

codex alimentarius commission



FOOD AND AGRICULTURE
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ORGANIZATION



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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS**

Fifteenth Session

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**PROPOSED DRAFT APPENDIX TO THE CODEX GUIDELINES ON THE JUDGEMENT OF
EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND
CERTIFICATION SYSTEMS**

(AT Step 3)

(Prepared by the United States with the assistance of Antigua and Barbuda, Argentina, Australia, Brazil, Burundi, Canada, Chile, Denmark, Ecuador, European Community, Finland, France, Guatemala, India, Iran, Italy, Japan, Kenya, Malaysia, Netherlands, New Zealand, Norway, Philippines, Republic of Korea, Romania, Rwanda, South Africa, Switzerland, Thailand, Consumers International and IAFI)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 September 2006** 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. At its 12th Session, CCFICS recommended¹, and the Commission agreed that new work be undertaken on proposed draft appendices to the adopted *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL - /2003). 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;
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";

¹ ALINORM 04/27/30, para 88(a).

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;
2. Over the next two Sessions CCFICS, considered Discussion Papers² prepared by the United States with the assistance of a working group. While, originally, the Committee proposed that work on the various appendices should be carried out in a step-wise fashion, at its 14th Session, CCFICS observed that certain elements of each of the five proposed appendices were needed to understand the others and that it might be better, both for logic flow and to avoid duplication, to develop a single combined appendix.
3. The Committee also agreed that: 1) to the extent possible, each section of the combined appendix should be referenced to corresponding paragraph(s) of the main document; 2) the appendix should clearly distinguish procedures for the determination of equivalence of a single measure and of an inspection system; 3) the physical Working Group should take into account the written comments submitted and the comments made at the 14th Session, as well as the draft structure contained in CRD 16, and 4) elements on technical assistance as presented in the *Discussion Paper on the Development of an Appendix on "Information Relating to the Need for Technical Assistance and Cooperation Between the Importing Countries to Exporting Countries" to the Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*⁴ should be considered for inclusion in the Appendix. The Committee agreed to return the document to Step 2 for redrafting as a single combined appendix by a Working Group led by the United States.
4. The United States, as the lead for the Working Group, prepared and circulated electronically for comment to the Working Group a revised paper based on comments submitted to CCFICS at its 14th (2005) Session and the discussion that occurred at that Session³. The revised paper had been reorganized substantially and based on the request of the committee, combined all previously-prepared annexes into a single annex. The Paper also contained initial drafts for those subjects agreed to in the project document and not originally developed, specifically "identifying which measures are to be the subject of an equivalence determination" and "terms for on-site audits". The paper also incorporated considerations on technical assistance with respect to equivalence determinations, previously developed and presented to the Committee in the *Discussion Paper on the Development of an Appendix on "Information relating to the need for technical assistance and cooperation between the importing country to the exporting country to the Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification"*⁴. The Working Group, met in Brussels, June 22-27, 2006 at the kind invitation of the European Commission. Participants to the Working Group are shown in Attachment 2. The Working Group considered the revised Paper along with comments submitted electronically by the Working Group⁵.
5. The Working Group revised the text substantially, considering a large number of key items including the following.
- The scope of the document, particularly whether the Annex should consider determining equivalence of only specific measures or whether the scope should be broader involving consideration of the entire food safety system including: infrastructure; program design, implementation, and monitoring; and specific requirements. While a few delegations believed the scope should be narrow, focusing only on an elaboration of paragraph 18 of the main document, most delegations believed the scope should be broad; that is, the Annex should consider the situation when it might be required that many elements comprising a food safety system may have to be considered in undertaking a determination of equivalence. This issue of scope arose frequently during the meeting and impacted on several aspects of the discussion.

