

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 7**

**CX/FICS 00/7 – Revised  
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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 TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS**

(Paper prepared by Australia)

#### **BACKGROUND**

1. The 7<sup>th</sup> Session of CCFICS (1999), in considering a “Discussion Paper on Issues Relating to the Judgement of Equivalence” (CX/FICS 99/6), decided that the Commission should be requested to initiate formal work on the elaboration of *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (see CX/FICS 00/6, Agenda Item 6). In regard to the proposal to develop guidelines on the judgement of equivalence of technical regulations other than sanitary measures, the Committee requested the advice of the Executive Committee and the Commission on how to proceed in this matter.<sup>1</sup>

2. The 46<sup>th</sup> Session of the Executive Committee (CCEXEC) noted that the equivalence of technical regulations was a recognised concept under the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade. 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 CCEXEC further stated that the question of determination of equivalence of specific measures, however, should be dealt with by individual (general subject or commodity) committees as required. The CCEXEC was also of the 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.<sup>2</sup>

3. The 23<sup>rd</sup> Session of the Codex Alimentarius Commission agreed with the recommendation of the 46<sup>th</sup> CCEXEC that CCFICS should proceed to develop guidance on the equivalence of systems for inspection and certification in relation to technical regulations other than sanitary measures in parallel with guidelines on food safety issues.<sup>3</sup>

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

<sup>2</sup> ALINORM 99/4, para 24 - 25

<sup>3</sup> ALINORM 99/37, para 217

## DISCUSSION

### Elements Addressed by Food Inspection and Certification Systems

4. The objectives of food inspection and certification systems are usually cited as protecting the health of consumers and promoting fair trade in food. Thus systems typically incorporate provisions designed to ensure the safety of the food supply and to guard against misleading or fraudulent trading practices.

5. Measures relating to food safety can be characterised as according consumers a level of protection against adverse health outcomes that are attributed to hazards in the food. Over time, different food inspection and certification systems have established a variety of interventions and approaches which are considered to afford an appropriate level of protection (ALOP) to the health of consumers. The WTO, through its 'Agreement on the Application of Sanitary and Phytosanitary Measures' (the SPS Agreement)<sup>4</sup> defines the rights and obligations of WTO members in adopting sanitary and phytosanitary measures and, *inter alia*, in recognising the equivalence of alternative means by which the exporting party may achieve an ALOP as defined by an importing party.

6. In terms of international trade in food, measures guarding against misleading or fraudulent trading practices which are applied by WTO members are, likewise, subject to WTO disciplines. Technical requirements not meeting the definition of a sanitary or phytosanitary measure are subject to the 'Agreement on Technical Barriers to Trade' (the TBT Agreement)<sup>5</sup>. This Agreement addresses technical regulations, standards and conformity assessment procedures incorporated into food inspection and certification systems. In order to facilitate trade, the TBT Agreement obliges Members to specify technical regulations based on product requirements in terms of performance rather than upon design of descriptive characteristics.<sup>6</sup> Members are further obliged to give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations<sup>7</sup>. With the intention of not creating unnecessary obstacles to trade, the technical regulations of WTO members may not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. In assessing such risks, relevant elements of consideration are, *inter alia*, available scientific and technical information, related processing technology or intended end-uses of products.<sup>8</sup>

7. Both the SPS and TBT Agreements require that technical requirements be applied in a non-discriminatory manner and be least restrictive of trade, and accord special status to international standards, such as those established by the Codex Alimentarius Commission. While the SPS Agreement requires that sanitary measures either reflect established international standards or be based on a scientific risk assessment process designed to accord an ALOP, the TBT Agreement, by comparison, urges harmonisation of technical regulations with international standards but allows for alternative measures provided these are expressed in terms of outcomes, are proportionate to the risks posed by non-fulfilments of the measure, and avoid excessive prescription. In so doing both agreements provide a framework for the application of the equivalence principle. However, the SPS and TBT Agreements are silent on the means of judging equivalence, both in a generic sense and, specifically, in terms of food inspection and certification systems.

