

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 3**

**CX/FICS 02/11/3  
September 2002**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS**

**Eleventh Session**

**Adelaide, Australia, 2 – 6 December 2002**

### **DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS**

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 30 October 2002** to: Codex Australia, Agriculture Fisheries and Forestry - Australia GPO Box 858, Canberra ACT, 2601 (fax: 61.2.6272.3103; E-mail: codex.contact@affa.gov.au), with a copy to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Via delle Terme di Caracalla, 00100 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: codex@fao.org).

## **BACKGROUND**

1. The 10<sup>th</sup> session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) could not reach a consensus on the draft *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* and therefore, decided to append the draft Guidelines, as originally presented and unchanged from the text adopted by the 24<sup>th</sup> Session of the Codex Alimentarius Commission, to its report for further comments (Alinorm 03/30, paras. 50-52 and Appendix III).
2. The Committee agreed that a drafting group<sup>1</sup> would prepare a revised version of the draft Guidelines for circulation, additional comment at Step 6 and further consideration at its next meeting. The Committee stipulated that the draft Guidelines should be revised on the basis of the Committee's discussion, written comments submitted at the 10<sup>th</sup> session and written comments submitted in response to CL2002/8-FICS.
3. The attached revised draft *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* was prepared by a drafting group led by New Zealand, with the assistance of Argentina, Australia, Brazil, Canada, France, Germany, the United States, Uruguay and the International Association of Consumer Food Organizations (IACFO), in Oakland, California from 26-28 August 2002.

---

1 Led by New Zealand with the assistance of Argentina, Australia, Brazil, Canada, France, Germany, Japan, Malaysia, United States, International Association of Consumer Food Organisations (IACFO), International Council of Grocery Manufacturers Association (ICGMA) and the European Commission (EC).

# DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS<sup>1</sup>

## SECTION 1 – PREAMBLE

1. It is often the case that importing and exporting countries operate different food inspection and certification systems. The reasons for such differences include differences in prevalence of particular food safety hazards, national choice about management of food safety risks and differences in the historical development of food control systems.
2. In such circumstances, and in order to facilitate trade while protecting the health of consumers, an exporting and an importing country may work together to consider the effectiveness of sanitary measures of the exporting country in achieving the appropriate level of sanitary protection of the importing country, consistent with the principle of equivalence as provided for in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS Agreement)<sup>2</sup>.
3. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. While protecting the health of consumers, it serves to facilitate trade, and minimize the costs of regulation to governments, industry, producers, and consumers by allowing the exporting country to employ the most convenient means in its circumstances to achieve the appropriate level of protection of the importing country.<sup>3</sup>
4. Importing countries should avoid the application of unnecessary measures when they have already been carried out by the exporting country. Importing countries may be able to reduce the frequency and extent of verification measures following a judgment of equivalence of measures applied in the exporting country.

## SECTION 2 – SCOPE

5. This document provides guidelines on the judgement of the equivalence of sanitary measures associated with food inspection and certification systems. For the purpose of determining equivalence, these measures can be broadly characterized as: infrastructure; programme design; implementation and monitoring; and/or specific requirements (refer paragraph 13).

## SECTION 3 – DEFINITIONS

6. The definitions presented in this document are derived from and consistent with those of the Codex Alimentarius Commission and the WTO SPS Agreement.

**Sanitary measure:** Any measure applied to protect human life or health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food or feedstuffs, or from risks arising from diseases carried by foods which are animals, plants, or products thereof or from risks arising from any other hazards in foods.

- 
- 1 These guidelines should be read in conjunction with other relevant Codex texts, including in particular the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems – CAC/GL 34-1999.
  - 2 Consistent with the definition of *equivalence* in Section 3, measures that are *equivalent* (i.e., are different from the measures used by the importing country but nonetheless achieve the importing country's appropriate level of protection) should be distinguished from measures that are the same as the measures of the importing country.
  - 3 The benefits to an exporting country of application of the principle of equivalence would be offset or negated if a request for an equivalence determination were, by itself, used as a pretext for the disruption of established trade. Such action by an importing country would be contrary to the principles of international trade and in particular in violation of Article 2 of the WTO SPS Agreement.

