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 6 **CX/FICS 00/6**
August 2000

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Ninth Session
Perth, Australia, 11 – 15 December 2000

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS
(At Step 3)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 29 September 2000** to: Digby Gascoine, Director, Policy and International Division, Australian Quarantine and Inspection Service, 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; ~~or~~ E-mail: codex@fao.org).

BACKGROUND

1. The 8th Session (February 2000) of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)[1] considered a discussion paper prepared by New Zealand, in cooperation with Australia, Canada and the United States, which included a suggested framework for determining equivalence of sanitary measures associated with food inspection and certification systems. The CCFICS supported the development of guidelines within the Codex step procedure and requested New Zealand, with assistance from Argentina, Australia, Canada, France, Japan, Morocco, the United States and the European Commission, to proceed with the development of Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems for circulation and comment at Step 3 prior to the 9th Session of the CCFICS. The CCFICS also noted that its

[1] ALINORM 01/30, paras 62 - 65

work in this area would be drawn to the attention of other Codex committees, including CCGP and CCFH.

2. The 15th Session (April 2000) of the Codex Committee on General Principles, in considering the general aspects of the development and application of "food safety objectives", noted that the CCFICS had decided to develop the Guidelines.[2]

3. The 47th Session of the Executive Committee (June 2000) approved the elaboration of Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems as new work at Step 1. The Executive Committee recognized the need to develop guidelines for determining equivalence of food control systems, covering not only safety but also quality and conformity. [3]

Current Status

4. The proposed draft G*uidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* is attached for comment at Step 3. The comments submitted will be considered by the Committee at its 9th Session when discussing the attached proposed draft Guidelines at Step 4.

[2] ALINORM 01/33, para. 64

[3] ALINORM 01/3, paras. 26, 43 and Appendix III

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS
(at Step 3)

(Paper prepared by New Zealand with the assistance of Argentina, Australia, Canada France, Japan, the United States and the European Union)

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, there is a need to determine the 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 has mutual benefits for both exporting and importing countries.

SCOPE

4. This document provides guidelines for judgement of the equivalence of sanitary measures, applied for the protection of human health, in international trade in foods. For the purpose of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly characterized as: infrastructure, programme design/implementation, and/or specific requirements (refer paragraph 7).

DEFINITIONS

5. The definitions presented in this document are based on those of Codex and the WTO SPS Agreement.

Sanitary measure:

Any measure applied to protect human health within the territory of the country from risks arising from additives, contaminants, toxins or disease-causing organisms in food [or feedstuffs].

[1] World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures.

Hazard:

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. [2]

Risk management:

The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant to the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[2]

Risk Assessment:

A scientifically-based process consisting of the following steps: (i) hazard identification; (ii) hazard characterisation; (iii) exposure assessment; and (iv) risk characterisation.[2]

Appropriate level of protection:

The level of protection deemed appropriate by the country establishing a sanitary measure to protect human health within its territory, which can be expressed in qualitative or quantitative terms. [This can otherwise be referred to as the "acceptable level of risk".]

Equivalence:

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 ALOP.

[SANITARY MEASURES INVOLVED IN THE DETERMINATION OF EQUIVALENCE]

6. To facilitate judgement of equivalence between countries and promote harmonisation of food safety standards, Codex members are encouraged to base their sanitary measures on Codex standards and related texts.

7. 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 labelling requirements directly related to food safety. 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);

---

[2] CAC Procedural Manual (11th Edition), pages 48-49.

(b) programme (design/implementation/monitoring); including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, and provisions for certification and audit; and/or
(c) specific requirements; including 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) and tests (e.g., laboratory tests for microbiological and chemical hazards).

8. 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 inspection and certification system. For example, a determination of equivalence for a specific sanitary measure at the programme (design/implementation/monitoring) 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/monitoring).

9. An objective basis for comparison of sanitary measures must be established to allow an equivalence determination to be made, and this may include the following elements:

(a) the reason/purpose for the sanitary measure(s);
(b) the relationship of the sanitary measure(s) to the ALOP;
(c) where appropriate, an expression of the level of control of the hazard(s) in a food that is achieved by the sanitary measure(s) [in relation to other Codex activities, this may be referred to as a "food safety objective"];
(d) where appropriate and available, risk assessment information relevant to the sanitary measures under consideration.