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<sup>4</sup> Agreement on the Application of Sanitary and Phytosanitary Measures. Published by the GATT Secretariat, Geneva, June 1994.

<sup>5</sup> Agreement on Technical Barriers to Trade. Published by the GATT Secretariat, Geneva, June 1994.

<sup>6</sup> TBT Agreement, Article 2.8

<sup>7</sup> *Ibid*, Article 2.7

<sup>8</sup> *Ibid*, Article 2.2

## Character of TBT Measures

8. TBT measures applying to food trade include compositional standards, packaging standards, product durability standards, organoleptic attributes, grading standards and labelling standards. However, if the stated purpose of any of these measures relates to the protection of human health then the measure, is usually an SPS measure. There exists an extensive array of TBT measures which form part of current food inspection and certification systems, including some (eg. nutritional labelling) that do have implications for consumer safety.

9. As distinct from SPS measures, a specific scientific risk assessment is not required for TBT measures which are not harmonised with international standards. However, a risk-based evidence-based approach is still required to TBT issues. The TBT Agreement does, however, require that technical regulations are proportionate to the risks posed by non-fulfilment of the measure and take into account scientific and technical information, related processing technology, and the intended end-uses of products. TBT measures should be performance (ie 'outcomes') based in their expression, and avoid excessive prescription, so as to facilitate the application of the equivalence principle. Further, the TBT Agreement binds members to ensure that standardising bodies in applying technical requirements, including in respect of conformance assessment, comply with the 'Code of Good Practice for the Preparation, Adoption, and Application of Standards'.<sup>9</sup>

## CONCLUSIONS

10. It can be concluded that the principle of equivalence, as contained in the TBT Agreement, operates through the definition of the outcome that a technical regulation is intended to achieve and by establishing that an alternative measure achieves the specified outcome. At this basic level the equivalence principle, as contained in both the SPS and TBT Agreements operates in a similar manner. However, because of the large potential array of TBT measures (eg labelling, grading standards, compositional limits, etc) frequently it is not possible to identify a derived measure (such as a food safety objective) which will facilitate quantitative or qualitative comparisons to underpin equivalence judgements. It is likely that an equivalence judgement of a TBT measure will uniquely depend upon the definition of the objective of each such measure and an iterative process being followed by the exporting and importing country authorities in making the requisite comparisons.

11. As technical regulations which are not sanitary measures may be met by alternative means, principles and guidelines for establishing the equivalence of alternative measures could be usefully elaborated in order to facilitate international trade in food. Accordingly, a proposed draft "Framework for Determining the Equivalence of Non-sanitary Measures Associated with Food Inspection and Certification Systems" is appended (see Attachment 1) with a view to assisting the discussion of the issues.

12. It should be noted that Attachment 1 closely follows the format of the draft guidelines document appended to the Discussion Paper dealing with the judgement of equivalence of sanitary measures (CX/FICS 00/6, Agenda Item 6). The principal difference with the Attachment 1 document is that it avoids reference to ALOP, as this concept applies exclusively to sanitary measures. However, it can be seen that many of the general principles and guidelines for the determination of equivalence apply equally to sanitary and other technical regulations within a food inspection and certification system. In particular a risk-based evidence-based consistent approach is still required.

13. Accordingly, the Committee may wish to give consideration to the feasibility of integrating the guidelines for technical regulations appearing at Attachment 1 with those for the judgement of equivalence of sanitary measures (CX/FICS 00/6, Agenda Item 6).

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<sup>9</sup> TBT Agreement, Annex 3

**RECOMMENDATION**

14. The Committee is invited to consider the attached draft framework and to recommend to the Executive Committee that the development of a guideline document on the judgement of equivalence of non-sanitary measures be approved within the Codex step process. The Committee's views on the desirability of integrating this work with that on the judgement of equivalence of sanitary measures could also be placed before the Executive Committee.