² CX/FICS 04/13/3, CX/FICS 05/14/3

³ ALINORM 06/29/30, paras 10-17

⁴ CX/FICS 05/14/8

⁵ Brazil, Canada, European Community, and India had submitted comments

- Clarifying whether the process of undertaking an equivalence determination would initially include an indication of those measures of the food safety system with which a country will comply in addition to those for which it is seeking a determination. This was noted to be essentially an aspect of the scope of the determination noted above. The notion of considering all measures encompassing the food safety system associated with the food product(s) under consideration, both those with which an importing country will comply and those for which it seeks an equivalence determination was included in the document.
- How the importing country's experience, knowledge, and confidence of the exporting country's food safety systems is utilized in the determination of equivalence, particularly with respect to determining which measures are to be the subject of an equivalence determination. The use of experience, knowledge and confidence was included within the document, recognizing that this aspect was, again, an aspect of the scope discussion.
- The extent to which the Appendix should address the need for a rationale for undertaking a determination of equivalence, as well as other factors that should initially be considered before undertaking an equivalence determination. Aspects considered at some length included trade facilitation, whether means other than equivalence (e.g., compliance) can achieve the desired objective, the availability of data and resources required to undertake an equivalence determination, and the benefits of an equivalence determination to the importing country. The Working Group agreed to include a brief section noting these aspects.
- Whether examples of an "Objective Basis of Comparison" (OBC) were necessary or whether the meaning and usage of OBCs could be conveyed through narrative text only. While different views were expressed on this matter, the Working Group agreed that, at least for the present, examples would be maintained, recognizing the importance and complexity of this aspect of the document. The Working Group had time only to discuss two of the four examples included in the text and left the final two examples in square brackets. The Working Group also noted that further discussion of the need for examples, and the precise nature and type of examples, should they be included in the Appendix, would be necessary. In discussing OBCs the Working Group noted that any reference to the use of Food Safety Objectives, Performance Objectives, or Performance Criteria in relation to OBCs needs to be carefully considered as these aspects are still under development within the context of Codex.
- The issue of on-site visits and the fact that such visits were to be conducted solely with respect to verifying aspects of the equivalence determination and not expand into broader aspects of the performance of a country's food inspection systems.
- Whether, and the extent to which, a section on technical assistance should be included in the Appendix. Views varied widely in this regard, extending from maintaining the section in its present form (essentially as a set of principles) to expanding or deleting it. The Working Group also expressed a range of views as to whether appropriate technical assistance with respect to equivalence should be limited to the scientific/technical aspects associated with a specific equivalence determination or deal more broadly with such areas as regulatory and food sector infrastructure. The Working Group agreed to retain the section in its present form pending consideration by the Committee. The Chairperson of CCFICS noted the possibility of holding a workshop immediately prior to the 15th Session of the Committee to discuss the area of technical assistance with respect to equivalence determinations and the nature and extent to which it should be included in the Appendix.

RECOMMENDATION

The Committee is invited to consider the attached proposed draft appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (Attachment 1) with a view towards their further progression in the Codex Step Procedure.

Attachment 1**PROPOSED DRAFT APPENDIX****FURTHER GUIDANCE TO ASSIST IMPORTING AND EXPORTING COUNTRIES IN IMPLEMENTING 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)*****INTRODUCTION AND PURPOSE**

1. This appendix provides further guidance on:
 - identifying which measures¹ are to be the subject of an equivalence determination;
 - documentation for determination of equivalence of measures ;
 - determining an objective basis of comparison;
 - the process of judging equivalence (including terms of reference for on-site visits by importing country authorities undertaking a determination of equivalence; and experience, knowledge and confidence in the exporting country's food inspection and certification system); and
 - technical assistance with respect to equivalence determinations.
2. The exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned.
3. The initial communications between the two countries should include exchange of contact information for the respective competent authorities to facilitate future information exchanges (e.g., contact person, address, phone, and e-mail, facsimile).
4. Information may be exchanged between the exporting and importing country during any stage in the equivalence determination process using tools, such as a questionnaire, that facilitate an organised compilation of material and subsequent equivalence determination.

