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

CAC/GL 34-1999

SECTION 1 – SCOPE

1. This document provides practical guidance for governments desiring to enter into bilateral or multilateral equivalence agreements concerning food import and export inspection and certification systems. Such agreements may be binding instruments taking the form of "international agreements" under the Vienna Convention on the Law of Treaties, or they may be other less formal arrangements such as memoranda of understanding.

SECTION 2 – DEFINITIONS

Audit is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.[1]

Certification is the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.[1]

Certification system means official and officially recognized certification systems.

Equivalence is the capability of different inspection and certification systems to meet the same objectives.[2]

Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.[1]

Inspection system means official and officially recognized inspection systems.

[1] Codex Alimentarius: *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995).

[2] Codex Alimentarius: *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997).

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.[1]

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.[1]

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.[1]

SECTION 3 – PURPOSE OF AGREEMENTS

2. Countries[3] may wish to enter into agreements[4] concerning food import and export inspection and certification systems to:

a) provide an enhanced means of assuring that exported products conform to importing country requirements;
b) eliminate duplication of activities and use collective resources more efficiently and effectively;
c) provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with requirements.

3. Equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin.

SECTION 4 – SCOPE AND TYPES OF AGREEMENTS

4. The guidelines herein are intended to cover both bilateral and multi-lateral agreements. Such agreements may cover trade in one or both directions between trading partners.

5. As agreed by the parties, an equivalence agreement covering control and certification systems may relate to any aspect of food safety or other relevant requirement for food. Such agreements may be limited to specific areas of trade or

[3] For the purpose of these guidelines, "country" includes regional economic integration organizations to which a group of countries have transferred competencies as regards food import and export inspection and certification systems and/or the negotiation of equivalence agreements with other countries.

[4] See Section I – Scope. Although this guideline refers to "countries" and "agreements," in many cases competent authorities will enter into agreements or other arrangements.

specific products. Such agreements may be entered into where equivalence has been established in respect of some or all requirements.

6. Equivalence agreements may include provisions for certificates or other forms of certification of particular traded products or may provide for dispensing with certificates and other forms of certification.[5]

SECTION 5 – CONSIDERATIONS BEFORE ENTERING INTO BILATERAL OR MULTILATERAL DISCUSSIONS

7. The importing country considers and determines whether the exporting country's measures meet the importing country's requirements. Any decision must, however, be made on the basis of objective criteria.

8. In general, significant resources are needed to develop agreements. Exporting and importing countries may therefore need to establish priorities for consultations leading to development of agreements in recognition of the limited resources available to conduct the necessary assessments. Such priorities should not conflict with World Trade Organization (WTO) rights and obligations.

9. Countries may wish to consider some or all of the following issues in setting priorities:

a) whether priority should be given to certain product categories because of the public health risks they pose;
b) whether there is significant trade between the exporting and importing countries for the product(s) that will be the subject of an agreement, and whether an agreement between the two countries would facilitate trade;
c) whether the exporting country appears to have sufficient infrastructure and resources to maintain an appropriate control system;
d) whether the exporting country's products have a low rate of non-compliance with importing country requirements;
e) whether the exporting country recognizes and abides by the Codex Code of Ethics in International Trade in Food;
f) whether significant resources would be conserved as a result of the agreement.

10. A country entering into discussions towards an equivalence agreement should be prepared to facilitate assessment and verification activities both before and after conclusion of the agreement.[6]

[5] See paragraph 45 in CAC/GL 26-1997.
[6] See CAC/GL 26-1997 for guidelines on the conduct of such assessment and verification activities.

11. Countries that are not yet ready to enter into equivalence agreements may wish to work jointly toward the development of such agreements. Amongst other things, information exchange, joint training, technical cooperation, and the development of infrastructure and food control systems can serve as building blocks towards the later development of agreements. An importing developed country should consider providing technical assistance to exporting developing countries to establish systems that enable food exports to meet importing country requirements and facilitate the development of equivalence agreements.

SECTION 6 – INITIATING DISCUSSIONS TOWARD AN EQUIVALENCE AGREEMENT

12. The country initiating discussion towards an equivalence agreement should identify:

a) the type of equivalence agreement proposed;
b) the product(s) to be covered;
c) the competent authority or authorities for each product; and
d) the scope of requirements to be addressed by the agreement (e.g., health and safety, quality assurance systems, labelling, consumer fraud, etc.).

