

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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Agenda Item 6

**CX/FICS 99/6
December 1998**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS
Seventh Session
Melbourne, Australia, 22 - 26 February 1999**

Discussion Paper on Issues Relating to the Judgement of Equivalence

BACKGROUND

The sixth session of the Codex Committee on Food Import and Export Inspection and Certification Systems(1998) considered a discussion paper prepared by New Zealand with assistance from Australia, Canada and the United States¹. This paper described the basis for the judgement of equivalence of sanitary measures associated with different food inspection and certification systems in regard to the relevant principles of the WTO SPS Agreement and the *Codex Principles for Food Import and Export Inspection and Certification*².

2. Following extensive discussion, and noting the division of opinion on whether or not to proceed with the elaboration of Codex guidance in this area, the Committee agreed to the following action:

- The Executive Committee would be requested to provide its opinion as to the extent to which issues relating to the judgment of equivalence, as presented in discussion paper CX/FICS 98/7, were within the mandate of CCFICS and/or other Codex Committees and how the subject should be considered further.
- There should be an examination of the relationship between the Codex Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997), the proposed draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems and issues raised in the discussion paper regarding the judgment of equivalence.
- The proposed draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems and the discussion paper on the subject of the judgment of equivalence should be maintained on separate but parallel paths for the time being.

¹ CX/FICS 98/7

² CAC/GL 20-1995

- Comments will be requested on the above and forthcoming discussions related to this subject after the 45th Session of the Executive Committee meeting in June 1998.
- Subject to the guidance of the Executive Committee, a revised discussion paper would be prepared by New Zealand for Committee's 7th Session, taking into account comments by governments and addressing the issues which had emerged during the meeting.³

3. The forty fifth session of the Executive Committee (1998) discussed in depth the matter of Judgement of Equivalence in relation to the Terms of Reference of the CCFICS and the overall work programme of the Commission. The Executive Committee noted the advice of Legal Counsel that the Terms of Reference of the Committee seemed to be sufficiently broad to cover consideration of the issue, that it was for the Commission or the Executive Committee to determine the allocation of functions between various Committees where there were overlapping competencies, and that the matter was primarily a technical one and not a legal one. The Executive Committee was of the opinion that in the area of determination of equivalence of measures, the mandate of CCFICS only referred to food inspection and certification systems and that the matter being discussed by the Committee involved issues which were also relevant to the responsibilities of other Codex Committees especially those dealing directly with science-based risk management and the Committee on General Principles.

4. The Executive Committee was of the opinion that the matter was a priority for the work of the Commission and that CCFICS was in the best position to deal with the subject with a view to developing concepts for equivalence in food control for import and export. This would require the Committee to develop concepts, to identify issues for consideration by the Commission and by other Codex Committees, and to suggest how a systematic approach might be applied. However, the Executive Committee should ensure that the issue was broadened. It suggested that as soon as work proceeded beyond the initial states, the other relevant Committees (eg Food Hygiene, Pesticide Residues, Residues of Veterinary Drugs in Foods, Food Additives and Contaminants, General Principles) should initiate their own work on this matter as appropriate.

5. In order to facilitate understanding of the issues involved, the Executive Committee invited the Secretariat to arrange for a revision of the basic paper and to circulate it to the relevant Committees for their information.⁴

6. Following the Executive Committee a circular letter invited comment on the paper considered by CCFICS⁵. Comments received are Annexed to this background. The Secretariat invited New Zealand, with the assistance of Australia, Canada and the United States to prepare a revised paper for consideration at the seventh session of CCFICS.

Considerations

7. The Committee is invited to consider the revised paper, at Attachment 1, in the light of the foregoing discussions at the sixth session of CCFICS and the forty fifth session of the Executive Committee.

³ ALINORM 99/30, para 52

⁴ ALINORM 99/3, paras 35 and 36.

⁵ CL 1998/24-FICS

CUBA

“The comments previously forwarded read: I wish to convey the agreement of the Republic of Cuba concerning the ‘Draft Guidelines for the development of equivalence agreements...’. We propose the addition of the words ‘that are developing countries’ after ‘exporting countries’, paragraph 20, Section 5, App. II to ALINORM 99/30. We also request an extension until 15 November to respond to CL 1998/24-FICS. Yours sincerely.