GENERAL PRINCIPLES FOR DETERMINATION [DEMONSTRATION] OF EQUIVALENCE

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

10.1 An exporting country should recognise that an importing country has the sovereign right to set a level of protection they deem appropriate in relation to their food supply.[3]

[10.2 An importing country should be able to describe how its sanitary measure achieves, or contributes to the achievement of, its ALOP.]

10.3 An importing should recognise that sanitary measures different from its own may be capable of achieving its ALOP, and are therefore equivalent[4].

---

[3] Rights and obligations as recognised in the SPS agreement.

[4] Principles of Food Import and Export Inspection and Certification; CAC/GL 20 – 1995.

10.4 The sanitary measures applied by the exporting country must meet the importing country's ALOP.

10.5 Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified sanitary measures[5].

10.6 It is the responsibility of the exporting country to demonstrate that its sanitary measures can meet the importing country's ALOP.

10.7 The comparison of countries' sanitary measures should be carried out in an objective manner.

[10.8 Where risk assessment is used in the demonstration of equivalence, countries should strive to achieve consistency in the techniques applied so as to ensure that findings can be objectively compared.]

[10.9 During equivalence discussions, an importing country should not unjustifiably impose more stringent sanitary measures than those already specified.]

10.10 When judging the equivalence of sanitary measures, the importing country should take into account any experience already gained in terms of food inspection and certification systems in the exporting country.

10.11 Countries should strive for transparency in both the demonstration and judgement of equivalence.

GUIDELINES FOR THE DETERMINATION [ASSESSMENT] OF EQUIVALENCE

11. Determination of equivalence presumes that the exporting country has already reviewed all applicable importing country sanitary measures for the food involved, and has identified those it will meet and those for which it seeks a determination of equivalence.

12. The exporting and importing countries should co-operate in the determination of equivalence by progressing through a series of steps.

13. The exporting country should present a submission for equivalence that facilitates the judgement process applied by the importing country. [Where 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.]

14. 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.

---

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

Steps

15. Determination of equivalence presumes that the exporting country has already reviewed all applicable importing country sanitary measures for the food involved, and has identified those it will meet and those for which it seeks a determination of equivalence.

16. 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:

16.1 The exporting country identifies the sanitary measure(s) of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure(s).

16.2 The importing country provides the reason/purpose for the identified sanitary measure(s).

16.3 On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue with a view to agree on an objective basis for comparison.

16.4 The exporting country develops the submission to demonstrate that the application of the different sanitary measure(s) achieves or contributes to the achievement of the ALOP of the importing country, and presents it to the importing country.[6]

16.5 If the importing country has any concerns with the submission as 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.

16.6 The exporting country should respond to such concerns by providing further information as appropriate.

16.7 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(s) is not equivalent.

16.8 An attempt may be made to resolve any differences of opinion over judgement of a submission, either interim or final, including its timeliness, by using an agreed mechanism to reach consensus.

Judgement

17. 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.

---

[6] ~~CCFICS~~ Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems; CAC/GL 34-1999.

18. Where countries already have extensive experience and detailed knowledge of each other's food inspection and certification systems, at the time that an exporting country initiates a determination of equivalence, a sanitary measure categorized as a specific requirement should be able to be judged equivalent without consideration of the supporting programme (design/implementation/monitoring) and infrastructure (refer paragraph 7).

19. Where countries do not already have extensive experience and detailed knowledge of each other's food inspection and certification systems, all categories of sanitary measures applicable to the product or group of products under consideration need to be taken into account in the 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 inspection and certification systems, this process may require a detailed side-by-side comparison of all relevant sanitary measures.

20. Judgement of equivalence should take into account those Codex texts relevant to the food safety matters under consideration.

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

- supporting data submitted by the exporting country;
- analysis of the strength of the relationship between the exporting country's specified sanitary measure, alone or in conjunction with other sanitary measures, and the achievement of the ALOP of the importing country;
- provision of objective parameters that have been given quantitative expression to the maximum extent possible;
- adequacy of qualitative descriptions where the level of control of hazards in foods in not quantified;
- consideration of uncertainty in quantitative data;
- reference to Codex risk assessment methodologies where available, if risk assessments are presented;
- consideration of all expected human health effects of the exporting country's identified sanitary measure(s).[7]

22. 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.

---

[7] 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, an identified sanitary measure may be shown to 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