

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 6**

**CX/FICS 00/6  
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## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

#### **Eighth Session**

**Adelaide, Australia, 21 – 25 February 2000**

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

#### **BACKGROUND**

1. The 7<sup>th</sup> Session of the CCFICS<sup>1</sup> requested the Commission to approve the elaboration of “Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems” as new work. The Committee also requested the advice of the Executive Committee and the Commission on how to proceed on the matter of the judgement of equivalence of technical regulations other than sanitary measures.
2. The 46<sup>th</sup> Session of Executive Committee (1999)<sup>2</sup> noted that the equivalence of technical regulations was a recognised concept under the WTO Agreement on Technical Barriers to Trade. It also noted that CCFICS had been requested to develop concepts for equivalence in food control for import and export. The Executive Committee recommended that the Committee proceed to develop guidance on the judgement of equivalence of systems for inspection and certification in relation to technical regulations other than sanitary measures. The Executive Committee also stated that the question of determination of equivalence of measures should be dealt with by specific technical (general subject or commodity) committees as required. The Executive Committee was of the further opinion that priority should be given to the development of judgement of equivalence regarding matters of food safety, but recommended that the Committee should decide whether the work of technical regulations relating to matters other than safety should be integrated or developed in parallel with food safety issues. It was noted that in some food control administrations there was no major difference between the systems in place that controlled these two elements.
3. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission<sup>3</sup>, noting the observation made by some countries that it was still premature to bring the work on these proposed Guidelines under the formal Codex Step Procedures, agreed that CCFICS should continue to study this item as a discussion paper. The Commission further agreed with the opinion of the 46<sup>th</sup> CCEXEC that CCFICS should proceed to develop guidance on the judgement of equivalence of systems for inspection and certification in relation to technical regulations other than sanitary measures in parallel with food safety issues.

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<sup>1</sup> ALINORM 99/30A, paras 69-84

<sup>2</sup> ALINORM 99/4, paras 24-26

<sup>3</sup> ALINORM 99/37 paras 203 and 217

4. Against this background New Zealand, in cooperation with Australia, Canada and the United States, has prepared draft guidelines (see Attachment 1, "Proposed Draft Framework for Determining the Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems) with the aim of reflecting comments made by countries on the earlier discussion paper (CX/FICS 99/6) considered by the 7<sup>th</sup> Session of CCFICS.

## **DISCUSSION**

5. The extensive consideration previously given by CCFICS to the issue of judgement of the equivalence of sanitary measures associated with food inspection and certification systems has facilitated the preparation of a more developed draft guidelines document. Attachment 1 is presented in a Codex guideline format and is intended to assist the Committee in its discussion of the issues by clearly defining the likely scope and content of such a guidance document.

6. Further to paragraph 3 above relating to the issue of judgement of equivalence of technical regulations other than sanitary measures in food inspection and certification systems, the Committee discussion of Attachment 1 may consider if both issues could be integrated into one guideline or should be progressed separately. The matter of technical regulations other than sanitary measures is further discussed under Agenda Item 7 (CX/FICS 00/7). The central issue under consideration relates to the need to compare sanitary measures on the basis of the Appropriate Level of Protection (ALOP) and, conversely, the need to compare other technical requirements on the basis of their stated objective (which, by definition, cannot be expressed as an ALOP).

## **RECOMMENDATION**

7. The Committee is invited to consider the attached draft guidelines and to recommend to the Executive Committee that further development of a guideline document on the judgement of equivalence of sanitary measures be approved within the Codex step process. The Committee's views on confirming this work with that on technical regulations other than sanitary measures could also be placed before Executive Committee.

## PROPOSED DRAFT FRAMEWORK FOR DETERMINING THE EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

(Paper prepared by New Zealand with the assistance of Australia, Canada and the United States)

### PREAMBLE

1. It is often the case that food inspection and certification systems operating in exporting countries incorporate sanitary measures that differ from those in the importing country. The reasons for such differences include the absence or very low prevalence of particular food safety hazards, the selection of alternative controls, and national choices about management of food safety risks.
2. In such circumstances, there is a need to determine effectiveness of sanitary measures of the exporting country in achieving the appropriate level of protection (ALOP) of the importing country. This has led to recognition of the principle of equivalence (1).
3. Application of the principle of equivalence is intended to facilitate trade and, at the same time, maintain the importing country's ALOP. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. These include flexibility in design of sanitary measures while enhancing their efficiency and ensuring the safety of the imported food with advantages to both the country receiving and the country producing the food.
4. [Countries may choose international standards as sanitary measures to achieve their appropriate level of protection, or they may choose different measures to achieve their appropriate level of protection.]