IDENTIFYING WHICH MEASURES ARE TO BE THE SUBJECT OF AN EQUIVALENCE DETERMINATION

5. Before identifying measures to be the subject of an equivalence determination, the exporting country should consider its rationale or purpose for, and other factors that relate to, the proposed request for an equivalence determination. The exporting country may consider:
 - The availability of data to support an equivalence determination;
 - Whether there is a need for facilitation of trade while ensuring the protection of health of consumers;
 - Current international standards and texts;
 - Resources necessary to proceed through the equivalence process;
 - Whether the purpose may be more easily or quickly achieved through a different mechanism (e.g., meeting importing country requirements);
 - Possible benefits of an equivalence determination to the importing country.

¹ In all cases the word "measure" is taken to refer to sanitary measures

6. The exporting country should then identify the sanitary measures of the importing country for which an equivalence determination is sought. The exporting country should:
 - Identify and document its own sanitary measure(s)^{2,3} associated with the food product or group of food products;
 - Where relevant, request the competent authority in the importing country to provide the nature and purpose of its sanitary control measures associated with the food product or group of products⁴;
 - Determine those sanitary measures of the importing country with which the exporting country will comply and those for which it proposes to seek equivalence of its sanitary measures
7. In some cases, it may be useful to carry out a side-by-side comparison of measures between systems. Such a comparison, in consultation with the importing country, should promote better understanding of each country's measures and the measures' purposes and, thus, enable the exporting country to identify the measures for which a determination of equivalence will be sought.

DOCUMENTATION FOR DETERMINATION OF EQUIVALENCE OF MEASURES⁵

8. Once the exporting country has indicated to the importing country its intent to seek equivalence of specified sanitary measures and has requested the reason/purpose and objective basis of comparison (see next section) of the measures, as needed, the exporting country will be ready to prepare its documentation for submittal to the importing country. In doing this, a dialogue is likely to be needed between the two countries, for example, to:
 - seek clarification by the importing country of the request being made by the exporting country; and,
 - seek clarification by the exporting country as to the requirements of the submittal package.

Submittal Package

9. Documentation provided by the competent authority of the exporting country to the importing country should:
 - a) clearly articulate the request for a determination of equivalence, and identify the food product or group of food products involved and the sanitary measure(s) that are to be the subject of the equivalence determination;
 - b) clearly identify the importing country's sanitary measure(s) to which the exporting country seeks an equivalence determination ;
 - c) provide documentation (for example, risk assessment, side-by-side comparison of specified measures, data) that the alternative sanitary measure(s) identified by the exporting country is/are equivalent to the measure(s) of the importing country; and,
 - d) provide documentation on the existence of the exporting country's legislative base and administrative systems for implementing and enforcing the alternative sanitary measure(s).
10. Factors affecting the detail and extent of the documentation provided in the submittal package may include:
 - a) the number and nature of the sanitary measure(s) to be the subject of the equivalence

² Hazard and measure may be singular or plural.

³ See note under the definition of sanitary measure in Section 3 of the main document.

⁴ This information may be available, for example, as part of the importing country's legislation, or in its standards, regulations, codes of practice, or policy guidelines.

⁵ Additional guidance elaborating section 7 of the main document.

determination; and,

- b) the experience, knowledge and confidence that an importing country has with respect to an exporting country's food inspection and certification system, including details of any existing trade.
11. Once the submittal package is received by the importing country, the competent authorities in the importing and exporting countries should use a mutually agreed process, including a timeframe for considering the request for a judgement of equivalence.

DETERMINING AN "OBJECTIVE BASIS OF COMPARISON"⁶

12. The OBC is the means by which alternative measures or groups of measures can be shown to achieve the same effect, relative to the achievement of the importing country's ALOP, as the corresponding sanitary measures applied by the importing country and, therefore, may be considered equivalent.
13. Depending upon the nature and extent of the measures subject to an equivalence determination, one or more OBCs may be needed 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 (e.g., controlling multiple hazards) to the achievement of the ALOP. Also, in the case of a food control system utilizing multiple measures to control multiple hazards, multiple OBCs may be needed.