13. A country which receives such an approach should respond in a timely manner.

14. In the event that the recipient of such an approach has difficulty in responding positively to the approach it should provide a statement of reasons and any relevant recommendations to facilitate the future development of equivalence agreements.

15. Both parties should verify that legal authority exists to discuss and enter into such an agreement.

SECTION 7 – CONSULTATIVE PROCESS FOR EQUIVALENCE AGREEMENTS

16. As a first step in the consultative process, the importing country should make readily available the texts of its relevant control measures and identify the objectives of these measures. For food safety control measures, the importing country should identify the health risk(s) addressed by each measure. Where certain health hazards, such as foodborne pathogens, are known to exist in the exporting country and not in the importing country, these hazards and the measures to address them should be identified.

17. The exporting country should provide information that demonstrates that its own safety control system achieves the importing country's objectives and/or level of protection, as appropriate:

- Equivalence agreements for food safety (sanitary) control measures are entered into after an importing country determines that an exporting country's control measures, even if different from those of the importing country, achieve the importing country's appropriate level of health protection.
- Equivalence agreements for other relevant requirements for food are entered into after an importing country determines that the exporting country's control measures, even if different than those of the importing country, meet the importing country's objectives.

18. The development of equivalence agreements is facilitated by the use of Codex standards, recommendations and guidelines by both parties.

19. To facilitate the consultative process, information should be exchanged, as appropriate, on:

a) legislative framework, including the texts of all relevant legislation, which provides the legal basis for the uniform and consistent application of the food control system that is the subject of the agreement;[7]
b) control programs and operations, including the texts of all the exporting country's pertinent measures that would be the subject of the agreement, as well as other materials that relate to control programs and operations;[8]
c) decision criteria and action;[9]
d) facilities, equipment, transportation and communications as well as basic sanitation and water quality;[10]
e) laboratories, including information on the evaluation and/or accreditation of laboratories, and evidence that they apply internationally accepted quality assurance techniques;[11]
f) details of the exporting country's systems for assuring competent and qualified inspection[12] through appropriate training, certification, and authorization of inspection personnel; and the number and distribution of inspectors;

[7] See paragraphs 20–23 in CAC/GL 26-1997.
[8] See paragraphs 24–29 in CAC/GL 26-1997.
[9] See paragraphs 30–37 in CAC/GL 26-1997.
[10] See paragraphs 38–40 in CAC/GL 26-1997.
[11] See paragraphs 41–42 in CAC/GL 26-1997.
[12] See paragraph 43 in CAC/GL 26-1997.

g) details of the exporting country's procedures for audit of national systems, including assurance of the integrity and lack of conflict-of-interest of inspection personnel;[13]
h) details of the structure and operation of any rapid alert systems in the exporting country.

20. Countries may wish to prepare side-by-side tables to organize the above-mentioned information and identify differences between the countries' control systems.

21. The importing and exporting countries should identify a process for jointly considering differences in measures/requirements.

22. Representatives of the importing country should have the opportunity to satisfy themselves that the exporting country's control systems operate as outlined. This can be accomplished by appropriate assessment and verification of processes as described in Section 9 and the related Annex of the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*.

23. Participants in the agreement should establish procedures to:
a) periodically audit and verify that equivalence continues to exist after conclusion of an equivalence agreement; and
b) resolve any problems identified during audit and verification.

24. A problem resolution procedure should be developed including provision for the importing country to re-examine products to verify that the exporting country has corrected its deficiencies.

25. The participants in the agreement should discuss and decide whether the equivalence agreement should include provisions for the use, in addition to or in lieu of certificates, of a list of establishments which have been shown to be in compliance with the exporting country's equivalent control measures. The importing country can use this list of establishments to monitor imported shipments. The exporting country would be responsible for providing the list, and updates when appropriate, to the importing country. The importing country retains the right to refuse imports from an establishment and to arrange with the exporting country the removal of an establishment from the list, providing reasons for its action.

[13] See paragraphs 47 and 52–57 in CAC/GL 26-1997.

26. Participants in the agreement should agree to procedures for information exchange in the event of a food emergency control situation.[14]

27. Participants in the agreement should agree to procedures to follow in the case of food shipments that are found not to comply with the terms of the equivalence agreement.

28. Participants in the agreement should agree to procedures for terminating the agreement, in case either party is not satisfied that the terms of the agreement are being met.