SPAIN

We wish to make the following comments:

Section 1. Preamble

At point 5, fifth line, we propose substituting the sentence: “... The inspection of produce at the time of importation may not necessarily determine these attributes in a reliable manner and the relevant regulatory authority...” for “... The inspection of produce at the time of importation may not necessarily determine these attributes in a reliable manner and the relevant competent authority...”

At point 7, third dash, we request that the reference to the example be dropped, since it is not necessary.

Section 3. Scope of the proposed guidelines

At point 19, third line, reference to “Step 3” should be changed for “Step 6”.

Section 5. Prerequisite considerations in judging equivalence

At point 23, B, last line, we cannot understand the wording in the Spanish version. It would be convenient to review it and compare it with the French and English versions.

Proposed draft guidelines for the judgement of equivalence of sanitary measures associated with food inspection and certification systems

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

1. PREAMBLE

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. In such circumstances, the regulatory authority in the exporting country must demonstrate the effectiveness of its food inspection and/or certification measures in achieving the appropriate level of protection (ALOP) of the importing country.

International recognition for the legitimacy of diverse approaches to food safety and inspection led to the equivalence provision in the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). This states: “Members shall accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection.”

The SPS Agreement envisions that the exporting country will initiate a request for an equivalence determination from the importing country. The principles and guidelines presented in this document provide a framework for the judgement of equivalence i.e. a determination that different sanitary measures associated with food inspection and certification systems in an exporting country achieve the same level of health protection as those of the importing country. The principles and guidelines presume that the exporting country has already reviewed all applicable importing country requirements for the food involved, and has identified those which it will meet and those for which it seeks a judgement of equivalence.

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. In the latter case, countries must assure that their measures are in conformity with the provisions of the WTO SPS Agreement. Application of the principle of equivalence has mutual benefits for both exporting and importing countries, and these include design of scientific and risk-based food safety programmes, and decreased reliance on end-product testing and “lot” certification.

2. SCOPE

The principles and guidelines set out in this document for judging the equivalence of sanitary measures associated with food import and export inspection and certification systems apply to human health only and incorporate a risk-based approach. They are for application within the context of food import and export inspection and certification systems, and are intended to deal with equivalence judgements under the provisions of the SPS Agreement. However, they may have wider application in the general context of food safety programmes.

Issues other than food safety also may be the subject of equivalence determinations. Judgement of these issues will need separate development of appropriate principles and guidelines.

3. DEFINITIONS

Sanitary measure:

A requirement, procedure, criteria or system, either alone or any combination of the foregoing, that is applied to protect human health from risks arising from food borne hazards.

Note: The definition of a sanitary measure in the WTO SPS Agreement states, in part, that measures include all relevant laws, decrees, and regulations; as well as procedures relating to end-product criteria, processes and production.

Hazard:

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

Risk:

A function of the probability of an adverse health effect and the severity of that effect in consumers, consequential to a hazard(s) in food.

Risk Analysis:

A process consisting of three components: risk assessment, risk management and risk communication.

Risk assessment:

A scientifically-based process consisting of the following steps:

- (i) hazard identification,
- (ii) hazard characterisation,
- (iii) exposure assessment, and
- (iv) risk characterisation.

Food safety objective (FSO):

The reason / purpose for a sanitary measure, and which includes a description of the expected / desired extent of control of foodborne hazards resulting from application of a sanitary measure(s). In the context of equivalence, a food safety objective should provide a rationale for how and why a sanitary measure achieves or contributes to the achievement of a country's appropriate level of protection.

Note: FSOs have been presented in different contexts in other Codex documents.

Appropriate level of protection:

A country's expressed goals in protecting its population from particular food borne hazards, as reflected in legislation, guidelines and other official documents. An appropriate level of protection can be expressed in quantitative or qualitative terms.

Note: The appropriate level of protection as expressed in the WTO SPS Agreement is: "The level of protection deemed appropriate by the Member establishing a sanitary measure to protect human, animal or

plant life or health within its territory. health. Members otherwise refer to this concept as the “acceptable level of risk.”

Equivalence

The demonstration by an exporting country that its sanitary measure(s) achieve the importing country’s appropriate level of sanitary protection.