Elements or Criteria for Developing an Objective Basis of Comparison

14. An OBC may be quantitative and/or qualitative in nature.
15. Developing a quantitative OBC may require data gathering and statistical analysis that leads to development of a measurable OBC. Developing a qualitative basis of comparison may also require data gathering and may include using appropriate subject matter experts, who can provide information to assist in judgements on the comparability of alternative measures.
16. The importing country should gather and assess scientific data and other information⁷ to develop an OBC and enter into a dialogue with the exporting country to seek agreement on the OBC. This process should, as appropriate:
 - a) Ensure sufficient data to provide valid support for conclusions;
 - b) Ensure the adequacy and accuracy of the data;
 - c) utilize risk assessments, as available; and
 - d) Utilize side-by-side comparisons of the data developed by the importing and exporting countries associated with the same or alternative measures.
17. Potentially, all measures associated with infrastructure, program design, implementation and monitoring, and specific requirements may be the subject of an equivalence determination and may require the development of an objective basis of comparison. Examples of measures for which an OBC may be required and/or that could be used to reach agreement on an objective basis of comparison include:⁸
 - a) **Infrastructure measures:**
 - legislation in place, e.g., food and enforcement laws, decrees, regulations, directives;

⁶ Additional guidance elaborating Section 6 of the main document.

⁷ In the context of this appendix data is taken to mean both quantitative and qualitative data and other information

⁸ Section 6 of the *Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) can provide a useful basis for identification and development of elements or criteria for an objective basis of comparison for infrastructure measures and program design, implementation and monitoring measures.

- structure or system of national or regional authorities;
- laboratory/testing infrastructure; and
- compliance/enforcement programs;

b) Program design, implementation and monitoring measures

- requirements for good manufacturing practices (GMPs), good hygienic practices (GHPs) and and/or Hazard Analysis and Critical Control Point (HACCP) systems;
- documented decision criteria and action plans demonstrating that compliance/enforcement programs are targeted at the most appropriate stages and operations to deliver the desired outcome;
- laboratory and analyst proficiency programs: methods validation programs; and
- training and certification programs

c) Specific requirement measures

- Maximum residue limits (MRLs);
- [performance criteria (e.g.,) a specified log reduction in a bacterial pathogen in a food];
- [performance objective (e.g.,) less than x organisms in y amount of a food at a specific point in the processing chain];
- process criteria (e.g., time and/or temperature requirements, water activity)
- methods of sampling and inspection; and,
- microbiological methods used for monitoring of pathogens.

19. Examples of objective bases of comparison include the following:

[**Note:** the following examples are provided as a starting point for discussion and use a consistent format to present examples of OBCs.]

JUICE PROCESSING TO REDUCE BACTERIAL PATHOGENS

Importing Country Sanitary Measure: Fruit juice processors are required to use processes that achieve a 5 fold or 100,000 reduction in the numbers of the most resistant pathogen in their finished product compared to levels that may be present in the untreated juice.

Reason/Purpose for the importing country's sanitary measure: to assure that fruit juices do not present unacceptable levels of food borne pathogens that may cause illness in consumers.

The OBC is the level of the most resistant pathogen that would achieve the importing country's level of hazard control, which is achieved in the importing country through the 5 log reduction (i.e. X number of pathogens per Y volume of processed juice).

SAMPLE COLLECTOR: exporting country utilises third parties for sample collection and importing country uses government employees.

Importing Country Sanitary Measure: Government employees collect ready-to-eat) product samples for *Listeria* testing according to importing country standard procedures.

Reason/purpose for the importing country's sanitary measure: To ensure sample collection integrity and reliability under the RTE *Listeria* program.

OBC: Controls to ensure competency and lack of conflict of interest of sample collectors. For example;

- There is a clearly written sampling plan with instructions for sample collection.
- The government has a means of ensuring that sample collection activities are in accordance with the intent and procedures of the sampling plan.

