

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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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

Fourteenth Session

Melbourne, Australia, 28 November – 2 December 2005

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, Brazil, Canada, Chile, China, European Community, France, Denmark, India, Italy, Japan, Malaysia, New Zealand, Norway, Republic of Korea, South Africa, Thailand and Consumers International)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 1 November 2005** 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 53-2003).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.

2. CCFICS, at its 12th Session, recommended that new work be undertaken on proposed draft appendices to the now adopted *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL - /2003).³ The Committee’s Project Document stated that the following main aspects would be covered in the proposed new work.

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

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

² ALINORM 03/30A, para 55

³ ALINORM 04/27/30, para. 88 (a).

2. Documentation for evaluation of submissions of requests for equivalence determinations;
3. Terms for on-site visits by importing country authorities undertaking a determination of equivalence;
4. Determining an “objective basis of comparison”;
5. More detail on the process of judging equivalence; and
6. Information relating to technical assistance to be provided by importing countries to exporting countries;

The Committee also noted that providing further information on these items would respond to the concerns raised at the 26th Session of the Commission by the Republic of Korea and Peru with respect to the need for further guidance to implement the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003).

3. The Codex Alimentarius Commission, at its 27th (2004) Session⁴, approved new work on *Proposed Draft Appendices to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*.

4. CCFICS, at its 13th Session⁵, considered a paper⁶ prepared by the United States with the assistance of a Working Group that proposed that the work on the various appendices should be carried out in a step-wise fashion. The paper also presented a proposed scope and content outline for each of the appendices.

5. The Committee agreed that work on the appendices should be carried out in a step-wise approach. The Committee also agreed that priority should be given to the development by a Working Group led by the United States of items 2, 4 and 5 above and that work on items 1 and 3 should be deferred. The Committee agreed that, as regards item 6 (Technical Assistance), the Delegation of the United States would prepare a Discussion Paper based on the recommendation of the Executive Committee⁷ pertaining to the need for technical assistance and cooperation referenced in other Codex texts on inspection and certification with a view to identifying what guidance might be developed by the Committee in this regard.

6. The United States developed and circulated electronically to the Working Group for comment proposed draft appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* on: 1) documentation for evaluation of submissions of requests for equivalence determinations; 2) determining an “objective basis of comparison”; and 3) details on the process of judging equivalence.

7. Utilizing the comments received, the Working Group, met in Brussels, Belgium on September 5-7, 2005, and revised the working draft substantially. A list of participants at the Working Group can be found at Attachment 4. The Working Group noted that the original draft of the Appendix on the “Details of Judging Equivalence” focused more on the process of determining equivalence rather than judging equivalence and revised the Appendix to better reflect the main aspects of work presented in the Project Document. This Appendix appears in outline form at present and may require further elaboration of some of the elements. The Committee may also wish to consider whether it would be beneficial to develop additional guidance on the process of judging equivalence beyond that currently appearing in CAC/GL 53-2003. Because of limited time, the Working Group was not able to fully address the Appendix on “Objective Basis of Comparison” and this Appendix also will require further elaboration. With respect to this Appendix, the Working Group decided to not present the examples originally contained in the draft text, awaiting further consideration by the Committee and the Working Group; in this regard, the Committee is invited to suggest pertinent examples that may be more fully developed. The Working Group also discussed the need for a definition of the term “Objective Basis of Comparison”; a draft definition appears in Annex 2 for the Committee’s consideration.

⁴ ALINORM 04/27/41, para. 98 and Appendix VI.

⁵ ALINORM 05/28/30, paras. 23-25.

⁶ CX/FICS 04/13/3.

⁷ ALINORM 04/27/4, paras. 18-19.

8. Reflecting the outcome of the Brussels meeting of the Working Group, attached for consideration by the Committee are the proposed draft appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* on: Attachment 1) documentation for evaluation of submissions of requests for equivalence determinations; Attachment 2) determining an “objective basis of comparison”; and Attachment 3) details on the process of judging equivalence.

RECOMMENDATION

The Committee is invited to consider the attached proposed draft appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* with a view towards their further progression in the Codex Step Procedure.

Annex

Proposed Draft Appendix to the
Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and
Export Inspection and Certification Systems on
Documentation for Determination of Equivalence of Sanitary Measures

INTRODUCTION AND PURPOSE

1. This appendix sets out documentation likely to be required to: 1) articulate the request from an exporting country to an importing country for a determination of equivalence⁸; 2) provide evidence that the alternative measure⁹ identified by the exporting country is equivalent to the measure of the importing country; and 3) demonstrate the exporting country's legislative base and administrative systems for implementing and enforcing the alternative measure.

