

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 5

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Tenth Session

Brisbane, Australia, 25 February – 1 March 2002

PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REGULATIONS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 30 November 2001** to: Codex Australia, Agriculture, Fisheries and Forestry – Australia, GPO Box 858, Canberra ACT, 2601 (telefax: +61.2.62723103; 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 9th Session (December 2000) of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)¹ discussed the proposed draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems prepared by a drafting group under the direction of Australia.
2. The Committee was of the opinion that the text as currently drafted was proceeding in the right direction but that it needed substantial revision in view of changes made to the corresponding text on sanitary measures. The Committee therefore requested the drafting group (Australia, France, South Africa, USA and the EC) to prepare a revised text on this basis that also took into account the oral comments and written comments provided at the meeting for circulation, comment and further consideration at its 10th Session of the CCFICS.

RECOMMENDATION

3. It is recommended that the Committee review the attached proposed draft guidelines and consider appropriate amendments.

¹ ALINORM 01/30A, paras 93 - 100

PROPOSED DRAFT GUIDELINES FOR THE JUDGEMENT OF EQUIVALENCE OF TECHNICAL REQUIREMENTS ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS

PREAMBLE

1. It is often the case that importing and exporting countries operate different food inspection and certification systems that incorporate different technical requirements. These requirements may relate to matters such as the control of production and processing systems, conformity assessment systems, language(s) used to label products and mechanisms for prevention of fraud.
2. Countries should wherever possible and appropriate, base their requirements on Codex or other international norms as the means of achieving their desired level of quality² and regulatory conformity for domestically produced and imported food. However, it is recognised that countries may choose to implement their own technical requirements in order to meet their legitimate objectives with respect to (*inter alia*) product characteristics and conformity assessment.
3. Application of the principle of equivalence is intended to facilitate trade while ensuring that the importing country's legitimate objectives are met. Application of the principle of equivalence has mutual benefits for both exporting and importing countries. In particular, flexibility that the application of equivalence allows an exporting country, in design and implementation of technical requirements, means that the technical requirements of the importing country can be met in the most efficient and effective way.

SCOPE

4. 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 are limited to technical regulations³ and conformity assessment requirements as defined by the TBT Agreement⁴, that have been mandated by governments. These mandatory technical regulations are defined as technical requirements in this document. This document does not cover judgement of equivalence of sanitary measures⁵.

² The *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995) notes that “the confidence of consumers in the quality (including safety) of their food supply depends in part of their perception as to the effectiveness of food control measures”. The term “quality” as used in this guideline similarly includes food safety.

³ “Technical Regulation” is defined in the WTO TBT agreement as: *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.*

⁴ The Agreement on Technical Barriers to Trade provides WTO members the right to adopt technical regulations, standards and conformity assessment procedures providing these do not constitute unnecessary barriers to trade.

⁵ Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems. To be considered at Step 5 at the 10th session CCFICS February 2002.

DEFINITIONS

*Equivalence*⁶

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.

Legitimate objective

The clearly stated purpose, that is both genuine and achievable, of a technical requirement intended to protect the health of consumers or prevent deception or fraud in relation to food trade. The fulfilment of the legitimate objective of a technical requirement intended to protect the health of consumers corresponds with the achievement of the appropriate level of protection as defined in the Agreement on the Application of Sanitary and Phytosanitary Measures.

Technical Requirement

Any requirement⁷, that is not a sanitary measure⁸, set down by the competent authorities, in order to fulfil a legitimate objective. Technical requirements may specify, 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; conformity assessment procedures (including sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval) and applicable administrative provisions.

GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE

5. Determination of the equivalence of technical requirements associated with food inspection and certification systems should be based on application of the following principles:
 - 5.1. An exporting country should recognise that an importing country has the sovereign right to apply technical requirements in order to achieve legitimate objectives that protect consumers against health and/or deceptive or unfair trading practices.
 - 5.2. An importing country should be able to describe the objective of its technical requirement(s).
 - 5.3. 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 of its technical requirements, or combination of technical requirements, can be subject of a request by an exporting country for determination of equivalence.
 - 5.4. It is the responsibility of the exporting country to demonstrate that its technical requirement(s) including conformity assessment procedures, can meet the importing country's legitimate objective for its technical requirement(s). When evaluating equivalence of its stated technical requirement(s), the importing country should take into account program design, implementation and monitoring that operate in the exporting country and underpin consistent achievement of equivalence of the importing country's technical requirement(s).

⁶ Equivalence is defined in CAC GL 26-1997: "Equivalence is the capability of different inspection and certification systems to meet the same objectives".

⁷ As defined in CAC/GL 20 – 1995 "Requirements are the criteria set down by the competent authorities relating to trade in food stuffs covering the protection of public health, the protection of consumers and conditions of fair trading."

⁸ as defined in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures

- 5.5. The judgement of equivalence by the importing country should be conducted using an analytical approach that is objective and consistent.
- 5.6. Countries should, upon request, promptly enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified technical requirements.
- 5.7. The conduct of the judgement process should not affect existing trade.
- 5.8. The importing country should present the objective of 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.
- 5.9. Countries should ensure transparency in both the demonstration and determination of equivalence.
- 5.10. 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 on both parties.

PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

6. 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.
7. Experience and detailed knowledge of an exporting country's food inspection and certification systems may in itself be sufficient to allow objective judgement of equivalence by the importing country.
8. Where countries lack extensive experience with, or detailed knowledge about, each other's food control systems or relevant conformity assessment programmes or where there is no previous history of significant trading in foods, the equivalence judgement process may require a detailed side-by-side comparison of system elements.
9. 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.
 - 9.1. The exporting country identifies the technical requirement of the importing country for which it wishes to apply a different requirement, and requests details of the technical requirement from the importing country.
 - 9.2. The importing country provides details of the identified technical requirement, with objective parameters as a basis for comparison. Objective parameters may include:
 - the objective of the technical requirement
 - risks that may be incurred through non-fulfilment of the technical requirement
 - elements of systems implemented to ensure compliance with the stated requirement.
 - 9.3. 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.

- 9.4. 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 this submission to the importing country.
- 9.5. 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.
- 9.6. The exporting country responds to such concerns by providing further information as appropriate.
- 9.7. The importing country determines whether the exporting country's technical requirements achieve the importing country's objective.
- 9.8. The importing country notifies the exporting country of its judgement within a reasonable period of time.
- 9.9. An attempt should 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.
- 9.10. A final judgement of equivalence is made by the importing country and the result reported to the exporting country, providing reasons should the judgement be that the proposed technical requirement is deemed not equivalent.

FOLLOWING THE JUDGEMENT PROCESS

10. 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. Agreements should be established according to the Codex *Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems* (CAC/GL 34 1999).
11. 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.
12. Consistent with Section 9 of CAC/GL 26-1997 *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems*, the verification and review of the effectiveness of technical requirements may be conducted by officials of the importing country.

Figure 1: Simplified flow chart for the determination of equivalence
(Individual steps may be repeated)