- Sample collectors have received appropriate training and there are adequate provisions to avoid conflicts of interest.

LABORATORIES

Importing Country Sanitary Measure: Government laboratories analyse ready-to-eat product samples for the presence of *Listeria*.

Regulatory or Food Safety Objective: To ensure the integrity and reliability of sample analysis under the RTE *Listeria* testing program.

OBC: Criteria used for equivalence decisions for exporting country's use of private laboratories in lieu of government laboratories:

- The laboratory must be accredited/approved by the government, accredited by a third party accrediting organization with oversight by the government, or a government contract laboratory.
- The laboratory must have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and recordkeeping capabilities.
- Results of analyses must be reported to the government or simultaneously to the government and establishment.

ANALYTICAL METHODS

Importing Country Sanitary Measure: Methods approved for the testing of ready-to-eat meat and poultry products for *Listeria monocytogenes* must include an enrichment step and enable the detection of less than one colony-forming unit per gram of tissue in a 25-g sample.

Regulatory or Food Safety Objective: To ensure that ready-to-eat meat and poultry products meet the Importing Country's tolerances for *Listeria monocytogenes*.

OBC: The criteria used for determining whether a different testing method used by an exporting country is equivalent are as follows:

- The method must detect less than one colony-forming unit per gram of *Listeria monocytogenes* in a 25 gram sample of ready-to-eat product.
- The method is a scientifically validated method of analysis for *Listeria monocytogenes* approved or adopted by an internationally recognized organization.]

20. Once an objective basis of comparison has been agreed and documented, the exporting country, if it wishes to proceed, should then develop the documentation to be presented to the importing country for a determination of equivalence.

MORE DETAIL ON THE PROCESS OF JUDGING EQUIVALENCE⁹, INCLUDING TERMS FOR ON-SITE VISITS¹⁰

On-going dialogue¹¹

21. An on-going dialogue between the importing and exporting countries will need to occur during the consideration by the importing country of the request for an equivalence consideration by the exporting country to, among other things, clarify technical points and respond to the need for additional information.

Experience, Knowledge and confidence¹²

⁹ Additional guidance elaborating Sections 7 and 8 of the main document.

¹⁰ Additional guidance elaborating on paragraph 7, k) of the main document.

¹¹ Additional guidance elaborating on the need for dialogue indicated in Figure 1 (simplified flow chart for the determination of equivalence). Also see paragraph 8 of this Appendix.

¹² Additional guidance elaborating paragraphs 10-12, and 20(a) of the main document.

22. Judgement of equivalence of measures may be expedited by experience, knowledge and confidence in the food inspection and certification system of the exporting country, based on the information/documentation available to the importing country in its own records or those supplied by the exporting country. Where further information is required by the importing country this will be contained in the submittal package (refer to paragraphs 9-11).
23. Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country may include the history of food trade between the two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved in the equivalence determination. Other factors include:
 - 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, including records of import rejections and alerts by the importing country as well as from other trading partners;
 - f. agreements the importing country may already have with the exporting country, including equivalence agreements;
 - g. bilateral or multilateral agreements on recognition of equivalence with other countries;
 - h. historical data regarding the importation and compliance of other food or groups of food products from the same country;
 - i. frequency of organisational/structural/administrative changes in the exporting countries competent authority/ies;
 - j. contingency plans for containing and mitigating the effects of food safety emergencies;
 - k. food borne disease surveillance data associated with the food product;
 - l. the degree to which industry in the exporting country uses appropriate processing controls;
 - m. adequacy of the exporting country's legislation and, as appropriate, quality control systems;
 - n. level/form of oversight of the food production system by the exporting country's certifying authority;
 - o. acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country.
 - p. any specific export control system in operation.
24. An importing country can apply such experience, knowledge and confidence to:
 - a. assist in making a decision as to whether and how to proceed with a request for a judgement of equivalence;
 - b. assist in setting priorities, as may be appropriate;
 - c. confirm, or not confirm, the conclusions of the exporting country's side-by-side comparison of its relevant sanitary measures with the importing country's sanitary measures;
 - d. narrow the scope of the sanitary measures that are to be the subject of the equivalence determination;
 - e. limit the need for seeking further scientific evidence to that necessary to determine equivalence,

bearing in mind the economic implications¹³.

