

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 02/11/6
September 2002**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Eleventh Session

Adelaide, Australia, 2 – 6 December 2002

DISCUSSION PAPER 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 15 November 2002** to: Codex Australia, Agriculture Fisheries and Forestry — Australia 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. At its 10th session (February 2002) the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)¹ considered the *Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems*.
2. The Committee agreed to defer for the time being further drafting of the proposed draft Guidelines within the context of the Codex step procedure. The Committee agreed that a drafting group led by Australia, with the assistance of Canada, France, Norway, Papua New Guinea, the United States and the European Commission should prepare a discussion paper for circulation, comment and further consideration at its next meeting.
3. In preparing this discussion paper, the drafting group focused on the possible application of equivalence to the separate issues of technical regulations and conformity assessment procedures as related to food inspection and certification systems.

RECOMMENDATIONS

4. The drafting group noted a lack of actual examples where the application of equivalence to technical regulation or conformity assessment procedures may have had a role in facilitating market access or simplification of trade, and invites members to provide examples from their own experience, where the determination of equivalence of technical regulation and/or conformity assessment procedures may have assisted in facilitation of trade, for discussion and consideration at the 11th meeting of CCFICS.
5. The Committee is invited to consider the recommendations in the paper.

¹ ALINORM 03/30 paras 69 - 75

TECHNICAL REGULATIONS AND CONFORMITY ASSESSMENT PROCEDURES - EQUIVALENCE AND RECOGNITION IN RELATION TO FOOD INSPECTION AND CERTIFICATION SYSTEMS

INTRODUCTION

1. The issue of equivalence of food inspection and certification systems has been discussed in CCFICS since its 5th session in 1997. The Committee has noted that:

- there was support for development of guidelines to address a system based approach to address WTO and Codex elements related to equivalence;
- priority for this work should be in respect of sanitary measures and assisting countries in determination of equivalence as per Article 4 of the SPS Agreement²;
- drafting of guidelines on judgement of equivalence for sanitary measures is now at an advanced stage; and
- while it had examined several draft versions, the value of a draft guideline to address the judgement of equivalence for other than sanitary measures was not so apparent to CCFICS members.

2. This discussion paper has been prepared to present for the consideration of the Committee, issues surrounding the notion of equivalence as it applies to technical regulation and conformity assessment procedures relevant to inspection and certification of food.

CONTEXT FOR THIS DISCUSSION PAPER:

10th CCFICS Meeting

3. The *Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations associated with Food Inspection and Certification Systems* were discussed at the 10th CCIFCS. The Committee noted that the document (*inter alia*):

- was intimately linked to the on-going discussion on the *Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems*³ and development of the SPS judgement of equivalence document should be a higher priority; and
- should be further clarified as to its practical scope, purpose and application and practical examples of its application should be included.

4. The 10th CCIFCS agreed to defer work on the Proposed Draft Guidelines on the Judgement of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems, pending consideration of a further discussion paper. The Committee agreed that a drafting group should prepare a discussion paper for circulation, comment and further consideration at its next meeting.

5. The discussion paper would:

- examine the need for the elaboration of guidelines on the judgement of equivalence of technical regulations to ensure conformity with essential quality requirements;
- present relevant examples for consideration; and
- present recommendations relating to the elements for inclusion in a draft guideline.

Codex Medium-Term Plan

² Agreement on the Application of Sanitary and Phytosanitary Measures. Published by the GATT Secretariat, Geneva, June 1994.

³ Appendix III- ALINORM 03/30

6. The “application of guidelines on the judgement of equivalence for specific purposes such as equivalence of measures to ensure food hygiene or measures to ensure conformity with essential quality requirements” is included as part of the Codex Medium Term Plan for 2003-2007.⁴

WTO Framework

7. Within the framework of the World Trade Organization, technical measures applicable to food in international trade are subject to either the SPS Agreement or the Agreement on Technical Barriers to Trade (TBT Agreement). Measures that are not sanitary measures as defined under the SPS agreement fall within the scope of the TBT Agreement.

TBT Agreement

8. The aim of the TBT agreement is to ensure that technical regulations⁵, standards⁶, and conformity assessment procedures⁷ do not create undue obstacles to trade. To do this, the Agreement sets out obligations for members. Key provisions are:

- *Non discrimination* - between imported and domestic products, or like product imported from different countries;
- *Harmonisation* - the TBT Agreement encourages the use of international norms as this can facilitate trade;
- *Transparency* - members are required to publish and notify the WTO about details of draft technical regulations, standards and conformity assessment procedures, which are not based on international norms and have a trade impact on other members;
- *Proportional to problem* - technical regulations of WTO members must not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Conformity assessment procedures must be no more strict or applied more strictly than is necessary to give the importing country adequate confidence that products conform with the applicable technical regulation;
- *Performance* - member countries should specify technical regulations based on product requirements in terms of performance rather than upon design or descriptive characteristics;
- *Equivalence* - in respect of technical regulations Article 2.7 states, WTO Members “*should 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*”. In respect of conformity assessment procedures, Article 6.1 states “*Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted, even when they differ from their own, provided they are satisfied that those procedures offer an assurance of conformity with applicable technical regulation or standards equivalent to their own procedures*”.

TECHNICAL REGULATIONS IN RESPECT OF FOOD

What they are

9. Technical regulations⁴ applying to food trade include (but are not limited to) requirements for product description, weights and measures, packaging, product durability, grading, and labelling. Such technical

⁴ Annex 1 to CL 2001/26, Project ID 27.

⁵ Technical regulation: Document which lays down product characteristics or their related processes and production methods, including the 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. TBT Agreement (Annex 1)

⁶ Standard : Document approved by a recognised body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product or production method. TBT Agreement (Annex 1)

NOTE As CCFICS is concerned about official (mandatory) requirements in relation to food inspection and certification the commentary in this paper does not deal with “standards” as defined in the TBT Agreement.

