

codex alimentarius commission



FOOD AND AGRICULTURE
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AGENDA ITEM 7

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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 TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

(At Step 3)

(Paper prepared by Australia, France, South Africa and the USA)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 15 October 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; E-mail: codex@fao.org).

BACKGROUND

1. The 23rd Session of the Codex Alimentarius Commission (CAC) agreed¹ with the views of the 46th Session of the Executive Committee (CCEXEC)² that the CCFICS should proceed to develop guidance on the equivalence of systems for inspection and certification in relation to technical regulations other than sanitary measures. The 47th Session of the CCEXEC recognized³ the need to develop guidelines for determining equivalence of food control systems, covering not only safety but also quality and conformity.

¹ ALINORM 99/37, para. 217

² ALINORM 99/4, paras 24-26

³ ALINORM 01/3, para. 26

2. The 8th Session of CCFICS (February 2000)⁴ supported the development of guidelines on the judgement of equivalence of technical regulations on a parallel, but separate, track to the judgement of equivalence of sanitary measures with the understanding that at a later stage the two papers could possibly be merged into one document.

3. The Committee agreed that the proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations associated with Food Inspection and Certification Systems would be developed by Australia, with the assistance of France, South Africa and the United States, for circulation and comment at Step 3 and further consideration at its 9th meeting.

CURRENT DRAFT

4. The draft guidelines have accordingly been redrafted taking into account comments arising from the 8th Session of CCFICS and from the on-going CCFICS work relating to the judgement of equivalence of sanitary measures.

5. The current draft has been compiled with a view to the following key considerations:

- elements of different food inspection and certification systems, or entire such systems are amenable to a risk-based, evidence-based and consistent approach for purposes of judging their equivalence. This equally applies to measures covered by the WTO Sanitary Phyto-Sanitary Agreement (SPS)⁵ and to technical regulations and conformance assessment systems covered by the TBT Agreement.
- the provisions of the TBT Agreement which are relevant to the application of the equivalence principle to food inspection and certification systems relate only to technical regulations and conformance systems which are specified by competent authorities as mandatory requirements. It follows that the concept of non-mandatory standards contained in the TBT Agreement is not applicable for the purpose of this draft guideline and, for ease of approach, a specifically defined term, “technical requirements” has been used.
- that the TBT Agreement covers obligations relating to development and implementation of technical regulations and notes that “technical regulations may not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create”. The TBT further notes that: “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”.⁶ The risks that TBT requirements may be implemented to cover include risks:
 - to public health (for example inadequate labelling of products which contains potential allergens);
 - of economic losses to consumers; and,
 - of economic losses to processors due to misrepresentation of ingredients, with consequences of quality impairment, economic losses and litigation.

⁴ ALINORM 01/30, paras 66-68

⁵ Agreement on the Application of Sanitary and Phytosanitary Measures. Published by the GATT Secretariat, Geneva, June 1994

⁶ TBT, *op cit*, Article 2.2

- the TBT Agreement obliges Members to “specify technical regulations based on product requirements in terms of performance rather than upon design or descriptive characteristics”.⁷
- the need for consistency with the Codex *Principles for Food Import and Export Inspection and Certification CAG/GL 20-1995* and *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certifications Systems CAG/GL 26-1997* documents adopted by Codex and with the approach for equivalence judgement of sanitary measures presently under elaboration with CCFICS.

CURRENT STATUS

6. The revised “Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems” (attached) is circulated at Step 3 for comment. The comments submitted will be considered by the committee at its 9th Session when discussing the attached proposed draft Guidelines at step 4.

⁷ TBT, *op cit*, Article 2.8

**PROPOSED DRAFT GUIDELINES FOR THE JUDGEMENT OF EQUIVALENCE OF
TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND
CERTIFICATION SYSTEMS
(At Step 3)**

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, conformity assessment systems, language(s) used to label products and fraud avoidance approaches.
2. While countries should choose, wherever possible, to base these requirements on Codex or other international standards as the means of achieving their desired level of quality for domestically produced or imported food, it is recognised that countries may legitimately institute their own requirements.
3. In such circumstances, and in order to facilitate trade, there is a need to determine the objective of the technical requirements of the importing country in order to facilitate assessment of alternative requirements maintained by an exporting country.
4. 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 for the exporting country, in design of regulatory requirements, including those pertaining to conformity assessment systems, which are the most efficient in their circumstances, while ensuring exported food meets the technical requirements of importing country.