29. To enhance public confidence in the agreement while respecting legitimate concerns to retain confidentiality, the relevant competent authorities of the particular countries should provide the public – including consumers, industry, and other interested parties – an opportunity to comment at an appropriate time on the proposed content of the agreement.[15]

SECTION 8 – PILOT STUDIES

30. Before entering into an agreement, the competent authorities in the importing and exporting countries may agree to the conduct of a trial or pilot study.

31. The pilot study draft agreement and protocol may include, but are not limited to, provisions in relation to:

a) description and time frame of the trial program;
b) roles and capabilities of involved government and officially recognized private organizations;
c) procedures for inspection and certification;
d) audit procedures and frequency;
e) description of training or information needs.

SECTION 9 – DRAFTING THE AGREEMENT

32. Information which may be included as appropriate in an agreement is listed in Appendix A.

[14] See Codex Principles and Guidelines for the Exchange of Information in Food Control Emergency Situations (CAC/GL 19-1995).
[15] See paragraph 58 in CAC/GL 26-1997.

SECTION 10 – IMPLEMENTING THE AGREEMENT

33. A notice announcing the agreement, or the text of the agreement itself, should be published by all the signatory governments. The text of the agreement should be made available to the public of each country in that country's official language(s).

34. After the agreement comes into effect, each party should promptly notify the other party or parties of any proposed new or revised measures that pertain to the agreement.

APPENDIX A

CONTENTS OF EQUIVALENCE AGREEMENTS

The following information may be included, as appropriate, in equivalence agreements.

(a) ***Title:*** The name given to the agreement may vary, depending on the preferences and legal requirements of the parties to the agreement.
(b) ***Parties:*** The name of the parties to the bilateral or multilateral agreement.
(c) ***Purpose:*** A brief statement of the specific purpose of the agreement.
(d) ***Scope:*** Identification of the products and measures that are the subject of the agreement. Note exceptions where necessary.
(e) ***Definitions:*** Definitions of terms in the agreement, as needed. Where possible, definitions in WTO and Codex documents should be used.
(f) ***Substantive obligations:*** A comprehensive description of each participant's obligations and specific responsibilities.
(g) ***Competent authorities:*** The title of each competent authority that will be responsible for the implementation of the agreement.
(h) ***Equivalence finding:*** A statement of the control systems or parts of systems that have been found to be equivalent by the importing party(ies) to the agreement.
(i) ***Assessment and verification provisions:*** A description of the methods to verify compliance with the provisions of the agreement, including audit procedures and/or provisions for participants to utilize officially recognized third parties (including competent authorities in countries that are not signatories to the officially recognized agreement). The plans for continuing verification should be clearly described.
(j) ***Criteria for certification:*** When certificates are part of agreements to meet requirements, a list of the criteria, by attribute, which should be used by the competent authorities of the exporting and importing countries to determine if the product meets the importing country's standards.
(k) ***Sample collection:*** A listing of references and sample procedures that the importing and/or exporting country will use for testing and/or certification.
(l) ***Analytical and other methodology:*** A listing of the methods and equivalence procedures that the participating competent authorities will use to determine the compliance of product(s) covered by the agreement.
(m) ***Administrative procedures:*** Procedures and guidance for the practical implementation and application of the agreement.
(n) ***Information exchange and cooperation:*** A listing of the types of sharing of expertise, providing assistance, and exchanging information that will help assure the quality and safety of the product(s) covered by the agreement.

(o) ***Transparency:*** Description of the types of information that should be exchanged on a routine basis, including but not limited to revised laws and standards, analytical findings, and inspection results.

(p) ***Notification:*** A description of the situations and procedures that should be followed when reporting significant changes in factors affecting the safety of traded products; situations where there is an identified risk of serious health effects related to traded products; and steps being taken to resolve such situations.

(q) ***Dispute settlement:*** A description of the consultative procedures, joint committee, and/or other mechanisms that should be employed by the participants to resolve disputes under the agreement. Such procedures and mechanisms should not limit the rights or obligations of the parties under the World Trade Organization (WTO) Agreements.

(r) ***Liaison officials:*** For each participating competent authority, at least one liaison official should be identified by title/position, address, telephone number, fax number and e-mail address. (It is not necessary to include the name of a specific individual.)

(s) ***Entry into force:*** The date on which the provisions of the agreement enter into force.

(t) ***Review, modification and termination:*** The methods for the review, modification and termination of the agreement.

(u) ***Signatures:*** Signatures, title, and names of officials representing the competent authority that are participants in the agreement and the date(s) of signature.