4. GENERAL PRINCIPLES FOR THE JUDGEMENT OF EQUIVALENCE

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

1. Countries should recognise that inspection and certification systems comprised of different sanitary measures may be capable of achieving the same level of protection, and are therefore equivalent⁶
2. Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified sanitary measures, where it can be objectively demonstrated by the exporting country that there is an appropriate system for inspection and certification of food⁷
3. The importing country should establish a food safety objective (FSO) for the sanitary measure that has been identified by the exporting country as the subject of the equivalence determination, and this should express how the sanitary measure achieves, or contributes to the achievement of, the importing country’s appropriate level of protection.
4. 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 its measures and as expressed through the FSOs for those measures.
5. Application of risk assessment provides a structural basis for judging 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.
6. Countries should strive for transparency in both the demonstration and determination of equivalence, in the interests of all parties involved.

5. GUIDELINES FOR THE JUDGEMENT OF EQUIVALENCE

General

⁶ CCFICS Principles of Food Import and Export Inspection and Certification; CAC/GL 20 - 1995

⁷ CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems ALINORM 97/13A, Appendix II

1. Any sanitary measure, or combination of sanitary measures, can be identified for judgement of equivalence. The exporting and importing countries should co-operate in the equivalence evaluation by progressing through a series of steps.
2. The exporting 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.
3. Importing and exporting countries should utilise an agreed process for exchange of information. This information should be limited to that which is necessary to facilitate the judgement of equivalence, and minimise administrative burden.

Steps

The judgement of equivalence requires that both exporting and importing countries follow a sequence of steps, such as those described below and illustrated in Figure 1.

1. The exporting country identifies the sanitary measure of the importing country for which it wishes to apply a different measure, and requests a FSO for the measure.
2. The importing country provides the FSO for the identified sanitary measure.

So as to facilitate a comparison of sanitary measures, the FSO should:

- include a description of the appropriate level of protection intended to be achieved by application of the identified sanitary measure, either alone or in conjunction with other sanitary measures;
- be practicable and achievable, and be given quantitative expression to the maximum extent possible

Note: Often it will not be possible to quantify the level of protection achieved by application of an identified sanitary measure, and indirect parameters will need to be utilised.

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 FSO has been expressed in a manner consistent with the relevant principles set out in this document.
4. The exporting country develops the submission to demonstrate that different sanitary measure(s) achieve the appropriate level of protection of the importing country as expressed in the FSO, and presents it to the importing country.⁸
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.

⁸ CCFICS Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems ALINORM 99/30, Appendix II

6. The exporting country responds to such concerns by providing further information as appropriate.
7. The importing country notifies the exporting country of its judgement within a reasonable period of time.
8. An attempt can 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

1. 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.
2. Where countries already have extensive experience of each other's food safety systems at the time that an exporting country identifies a specific sanitary measure for comparison with an alternative measure, equivalence should be able to be judged without consideration of supporting programmes and infrastructure. This is likely to be the usual circumstance and therefore the most common sanitary measures proposed for judgement of equivalence will be:
 - specific requirements e.g. individual facilities, equipment, processes, procedures and tests
 - programmes and systems (including their documentation, implementation, performance criteria, certification and provisions for audit and enforcement).

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.

3. Where countries do not already have extensive experience of each other's food safety systems, particular aspects of infrastructure (including legislative base, regulations, directives and administration) also may be identified for equivalence judgements. 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.
4. 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.
5. Judgement of the equivalence of a sanitary measure will be greatly facilitated if quantitative data has been presented by the exporting country to show that the appropriate level of protection, as expressed through the FSO, has been achieved.
6. Where the level of control of hazards in food is not quantified in establishing an FSO for an identified sanitary measure e.g. an infrastructure component, the judgement of equivalence may be based on qualitative descriptions.

7. Judgement of equivalence should consider the expected effect of the identified sanitary measure on all relevant hazards.⁹
8. Judgement of the case for equivalence should include:
- Consideration of uncertainty in quantitative data
 - Reference to Codex risk assessment methodologies where available, if risk assessments are presented
 - Consideration of existing Codex standards.

⁹ 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 FSO, the 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