### SCOPE

5. This document provides principles and processes to facilitate the determination of equivalence of sanitary measures as they relate to human health.
6. Food safety issues other than human health and non food safety issues also may be the subject of equivalence determinations related to food control. This document may also provide a resource for such determinations.

### DEFINITIONS

7. The definitions presented in this document have been taken from Codex and the WTO SPS Agreement.

#### *Sanitary measure*<sup>4</sup>:

Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

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<sup>4</sup> World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, Annex A

**Hazard:**

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect in consumers.

**Risk management:**

Is the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.<sup>5</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.

**Appropriate level of protection:**

The level of protection deemed appropriate by the country establishing a sanitary measure to protect human health within its territory. This can otherwise be referred to as the “acceptable level of risk.”

**Equivalence:**

The state wherein sanitary measures applied in an exporting country, though different from the measures applied in an importing country, achieve the importing country's appropriate level of protection. Equivalence is the capability of different inspection and certification systems to meet the same objectives<sup>6</sup>.

**Determination of equivalence:**

The process whereby the sanitary measures applied in an exporting country are determined to be consistent with the achievement of the appropriate level of protection of the importing country.

**CONSIDERATIONS IN DETERMINATION OF EQUIVALENCE**

8. Determination of equivalence requires establishment of a relationship between two "building blocks": the appropriate level of protection (ALOP) and the sanitary measures.

*Appropriate level of protection*

9. It is the sovereign right of an importing country to set any level of protection they deem appropriate in relation to their food supply, while having regard to Codex standards as international benchmarks. An ALOP can be expressed in qualitative or quantitative terms. In determining equivalence, the ALOP of the importing country must be met by the exporting country [and is not contestable in this context.]

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<sup>5</sup> Hazard Analysis and Critical Control Point System and Guidelines for its Application, Annex to the Recommended International Code of Practice – General Principles for Food Hygiene (CAC/RCP 1- 1969, Rev 3. 1997)

<sup>6</sup> CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997

### *Sanitary measures*

10. For the purposes of determining equivalence, the sanitary measures that comprise a food control 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)
- b) programme design/implementation; including documentation of systems, performance, decision criteria and action, laboratory capability, and provisions for certification and audit,
- c) specific requirements; including individual facilities (e.g. premises design), equipment (e.g. design of food contact machinery), processes (e.g. retorting, HACCP plans), procedures (e.g. post mortem inspection) and tests (e.g. tests for microbiological and chemical hazards).

11. A sanitary measure proposed for determination of equivalence may fall into one or more of these categories, which are not mutually exclusive. A single measure, however, on which an equivalence determination may be made cannot be considered in a vacuum. In other words, whether the importing country's ALOP is likely to be achieved can only be determined in most cases through an evaluation of all relevant components of an exporting country's food control system. For example, a determination of equivalence for a specific sanitary measure at the programme design/implementation level will require a prior determination of an equivalent infrastructure. A determination of equivalence for a specific sanitary measure at the specific requirements level will require a prior determination of an equivalent infrastructure, and equivalent programme design/implementation.

### *Relationship between ALOP and sanitary measure*

12. Demonstration of achievement of an importing country's ALOP by application of different sanitary measures is the goal of determinations of equivalence. In this context, it is the importing country's ALOP that must be met by the exporting country.

13. Sanitary measures are often narrowly focused and specific while the ALOP may be expressed in specific terms, e.g. number of cases of disease per year in a defined population, or far less specific terms, e.g. broad goals relating to food safety. Irrespective of the expression of the ALOP, an objective basis for comparison of sanitary measures must be established.

14. Presentation of an objective basis for comparison may include the following elements:

- 1) the reason/purpose for the sanitary measure
- 2) the relationship to the ALOP, with quantitative expression wherever possible
- 3) where risk assessment information is available, expression of the level of a hazards in a food that is tolerable in relation to an ALOP (in relation to other Codex activities, this is referred to as a "food safety objective")

## **GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE**

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

- 15.1. An importing country should recognise that different sanitary measures may be capable of achieving its appropriate level of protection, and are therefore equivalent <sup>7</sup>
- 15.2. It is the responsibility of the exporting country to demonstrate that its sanitary measures can meet the importing country's appropriate level of protection as achieved through the importing country's sanitary measures