SCOPE

5. This document sets out principles and processes to facilitate the determination of equivalence of technical requirements including conformity assessment systems concerning food. The technical requirements covered by this guideline do not include sanitary measures; the determination of sanitary measures is dealt with in a separate guideline¹ The document's primary aim is to provide methodology for comparison of technical requirements between importing and exporting countries, however the principles and mechanisms described are applicable within countries.

DEFINITIONS

Equivalence

Equivalence is the capability of different inspection and certification systems to meet the same objectives.²

¹ Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems. Agenda Item 6 CX/FICS 00/6 to be considered at Step 3 at the 9th session CCFICS December 2000.

² CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems CAC/GL 26-1997

The state wherein technical requirements applied in an exporting country, though different from the requirements applied in an importing country, achieves the importing country's stated objective for that technical requirement.

Technical Requirement

Any regulation, rule, standard, code or other criteria for food, not being a sanitary or phyto-sanitary measures³ set down by the competent authorities, a condition of importation. Technical requirements include, but are not limited to: product characteristics or their related processes and production methods, including terminology, symbols, packaging, marking or labelling provisions applying to such characteristics, processes and production methods; sampling, testing, inspection, certification or other conformity assessment procedures; and applicable administrative provisions, with which compliance is mandatory.

GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE

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

- 6.1. An exporting country should recognise that an importing country has the sovereign right to implement measures to protect consumers from risks to public health, deceptive and unfair trading practices through application of technical requirements.
- 6.2. An importing country should recognise that different means may be capable of achieving the objective of its technical requirement, and are therefore equivalent and that any technical requirement, or combination of technical requirements, can be identified by an exporting country for determination of equivalence.
- 6.3. It is the responsibility of the exporting country to demonstrate that its technical requirement(s) can meet the importing country's objective for its technical requirements.
- 6.4. The judgement of equivalence by the importing country should be conducted using an objective, evidence-based analysis and should involve all interested parties to the extent practicable and reasonable.
- 6.5. Judgement of equivalence should consider the expected effect of the identified technical requirement on all relevant requirements
- 6.6. Countries should, upon request, enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified technical requirements.
- 6.7. The importing country should present the objective for the technical requirement that has been identified by the exporting country as the subject of the equivalence determination, and express this in a way which facilitates comparison.
- 6.8. When judging technical requirements 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. Where countries do not already have extensive

³ as defined in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures

experience of each other's food control systems or relevant conformity assessment programmes or no previous history of significant trading in foods or detailed knowledge of each other's food control systems, the equivalence judgement process may require a detailed side-by-side comparison of system elements. Where countries already have extensive experience of each other's food inspection and certification systems, a determination for a particular objective may be confined to relevant system elements on the basis that supporting programmes and infrastructure are known to operate effectively.

- 6.9. Countries should strive for transparency in both the demonstration and determination of equivalence, in the interests of all parties involved.
- 6.10. 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 FOR THE DETERMINATION OF EQUIVALENCE

7. Determination of equivalence presumes that the exporting country has already reviewed all applicable importing country technical requirements for the food involved, and has identified those for which it seeks a determination of equivalence.

8. 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.

- 8.1. The exporting country identifies the technical requirement of the importing country for which it wishes to apply a different requirement, and requests the reason/purpose for the requirement.
- 8.2. The importing country provides the reason/purpose for the identified technical requirement, including an objective basis for comparison. The basis for comparison should provide objective parameters, and include systems that are implemented to ensure compliance.
- 8.3. On the initiative of the exporting country, the importing and exporting countries should enter into a dialogue with the view to ensuring that the basis for comparison of technical requirements has been expressed in a manner consistent with the relevant principles set out in this document.
- 8.4. The exporting country develops the submission to demonstrate that its different technical requirement(s) is consistent with achievement of the importing country technical requirement, and presents it to the importing country. Judgement of the case for equivalence should include:
 - supporting quantitative data and qualitative information submitted by the exporting country;
 - analysis of the relationship with the exporting country's technical requirements and the achievement of the stated outcomes of the technical requirements of the importing country;
 - consideration of uncertainty in quantitative data;

- reference to Codex risk assessment methodologies where available, if risk assessments are presented; and,
 - consideration of existing Codex standards.
- 8.5. If the importing country has any 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.
 - 8.6. The exporting country responds to such concerns by providing further information as appropriate.
 - 8.7. The importing country notifies the exporting country of its judgement within a reasonable period of time.
 - 8.8. 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.
 - 8.9. A final judgement of equivalence is made by the importing country and the result reported to the exporting country.

FOLLOWING THE JUDGEMENT PROCESS

9. 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. Exporting and importing countries, subsequent to a successful agreement in regard to equivalence of technical requirements, should advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

Figure 1: Flow chart for the determination of equivalence