Note: Sanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.<sup>4</sup>

**Risk:** A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.<sup>4</sup>

**Risk Assessment:** A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.<sup>4</sup>

**Appropriate level of sanitary protection (ALOP):** The level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory. (This concept may otherwise be referred to as the “acceptable level of risk”.)

**Equivalence of sanitary measures:**<sup>5</sup> Equivalence is the state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve, as demonstrated by the exporting country, the importing country’s appropriate level of sanitary protection.

## SECTION 4 - GENERAL PRINCIPLES FOR THE DETERMINATION OF EQUIVALENCE

7. Determination of the equivalence of sanitary measures associated with food inspection and certification systems should be based on application of the following principles:

- a) An importing country has the right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health.<sup>6</sup> The ALOP may be expressed in qualitative or quantitative terms.
- b) The sanitary measure<sup>7</sup> applied in an importing country should in practice achieve the ALOP of the importing country and be applied consistent with article 2.3 of the SPS agreement.<sup>8</sup>
- c) An importing country should describe how its own sanitary measure achieves its ALOP.
- d) An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found to be equivalent.
- e) The sanitary measure that the exporting country proposes as equivalent must be capable of achieving the importing country’s ALOP.
- f) An importing country should, upon request by an exporting country, promptly enter into consultations with the aim of determining the equivalence of specified sanitary measures within a reasonable period of time<sup>9</sup>.
- g) It is the responsibility of the exporting country to objectively demonstrate that its sanitary measure can achieve the importing country’s ALOP.
- h) The comparison of countries’ sanitary measures should be carried out in an objective manner.

---

4 Codex Alimentarius Commission: Procedural Manual (12<sup>th</sup> Edition), pages 43-44.

5 Equivalence is defined in CAC/GL 26-1997 as “the capability of different inspection and certification systems to meet the same objectives”.

6 The SPS Agreement sets out the rights and obligations of WTO Members in relation to the determination of an appropriate level of sanitary protection.

7 Where this guideline refers to ‘measure’ in the singular it may also be taken to refer to ‘measures’ or ‘a set of measures’, as appropriate to the circumstances.

8 Equivalent measures may achieve the ALOP of the importing country or, in combination with other measures, they may contribute to the achievement of the importing country’s ALOP. In the remainder of this guideline any reference to the former should be taken to include the latter possibility.

9 Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems - CAC/GL 26- 1997.

- i) Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied, using internationally accepted methodology where available and taking into account relevant Codex texts.
- j) The importing country should take into account any knowledge it has of the food inspection and certification systems in the exporting country to make the determination as efficiently and quickly as possible.
- k) The exporting country should provide access to enable the inspection and certification systems which are the subject of the equivalence determination to be examined and evaluated upon request of the food control authorities of the importing country.
- l) All judgments of equivalence should consider the means by which that equivalence will be maintained.
- m) Countries should ensure transparency in both the demonstration and judgment of equivalence, consulting all interested parties to the extent practicable and reasonable. The exporting and importing countries should approach an equivalence determination procedure in a cooperative way.
- n) An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination.

## SECTION 5 - THE CONTEXT OF AN EQUIVALENCE DETERMINATION

8. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members should base their sanitary measures on Codex standards and related texts.<sup>10</sup>

9. An equivalence determination can be sought for any sanitary measure or set of measures relevant to a food product or group of food products. Relevant sanitary measures making up a food control system in the exporting country that are not the subject of an equivalence determination should meet importing country requirements.

10. The extent of the equivalence determination will depend on the prior experience, knowledge, and confidence that the importing country has regarding the food control measures of the exporting country.

11. When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system.

12. When an importing country does not have prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries have not determined that import requirements are being fully met, e.g., where trade in a food product or group of food products is being proposed for the first time, determination of the equivalence of sanitary measures will require further consideration of those other relevant measures making up the food control system.