- f. [determine the extent to which equivalence may be judged without the need for any further work.; determine the necessity or scope of an on-site visit by the importing country of the exporting country's system];
 - g. formally recognize existing trade relationships with an exporting country.
25. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

On-site Visits¹⁴

26. On-site visits may be useful in the determination of equivalence to verify information contained in the submittal package. The rationale for on-site visits related to the determination of equivalence may include:
- a. To help verify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
 - b. To gather additional information on the exporting country's food inspection system that may be required by the importing country to undertake a judgement of equivalence of sanitary measures;
 - c. As an optional undertaking of the importing country to improve knowledge and confidence in the exporting country's food inspection system.
27. In preparing for an on-site visit, the importing country should consider:
- a. Limiting the scope of on-site activities to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination
 - b. The desirability for agreement between the importing and exporting countries regarding protocols for on-site activities.

Decision regarding a Judgement of equivalence¹⁵

28. A decision regarding the judgement of equivalence could be made at several points including:
- a. At initial contact by the exporting country;
 - b. Following review of the submittal package by the importing country;
 - c. Following onsite visits by the importing country;
 - d. Following an assessment based on experience, knowledge and confidence;
 - e. Following an assessment based on an objective basis of comparison.
 - f. Following further exchange of information that resolves any differences of opinion.
29. Equivalence of sanitary measures proposed by the exporting country should be granted by the importing country when:
- a. The experience, knowledge and confidence of the importing country with the pertinent measures of the exporting country is such that the importing country can determine that measures are equivalent;
 - b. The exporting country demonstrates, through the use of the objective basis of comparison, that its alternative measures are equivalent to those of the importing country. This comparison is facilitated with the use of quantitative data but also can be done on a qualitative basis.

¹³ Paragraph 32 of this document deals with Technical Assistance With Respect To Equivalence Determinations

¹⁴ Additional guidance elaborating on paragraph 7, k) of the main document.

¹⁵ Additional guidance elaborating on Section 8 of the main document.

30. As agreed between the importing and exporting countries, the importing country should provide to the exporting country a written report as to whether or not equivalence has been found with respect to the exporting country's alternative measure/s. At any point in the process, an importing country should have the possibility in consultation with the exporting country and when evidence exists that equivalence is not possible, to stop the process. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be included in the written report with suggestions for solutions where possible.

TECHNICAL ASSISTANCE WITH RESPECT TO EQUIVALENCE DETERMINATIONS¹⁶

31. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:
- Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.
 - Appropriate areas for technical assistance associated with an equivalence determination could include:
 - assistance in evaluating which measures would be the subject of an equivalence determination;
 - assistance with the preparation of documentation, including the submittal package;
 - assistance in undertaking necessary risk assessments;
 - assistance with data analysis; and
 - assistance in assessing whether measures meet the importing country's stated objective basis of comparison.
 - It would not normally be expected that the governmental body responsible for evaluating the exporting country's equivalence proposal would provide technical assistance relating to broad infrastructure (e.g., improvements to food regulatory control systems, improvements to food production/processing systems).¹⁷
 - The request for technical assistance should normally come from the exporting country, usually a developing country, to the importing country, usually but not always, a developed country, as part of the initial request for an equivalence determination.

¹⁶ Additional guidance elaborating paragraph 7, n) of the main document.

¹⁷ Developing countries may, however, in their consideration of undertaking an equivalence determination, recognize the need for broad infrastructure enhancements and seek technical assistance to undertake such enhancements from other entities (e.g., national technical assistance agencies, international development banks, etc.)

Attachment 2

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