2. Factors affecting the detail and extent of the documentation provided may include: 1) the number and complexity of the sanitary measure(s) to be the subject of the equivalence determination; and, 2) the experience, knowledge and confidence of an importing country with an exporting country's food inspection and certification system, including details of any existing trade.

DOCUMENTATION

3. The documentation for an equivalence determination [should as appropriate] include the following:

An Initial Request

4. The exporting country should provide written notification to the importing country stating its interest in obtaining an equivalence determination and requesting pertinent information regarding the importing country's sanitary measure or set of measures relevant to a food product or group of food products.

5. The exporting country should submit the following basic information with the initial request:

- Contact information for the submitting competent authority (e.g. contact person, address, phone, email, FAX);
- The rationale or 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.);
- The exporting country's sanitary measure(s) associated with a food product or group of food products for which determination of equivalence is sought;
- The importing country measure (s) which is the subject of the equivalence determination, where such has already been identified and the rationale;
- [The result of the comparison between the exporting country's relevant sanitary measure and the importing country's sanitary measure which indicates the measures that are to be the subject of an equivalence determination and the measures that are compliant;

⁸ See Appendix \$\$, *Assessing which measures are to be the subject of an equivalence determination* (to be developed). Ref. Section 5 of CAC/GL 53-2003: Relevant measures will be associated with infrastructure, program design, implementation and monitoring, and specific requirements; an equivalence determination can be sought for any measure(s); all measures are initially under consideration; the exporting country determines with which relevant measure(s) of the importing country it or the exported products will comply- these are removed from the equivalence determination; the importing country determines which further relevant measures of the exporting country are equivalent based upon its prior experience, knowledge and confidence in the exporting country's systems—these are also removed from the equivalence determination; the remaining measure(s) are subject to the equivalence determination.

⁹ Commodity, hazard, and measure may be plural. Only the singular is used in this appendix.

- The exporting country's basis and rationale for proposing equivalence with the importing country's measures. Where relevant measures that have previously been agreed as equivalent with this importing country and/or where relevant with other importing countries should also be included;
- The relevant measures where there has already been an equivalence determination.]

6. Upon receipt of the initial request from an exporting country, the importing country should acknowledge such receipt and provide contact information to the exporting country's submitting competent authority.

Preparations for Development of a Submittal Package or Exchange of Information Between the Exporting and Importing Country

7. The importing country should provide written or electronic copies of all pertinent sanitary measures relating to: infrastructure; program design, implementation and monitoring; and specific requirements for the same products, as relevant to the request from the exporting country.

8. When the exporting country deems necessary/appropriate, it may ask for additional information including: the reason/purpose for the sanitary measure; how the sanitary measure achieves or helps to achieve the ALOP; and the scientific basis for the sanitary measure and the importing country should supply this information¹⁰.

9. The importing country should specify as precisely as possible an objective basis of comparison for the sanitary measures and provide supporting information as appropriate.¹¹

Submittal Package

10. The general nature of the documentation required to assess the equivalence of a measure is generally the same whether the measure is involved with infrastructure; program design, implementation and monitoring; or specific requirements¹².

11. A useful method for determining the information that needs to be submitted is to carry out a side-by-side comparison of pertinent sanitary measures of the importing and exporting country. This side-by-side comparison, in conjunction with consultation with the importing country, should enable the exporting country to determine the measures:

- with which it and its exported products will comply;
- which can be accepted by the importing country as equivalent based on knowledge, experience and confidence in the exporting country's systems; and
- which are to be the subject of the equivalence determination.

12. The submittal package to be forwarded from the exporting country to the importing country should include the following:

- A copy of the initial notification letter;
- Results of side-by-side comparisons of the importing and exporting countries' measures for the commodity/hazard combinations, indicating which measures are to be complied with, which should be equivalent based on experience, knowledge and confidence; and which are the subject of the equivalence determination;
- The results of the analysis of the measure subject to the equivalence determination and the finding as to whether the alternative measure is equivalent;
- For each broad measure type (infrastructure; program design, implementation, monitoring; requirements) a summary of findings including specific measures that will be complied with,

¹⁰ Paragraph 16, CAC/GL 53-2003

¹¹ See Section 6 and Appendix 2

¹² See Section 5 paragraph 13(a), (b), (c).

measures found to be equivalent based on experience, knowledge and confidence; and alternative measure(s) proposed to be equivalent.