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<sup>7</sup> CCFICS Principles of Food Import and Export Inspection and Certification; CAC/GL 20 - 1995

- 15.3. Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified sanitary measures.<sup>8</sup>
- 15.4. The importing country should present the reason/purpose for the sanitary measure that has been identified by the exporting country as the subject of the equivalence determination, and, in reference to the expression of its ALOP, this should provide an objective basis for comparison. [The basis for comparison should allow determination of how a sanitary measure achieves, or contributes to the achievement of the importing country's appropriate level of protection.]
- 15.5. Where appropriate, application of risk assessment principles provides a basis for determining the equivalence of specified sanitary measures. Countries should strive to achieve consistency in risk assessment techniques applied for this purpose so as to ensure, to the extent possible, that findings can be objectively compared.
- 15.6. When judging sanitary measures for equivalence, the importing country should take into account any experience already gained in terms of food inspection and certification systems in the exporting country.
- 15.7. Countries should strive for transparency in both the demonstration and determination of equivalence, in the interests of all parties involved.

## **GUIDELINES FOR THE DETERMINATION OF EQUIVALENCE**

### General

16. Any sanitary measure, or combination of sanitary measures, can be identified for determination of equivalence. The exporting and importing countries should co-operate in the equivalence evaluation by progressing through a series of steps.
17. The exporting country should present a submission for equivalence that facilitates the judgement process applied by the importing country. When achievement of equivalence is agreed upon by the importing country, the importing and exporting countries may enter into a formal agreement giving effect to that decision.
18. Importing and exporting countries should utilize an agreed process for exchange of information. This information should be limited to that which is necessary to facilitate the determination of equivalence, and minimize administrative burden.

### **Steps**

19. Determination of equivalence presumes that the exporting country has already reviewed all applicable importing country requirements for the food involved, and has identified those it will meet and those for which it seeks a determination of equivalence.
20. 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.
  - 20.1. 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.

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<sup>8</sup> CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997

- 20.2. The importing country provides the reason/purpose for the identified sanitary measure, including an objective basis for comparison.
- The basis for comparison should :
  - Describe the relationship of the identified sanitary measure to the ALOP, either alone or in conjunction with other sanitary measures;
  - provide objective parameters and be given quantitative expression to the maximum extent possible
- 20.3. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue with the view to ensure that the basis for comparison of sanitary measures has been expressed in a manner consistent with the relevant principles set out in this document.
- 20.4. The exporting country develops the submission to demonstrate that different sanitary measure(s) is consistent with achievement of the appropriate level of protection of the importing country, and presents it to the importing country.<sup>9</sup>
- 20.5. If the importing country has any technical concerns with the manner in which the submission is presented, it should notify 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.
- 20.6. The exporting country responds to such concerns by providing further information as appropriate.
- 20.7. The importing country notifies the exporting country of its judgement within a reasonable period of time.
- 20.8. An attempt may be made to resolve any bilateral differences of opinion over judgement of a submission, either interim or final, by using an agreed mechanism to reach consensus.

## Judgement

21. Judgement of equivalence by the importing country should be based on an analytical process that is objective and consistent, and should involve all interested parties to the extent practicable and reasonable.
22. Where countries already have extensive experience of each other's food safety systems at the time that an exporting country initiates a determination of equivalence, a specific requirement should be able to be judged equivalent without consideration of supporting programmes and infrastructure.
23. Where countries do not already have extensive experience of each other's food control systems, all categories of sanitary measures need to be taken into account in determination of equivalence. If the exporting and the importing country have no previous history of significant trading in foods or detailed knowledge of each other's food control systems, this process may require a detailed side-by-side comparison.
24. Following any judgement of equivalence, exporting and importing countries should advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

Judgement of equivalence should consider the expected effect of the identified sanitary measure on all relevant hazards.<sup>10</sup>

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<sup>9</sup> CCFICS Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems; ALINORM 99/30, Appendix II

25. Judgement of the case for equivalence should include:

- a) Consideration of uncertainty in quantitative data
- b) Reference to Codex risk assessment methodologies where available, if risk assessments are presented
- c) Consideration of existing Codex standards.

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<sup>10</sup> Consideration should be given to the effects of the sanitary measure on all hazards that may have been identified during development of the case for equivalence. With regard to hazards not specified in the reason/purpose provided, identified sanitary measure may be shown have an unintended adverse effect, or an alternative sanitary measure may be shown to have a beneficial effect).

Figure I: Flow chart for the determination of equivalence