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

## PREAMBLE

1. It is often the case that food inspection and certification systems operating in exporting countries incorporate technical requirements that differ from those in the importing country. The reasons for such differences include variations in production and processing systems, language(s) used to label products and fraud avoidance approaches.
2. In such circumstances, there is a need to determine the objective of the technical regulation of the importing country in order to facilitate assessment of alternative measures maintained by an exporting country.
3. Application of the principle of equivalence is intended to facilitate trade and, at the same time, allow the importing country's legitimate requirements to be met. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. These include flexibility in design of regulatory measures while enhancing their efficiency and ensuring the quality of imported food with advantages to both the country receiving and the country producing the food.
4. Countries should choose, wherever possible, international standards as the means of achieving their desired level of quality for domestically produced or imported food.

## SCOPE

5. This document provides principles and processes to facilitate the determination of equivalence of technical measures relating to the food as covered by the TBT agreement.

## DEFINITIONS

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

### *Technical Regulation:*

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

### *Equivalence:*

The state wherein technical regulations applied in an exporting country, though different from the measures applied in an importing country, achieves the importing country's stated objective for that regulation. Equivalence is the capability of different inspection and certification systems to meet the same objectives.<sup>10</sup>

### *Determination of equivalence*

The process whereby the technical measures applied in an exporting country are determined to be consistent with the achievement of the objective of the importing country's measure.

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<sup>10</sup> CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997

## GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE

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

- 7.1 An importing country should recognise that different measures may be capable of achieving the objective of its regulation, and are therefore equivalent<sup>11</sup>.
- 7.2 It is the responsibility of the exporting country to demonstrate that its technical measures can meet the importing country's objective for its technical regulation.
- 7.3 Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified technical measures.<sup>12</sup>
- 7.4 The importing country should present the reason/purpose for the technical measure that has been identified by the exporting country as the subject of the equivalence determination, and express this proposal in a way which facilitates comparison.
- 7.5 When judging technical 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.
- 7.6 Countries should strive for transparency in both the demonstration and determination of equivalence, in the interests of all parties involved.
- 7.7 Judgement of equivalence must be conducted using a risk-based evidence-based approach.

## GUIDELINES FOR THE DETERMINATION OF EQUIVALENCE

### General

8. Any technical measure, or combination of technical 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.
9. 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.
10. 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**

11. 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.

The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps, such as those described below.

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<sup>11</sup> CCFICS Principles of Food Import and Export Inspection and Certification; CAC/GL 20 - 1995

<sup>12</sup> CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997

- 11.1 The exporting country identifies the technical measure of the importing country for which it wishes to apply a different measure, and requests the reason/purpose for the measure.
- 11.2 The importing country provides the reason/purpose for the identified technical measure, including an objective basis for comparison. The basis for comparison should provide objective parameters, and be given quantitative expression to the maximum extent possible.
- 11.3 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 technical measures has been expressed in a manner consistent with the relevant principles set out in this document.
- 11.4 The exporting country develops the submission to demonstrate that different technical measure(s) is consistent with achievement of the legitimate importing country requirement, and presents it to the importing country.<sup>13</sup>
- 11.5 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.
- 11.6 The exporting country responds to such concerns by providing further information as appropriate.
- 11.7 The importing country notifies the exporting country of its judgement within a reasonable period of time.
- 11.8 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

12. 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.
14. Where countries already have extensive experience of each other's food inspection and certification 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.
15. Where countries do not already have extensive experience of each other's food control systems, all categories of technical 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.
16. 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.
17. Judgement of equivalence should consider the expected effect of the identified technical measure on all relevant requirements<sup>14</sup>.

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<sup>13</sup> CCFICS Draft Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems; ALINORM 99/30, Appendix II

<sup>14</sup> Consideration should be given to the effects of the technical measure on all requirements that may have been identified during development of the case for equivalence. With regard to requirements not specified in the reason/purpose provided, the identified technical measure may be shown to have an unintended adverse effect, or an alternative technical measure may be shown to have a beneficial effect.

18. 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.