work Items

Work Item 1. Assessing which measures are to be the subject of an equivalence determination

11. Scope of this work to include the following:

- a) Factors for exporting countries to consider when deciding whether or not to request an equivalence determination.
 1. Rationale for undertaking equivalence (e.g., ease of using own system to qualify product for import, new technology replacing older control measure, etc.).
 2. Are other lower cost means of meeting import country requirements equally effective (e.g., compliance, third party compliance, MOU)?
 3. Technical complexity involved and technical capability to pursue an equivalence determination with respect to measures selected.
 4. Legal requirements of the importing country.
- b) Selection of measures for which equivalence will be sought.

An exporting country may identify a food production/processing sector (e.g., beef) for which it seeks an equivalence determination. Alternatively, the exporting country may identify a specific portion of a food production/processing sector involving one or more control measures (e.g., replacing a thermal step with an alternative means to control a pathogen to a specified level) for which equivalence is sought. In some cases, an equivalence determination may be needed for an entire inspection system.

With respect to the importing country, all relevant measures associated with the hazard/commodity must initially be considered (including infrastructure; programme design, implementation and monitoring; and specific requirements: ref: (ref: Paragraph 13 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* (CAC/GL - /2003)).

The actual measure(s) that will be the subject of an equivalence determination will be determined by:

1. The alternative measure(s) identified by the exporting country.
 2. Measures of the importing country with which the exporting country will comply. These measures will not be subject to the equivalence determination.
 3. The importing country's prior experience, knowledge and confidence in the exporting country's food control measures. Prior knowledge, experience, and confidence of the importing country with the exporting country's food control system may permit a determination of equivalence of certain measures (e.g., legislation, program design, implementation, monitoring) without further consideration⁶. These measures would not, therefore, be the subject of the specific equivalence determination of the alternative measure.
 4. Based on (1), (2), and (3), a final determination will be made of the measure(s) that will be the subject of the equivalence determination.
- c) An iterative process between the exporting and importing countries is likely to be required to arrive at a final determination of which measure(s) will be subject to the equivalence determination.

Work Item 2. Documentation for evaluation of submissions of requests for equivalence determinations

12. The purpose of required documentation is to: 1) articulate the request for an equivalence determination; 2) provide evidence that the alternative measure(s) is equivalent; and 3) demonstrate the country's legislative base and administrative systems for implementing and enforcing the alternative measure(s).

13. The extent of documentation required will depend, among other things, on the legal requirements of the importing country and the extent of knowledge the importing country has of the exporting country. Fulfilling documentation requirements is likely to be the subject of an iterative process between the exporting and importing country.

14. The scope of documentation to be provided could include the following.

- a) The rationale/purpose for the request for an equivalence determination (e.g., desire to begin exporting a specific commodity, new technology providing an alternative control measure, resolution of an existing trade difficulty, etc.).
- b) The hazard(s)/commodity (-ies) combination(s) involved.
- c) The importing country measure(s) which is the subject of the equivalence determination.
- d) The exporting country alternative measure(s) for which equivalence is requested.
- e) Information on the exporting country's food safety infrastructure, food safety programme design, implementation, monitoring and specific requirements (ref: Paragraph 13 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems*). This may include relevant laws, decrees, regulations and other policy documents that demonstrate the country's legislative base and administrative systems for implementing and enforcing the alternative measures.

⁶ While the process of using prior knowledge, experience and confidence to eliminate certain measures is, in fact, an equivalence determination, the intent is to focus on the relevant exporting country food safety control measures that are proposed as alternatives to specific importing country food safety control measures.

- f) Data supporting the equivalence of the alternative measure(s).
- g) Exporting country agency contact information.

Work Item 3. Terms for on-site visits by importing country authorities undertaking a determination of equivalence

15. The purpose of on-site visits is to allow the importing country to verify the documentation and the ability of the exporting country to implement and adequately enforce the alternative measure(s).

16. Scope of this work item would include:

- a) Prerequisites for determining the need for an on-site visit, to include:
 - 1. Can equivalence be determined without an on-site visit to observe how alternative measure(s) operate in-practice?
 - 2. If an on-site visit(s) is needed, at what point in the equivalence process should it occur?
 - 3. Is documentation from the exporting country adequate?
 - 4. Has an adequate analysis been conducted by the exporting country on its alternative measure(s) to demonstrate equivalence with the importing country measure(s)?
- b) Basis for determining the elements of an on-site visit, to include:
 - 1. Documentation provided by the exporting country.
 - 2. Knowledge and experience of the exporting country's pertinent food safety systems by the importing country.
 - 3. Criteria for on-site audits.
 - 4. Need of the importing country to determine how the exporting country is implementing the measures subject to the equivalence determination.
 - 5. Identification and communication by the importing country regarding which parts of the foods safety system of the exporting country it wishes to review.
- c) Protocols for on-site audit⁷, to include:
 - 1. Extent of the food safety system subject to audit.
 - 2. Clear indication of the purpose and scope of the audit.
 - 3. Number/types of facilities to be visited (headquarters facilities, laboratories, processing establishments by type and number, etc.).
 - 4. Entrance and exit interviews/meetings with the competent authority (-ies).
 - 5. Identification of auditors

Work Item 4. Determining an “objective basis of comparison”

17. Paragraphs 15 and 16 of Section 6 *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* describe the concept of the objective basis of comparison and provide guidance for its utilization.