- For each alternative measure found to be equivalent, a summary of the scientific rationale as to why the measure is equivalent and detailed supporting information. These will include analysis, based when appropriate, on the objective basis of comparison, and include the result of side-by-side comparisons or analytical data packages.¹³ Detailed supportive analytical information can be placed in annexes.
- Copies of all pertinent communications including substantive findings and interpretations.

Judgment of Equivalence

13. Both the exporting and importing country should retain, as relevant, written or electronic copies of correspondence, and written records of verbal communication, between the importing country and exporting country regarding the results of clarifications, interpretative findings, physical visits, conversations, etc.

14. The importing country should provide to the exporting country a written report as to whether equivalence has been found with respect to the exporting country's alternative measure. Where equivalence is not found, the reasoning for this should be included in the written report.

¹³ The analysis should demonstrate that the two measures will achieve the same level of public health protection for specified hazard in the commodity under consideration, employing, as appropriate, one or more objective basis of comparison.

Annex

**Proposed Draft Appendix to the
Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import
and Export Inspection and Certification Systems on
Determining an “Objective Basis of Comparison”**

1. This annex provides an elaboration of the guidance given in Section 6, paragraphs 15 and 16 of the base document.
2. Once countries have decided which measures are to be the subjects of an equivalence determination, the importing country, at the request of the exporting country, should provide the objective basis of comparison for the sanitary measure identified in the submittal package. This objective basis of comparison may be elucidated in qualitative or quantitative terms. The value of utilizing the objective basis of comparison as a tool can be considered at this stage.
3. An “objective basis of comparison” is the [means/method/tool/instrument/reference point/result] by which alternative measures or groups of measures may be shown to achieve the importing country’s ALOP, and thus may be considered equivalent.
4. Depending upon the nature and extent of the measures subject to an equivalence determination, one or more objective basis of comparison may be needed in order to effectively evaluate alternative sanitary measures or groups of sanitary measures. For example, more than one objective basis of comparison may be required where a single measure applied by an importing country contributes in several different ways to the achievement of the ALOP, or where subsets of a group of measures for which an equivalence determination is sought make distinct contributions to the outcome.
5. The importing country should specify as precisely as possible the objective basis of comparison and, to the extent possible, provide supporting information¹⁴.
6. Depending upon the nature of the measure subject to the judgment of equivalence, the objective basis of comparison may take different forms. For example:
 - a. An objective basis of comparison is preferably a quantitative value against which the outcome of two sets of alternative sanitary measures used to control a hazard in a food can be compared. For example, an objective basis of comparison may be stated as a performance objective (e.g., a log reduction in a bacterial pathogen in a food or a percent reduction of the hazard in a food that must be achieved).
 - b. Alternatively, the objective basis of comparison may be a specified performance of a control system based on a statistically designed means of evaluating the system (e.g., product lot examination, farm and/or establishment inspection).
 - c. In some instances, while the objective basis of comparison may be the scientific basis of a measure (e.g., the requirement for a particular food contact surface based on the demonstrated ability of that surface to prevent microbial biofilm formation), the actual activity of showing that the objective basis of comparison has been met could be a side-by-side comparison/assessment of measures based on the knowledge of scientific/technical experts.
7. Initially all sanitary measures (infrastructure, program design, implementation, monitoring and specific requirements) pertinent to the control of a hazard in a food are subject to an equivalence determination. The exporting country will determine which measures and/or its exported goods/products it will comply with and which will be subject to an equivalence determination.

¹⁴ Supporting info can include (see Section 6): the reason/purpose for the sanitary measure; how the sanitary measure achieves or helps to achieve the ALOP; the scientific basis for sanitary measure.

8. The determination may remove certain measures from further consideration based on the importing country's knowledge of, experience with, and confidence in the exporting country's food control system, leaving a final measure or set of measures for which an assessment of equivalence must be made. In each of these instances, an objective basis of comparison to enable comparison of outcomes should be identified and used.

EXAMPLES OF APPLYING AN OBJECTIVE BASIS OF COMPARISON

(Examples of developing an objective basis of comparison will be provided for use as an illustrative tool).

Annex

Proposed Draft Appendix to the
Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and
Export Inspection and Certification Systems on
Details on the Process of Judging Equivalence

This annex provides an elaboration of the provisions of Section 8 of this Guideline. The additional details provided below are intended to assist countries in the practical application of the concepts in Paragraph 20 of Section 8 and to provide guidance as to judgement of equivalence of sanitary measures.

1. 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 importing and exporting countries and the history of compliance of foods, particularly the food products involved in the equivalence determination provided by the exporting country to the importing country.