13. For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorised as:

- a) infrastructure; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organisation of national and regional authorities, enforcement systems, etc.);
- b) programme design, implementation and monitoring; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or

---

10 Article 3 of the WTO SPS Agreement states, *inter alia*, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. Such measures must be based on a risk assessment appropriate to the circumstances.

- c) specific requirements; including requirements applicable to individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.

14. Categorization in this manner is likely to facilitate agreement between countries on the basis for comparison of sanitary measures subject to an equivalence determination (see section 6). Further, allocation of measures to a particular category may assist countries in simplifying the extent of the equivalence determination relative to other sanitary measures making up the food control system.

## **SECTION 6 - OBJECTIVE BASIS OF COMPARISON**

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 sanitary measures applied by the importing country by using an objective basis of comparison.]

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.<sup>11</sup> Dialogue between the exporting 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.

## **SECTION 7 - PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE**

17. The importing country should make available details of its sanitary measures to the exporting country on request. The exporting country should review all applicable sanitary measures of the importing country for the food involved and identify those it will meet and those for which it seeks determination of equivalence. The importing and exporting countries should then use an agreed process for exchange of the relevant information to facilitate the determination of equivalence. This information should be limited to that which is necessary for this purpose.

18. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below and illustrated in Figure 1. The parties should work through these steps in a cooperative manner with the aim of reaching agreement:

---

11 The objective basis for comparison of sanitary measures categorized as "Infrastructure" is likely to be of a qualitative nature, e.g., the ability of food control legislation to achieve broad food safety goals. The objective basis of comparison of sanitary measures categorized as "Specific Requirements" is likely to be quantitative in nature e.g., a comparison of levels of hazard control achieved by the measure. The objective basis of comparison of sanitary measures categorized as "Programme" is likely to contain a mixture of qualitative and quantitative elements e.g., correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

- a) The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.
- b) The importing country provides the reason/purpose for the identified sanitary measure and other relevant information in accordance with section 6.
- c) In accordance with section 6 the importing country should specify as precisely as possible an objective basis for comparison of the sanitary measures proposed by the exporting country and its own measures. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue concerning this objective basis for comparison with a view to reaching agreement.
- d) The exporting country develops a submission using risk assessment or other relevant methodology as appropriate, to demonstrate that the application of the different sanitary measure achieves the ALOP of the importing country, and presents it to the importing country.
- e) The importing country reviews the submission and, if adequate, uses the submission to determine whether the exporting country's measure achieves the importing country's ALOP.
- f) If the importing country has any concerns with the submission as presented, it should notify them to the exporting country at the earliest opportunity and should detail the reasons for concern. If possible, the importing country should suggest how the concerns might be addressed.
- g) The exporting country should respond to such concerns by providing further information, modifying its proposal or taking other action as appropriate.
- h) The importing country notifies the exporting country of its judgement within a reasonable period of time and provides the reasoning for its decision, should the judgement be that the sanitary measure is not equivalent, i.e., does not achieve the importing country's ALOP.
- i) An attempt should be made to resolve any differences of opinion over judgement of a submission, either interim or final.

## **SECTION 8 – JUDGEMENT**

19. Judgement of equivalence by the importing country should be based on a transparent analytical process that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.

20. Judgement of the equivalence of sanitary measures should take into account:

- a) experience and knowledge of an exporting country's food inspection and certification systems (see section 5);
- b) supporting data submitted by the exporting country;
- c) analysis of the strength of the relationship between the exporting country's specified sanitary measure, and the achievement of the ALOP of the importing country as reflected in the objective basis for comparison (see section 6);
- d) that parameters should be stated in quantitative terms to the extent possible;
- e) adequacy of qualitative descriptions where the level of control of hazards in foods is not quantified;
- f) consideration of variability and other sources of uncertainty in data;
- g) consideration of all expected human health outcomes of the exporting country's identified sanitary measure;
- h) those Codex texts relevant to the food safety matters under consideration.

Following any judgment of equivalence, exporting and importing countries should promptly advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

**Figure I: Simplified flow chart for the determination of equivalence  
(individual steps may be iterated)**