⁷ Refer to Annex: *Guidelines on Procedures for Conducting an Assessment and Verification by an Importing Country of Inspection and Certification Systems of an Exporting Country*, in the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*, CAC/GL 26-1997.

Paragraph 15: *Since the sanitary measures applied by an importing country have the purpose of achieving its ALOP, an exporting country may demonstrate achievement of the importing country's ALOP by demonstrating that the measures it proposes as equivalent have the same effect, relative to the achievement of the importing country's ALOP, as the corresponding measures applied by the importing country by using an objective basis of comparison.*

Paragraph 16: *The importing country should, at the request of the exporting country, specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures. Dialogue between the exporting country and importing country will assist in the development of understanding and, desirably, agreement on the objective basis for comparison. Supporting information to be provided by the importing country may include:*

- a) the reason/purpose for the sanitary measure, including identification of the specific risks that the measure is intended to address;*
- b) the relationship of the sanitary measure to the ALOP, i.e., how the sanitary measure achieves the ALOP;*
- c) where appropriate, an expression of the level of control of the hazard in a food that is achieved by the sanitary measure;*
- d) the scientific basis for the sanitary measure under consideration, including risk assessment where appropriate;*
- e) any additional information that may assist the exporting country in presenting an objective demonstration of equivalence.*

18. Although the guidance above is useful, examples of how this guidance can be applied in practice would assist countries in understanding the application of an objective basis of comparison with respect to an equivalence determination. Such examples might include: a) food safety objectives, performance objectives, and performance criteria established with respect to food hygiene⁸; b) microbiological criteria⁹; c) maximum residue limits for pesticide residues and residues of veterinary drugs in foods; d) maximum limits for contaminants in foods; and e) the application of statistical verification procedures to verify that process control with respect to a hazard has been achieved.

19. The scope of work would, therefore, consist primarily of a series of examples demonstrating the application of a-e above and, thus, how the objective basis of comparison would be established and applied in practice.

Work Item 5. More detail on the process of judging equivalence

20. Scope involves the elaboration of the provisions of Section 8 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* to include the following.

- a) Elaboration on what constitutes experience, knowledge and confidence by an importing country of an exporting country's food inspection and certification system including the history of food trade between the importing and exporting countries and the history of compliance of foods (particularly the food(s) products involved in the equivalence determination) provided by the exporting country to the importing country.
- b) How and when to apply such experience, knowledge and confidence.
- c) Mechanisms/approaches to evaluating data packages.
- d) Mechanisms/approaches to assessing on-site visit findings.
- e) Mechanisms/approaches to dealing with data uncertainty and qualitative descriptions of controls.
- f) Reaching conclusions on whether equivalence is achieved.

⁸ ALINORM 04/27/13 Appendix III

⁹ *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/G: 21 (1997).

Note: the Working Group is asked to provide information on how to further develop each of these sections.

Work Item 6. Information relating to technical assistance¹⁰ to be provided by importing countries to exporting countries

21. The purpose of technical assistance is to enable a developing exporting country to better undertake an equivalence determination. The following is presented for consideration.

22. Technical assistance would be provided by an importing country to an exporting developing country, within the means and capabilities of the importing country. Technical assistance would not be considered as a mandatory pre-requisite by either party in undertaking a determination of equivalence.

23. The request for technical assistance should be provided by the exporting developing country to the importing country as part of its initial submittal for a request for an equivalence determination.

24. As part of its submittal, the developing country would identify anticipated specific technical areas for which assistance from the importing country is requested. Such areas may include, for example: assistance with the preparation of documentation; undertaking risk assessments; assistance with data analysis; and assessing whether measures meet the importing country's stated objective basis of comparison.

Recommendations

1. The Committee **is invited** to consider the various elements specified for each new work item and determine whether they will, when fully elaborated, fulfil the need for additional guidance.
2. The Committee **is invited** to consider how best to prioritize the work. It is recommended that work on drafting detailed guidance be undertaken the first year on work items 1, 2, and 3 and continued to completion. Work would begin on items 4, 5, and 6 the second year. Depending upon the extent of progress on the various work items, the Committee, during the second and following years, may have more than three concurrent work items on SPS equivalence.
3. The Committee **should consider** extending the duration of the electronic working group to accomplish the work needed and to extend an invitation to other Members to join the working group.

¹⁰ The Committee may wish to consider whether providing guidance on the area of technical assistance falls within the Committee's Terms of Reference.