- a. General knowledge of the exporting country's food safety system as demonstrated by, among other things, a side by side comparison.
- b. Results of audits/inspections/field examinations by the importing country, other countries or other officially recognized third party organizations.
- c. Information on the exporting country's application and implementation of the risk analysis framework in the food safety system.
- d. Available exporting country risk assessments.
- e. Port of entry inspection and test results.
- f. Records of import rejections and alerts by the importing country as well as from other trading partners.
- g. Agreements the importing country may already have in place with the exporting country, including equivalence agreements.
- h. Bilateral or multilateral agreements on recognition of equivalence with other countries which are in place.
- i. Experience acquired with the exporting country, including historical data regarding the importation and compliance of other food or groups of food products from the same country.
- j. Frequency of organisational/structural/administrative changes in the exporting countries competent authority (ies).
- k. Contingency plans for containing and mitigating the effects of food safety emergencies.
- l. Foodborne disease surveillance data associated with the food product.
- m. The degree to which industry uses appropriate processing controls.
- n. Completeness of the exporting country's legislation and, as appropriate, quality control systems.
- o. Level/form of oversight of the food production system by the exporting country's certifying authority.
- p. Acknowledgment and evaluation of pre-existing certification systems conducted or carried out by the exporting country.

2. How and when the importing country should apply such experience, knowledge and confidence used by the importing country to determine priority including a decision whether to proceed with the request

- a. To assist in setting priorities, as may be appropriate.
- b. To confirm, or not confirm, the conclusions of the exporting country's side by side comparison of its relevant sanitary measures against the importing country's sanitary measures.
- c. To narrow the scope of the sanitary measures that are to be the subject of the equivalence determination.
- d. To determine the economic feasibility to pursue further scientific evidence.
- e. To determine if equivalence can be accepted without the need for any further work, when the risks associated with the food product(s) in question are considered low.
- f. To determine the necessity of or scope of an on-site audit/inspection by the importing country of the exporting country's system.
- g. To be applied in every case during the initial stage if the information is available.
- h. To substitute for, or to be used in conjunction with, risk assessment/scientific analysis.

Note: Transparency in the application of experience, knowledge and confidence is essential to that the use and application of this information is clear to all parties.

3. Mechanisms /approaches to gathering and evaluating quantitative and qualitative data
 - a. Assure the adequacy and accuracy of the data.
 - b. Maximize the amount/extent of data.
 - c. Utilize statistical data when appropriate.
 - d. Utilize risk assessments.
 - e. Utilize scientific principles of risk analysis.
 - f. Utilize, as appropriate, an iterative approach to evaluate the data.
 - g. Utilize data to establish an objective basis of comparison.
 - h. Include concepts such as performance objective, food safety objective and performance criteria and their associated data.
 - i. Utilize appropriate subject matter experts to evaluate qualitative or quantitative data.
 - j. Utilize side-by-side comparisons of the data developed by the importing and exporting countries associated with the same or alternative measures.
4. On-site visits/audits: Mechanisms/approaches to assessing findings
 - a. Use to gather information on the exporting countries food inspection system.
 - b. Use to verify implementation of exporting country food safety inspection system.
 - c. Use to assist in confirming compliance with country requirements.
 - d. Use as an optional undertaking of the importing country where prior knowledge and experience are not sufficient.
 - e. Limit in scope to the commodity and the related food safety systems that are the subject of the equivalence determination.
 - f. Establish protocols for undertaking on site visits/audits.
 - g. When appropriate, the importing country may utilize information provided by officially recognized third party organizations regarding the exporting country's food safety inspection system.

- h. Recognise the provisions of the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).
 - i. Recognise the provisions of the WTO SPS Agreement Article 4 (Equivalence).
5. Mechanisms/approaches to dealing with data variability and uncertainty
- a. Accepted methods in evaluating data for variability and uncertainty should be used and applied consistently.
 - b. The data should be presented in a means which permits easy separation of variability and uncertainty.
 - c. Evaluation/use of quality control mechanisms and possible accreditation procedures in place in the exporting country.
 - d. Use appropriate subject matter experts to evaluate qualitative descriptions of controls.
 - e. The importing country should objectively review the equivalence data of the exporting country regardless of data variability and uncertainty.
 - f. Provide for flexibility in the appreciation of variability and uncertainty for low risk products.

In reaching a conclusion regarding a judgement of equivalence the considerations in the above sections should be taken into account, as appropriate, as well as the provisions of Section 8, paragraphs 20 (c) and (h) of the base document. Guidance relating to the objective basis of comparison (Section 8 c of the base document) can be found in Section 6 of the base document and Annex 2.

Attachment 4

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