⁷ Conformity assessment procedures: Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. *TBT Agreement (Annex 1)*

regulations may include requirements that have the purpose of protecting human health and safety and the prevention of deceptive practices. These are identified as *legitimate objectives* in Article 2.2 of the TBT Agreement. The Agreement allows the possibility that there may be other legitimate objectives.

10. Codex norms may be relevant international standards in terms of Article 2.4 of the TBT Agreement.

11. The following table gives some specific examples of technical regulations.

Table 1 – some examples of technical regulations applied to food.

Category	Specific examples
Product description and composition	Product definitions and standards of identity – eg “orange juice” is the extract from endocarp of <i>Citrus sinensis</i> . Requirement for salt to be iodised in areas where goitre is a problem. Specifications for concentration of minerals in bottled water. Specified minimum processing to enable use of terms such as “fresh”.
Weights and measures	Units of measure (metric, avoirdupois, imperial) Mandatory volume or weight prescription for food.
Packaging	Packaging shape size and appearance.
Product durability	“Use by” / “Best by” / “Sell by” dates.
Grading	Appearance or size grading of fruit and vegetables.
Labelling	Nutrition labelling, organic product labelling.

Application of the concept of equivalence to technical regulations.

12. The Agreement says (Article 2.7) that Members “*should 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*”.

13. The applicability of equivalence in relation to technical regulations will depend on how the technical regulation is formulated. The concept of equivalence concerns the use of different means to achieve the same outcome. From this perspective, an equivalence determination would be most simply applied where technical regulations are specified in terms of performance, which may include process and production methods and an exporting country proposes to use an alternative process or production methods.

14. Where technical regulations are not specified in terms of performance or outcomes, for example for nutritional objectives, limits are placed on components of baby food, the concept of equivalence will typically be less applicable or not applicable at all.

15. The discussion at the 10th CCFICS meeting included the point that a text should focus on “judgement of procedures and rules to establish technical regulations....”⁸. CCFICS should note that Article 2.8 of the TBT Agreement deals with the preparation of technical regulations, and states... “*Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.*” This is not strictly about equivalence, and CCFICS may need to clarify its mandate in respect of this point.

The need for “equivalence” in relation to (food) technical regulations

16. The drafting group is not aware of any significant examples where trade could have been facilitated by the application of the concept of equivalence to technical regulations. The implication that the issue of equivalence of technical regulations is not a priority issue in trade to date is supported by the fact that it has not been raised in regular sessions of the WTO TBT Committee. It remains a matter of conjecture whether the issue may arise in future.

⁸ ALINORM 03/30, para 70.

CONFORMITY ASSESSMENT PROCEDURES RELATING TO FOOD INSPECTION AND CERTIFICATION

What they are

17. Conformity assessment procedures are the procedures used directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Some examples within the scope of food regulation include:

- assessment procedures covering production methods for claims such as “organic”;
- visual inspection of products and relevant documentation at importation for compliance with labelling regulations;
- sampling plans and corresponding laboratory analysis (using specified methods) of mineral water for chemical composition;
- size grading of fruit for conformity with minimum size requirement; and
- procedures to identify meat processed under religious dietary laws.

18. Paragraph 8 outlines the broad obligations of members that apply to development and implementation of technical regulations and conformity assessment procedures. There are some adjuncts to these, set out in Article 5 of the TBT Agreement that are specific to conformity assessment procedures, including:

- requirements for efficient operation without hidden impediments, i.e. minimise delay in testing⁹, have facilities for testing conveniently sited¹⁰, charge fair fees for testing¹¹;
- limits on information requested from exporting member to that necessary to assess conformity and determine fees¹²; and
- restricting the need for full re-evaluation of conformity for a product previously deemed complying, when that product has some specification amended.¹³

The need for “equivalence” in relation to conformity assessment procedures

19. The lack of acceptance by importing countries of results of tests undertaken by foreign conformity assessment bodies is a recognised problem in international trade, and has been raised often in TBT Committee discussions.

20. The second triennial review of the TBT Agreement addressed the issue and listed several approaches which facilitate the recognition or acceptance of results of conformity assessment. Those that include the notion of equivalence are:

- the use of accreditation to qualify conformity assessment bodies – where parties involved recognise accreditation or certificates issued by any other party to the particular agreement as being equivalent to that granted by itself; and
- unilateral recognition of results of foreign conformity assessment – where, on the basis of equivalent competence of the conformity assessment body, foreign test reports and certificates are recognised unilaterally.

21. The report does not provide any further elaboration on the mechanism to assess equivalence in these situations.

⁹ TBT Agreement Article 5.2.1. “conformity assessment procedures are undertaken and completed as expeditiously as possible and in a no less favourable order for products originating in the territories of other Members than for like domestic product”

¹⁰ TBT Agreement Article 5.2.6 “the siting of facilities used in conformity assessment procedures and the selection of samples are not such as to cause unnecessary inconvenience to applicants or their agents”

¹¹ TBT Agreement Article 5.2.5 “any fees imposed for assessing the conformity of products originating in the territories of other Members are equitable in relation to any fees chargeable for assessing the conformity of like products of national origin or originating in any other country,....”

¹² TBT Agreement Article 5.2.3 “information requirements are limited to what is necessary to assess conformity and determine fees”

¹³ TBT Agreement Article 5.2.7 “whenever specifications of a product are changed subsequent to the determination of its conformity to the applicable technical regulations or standards, the conformity assessment procedure for the modified product is limited to what is necessary to determine whether adequate confidence exists that the products still meets the technical regulations or standards concerned”

22. Hypothetical examples 3 and 4 are scenarios where equivalent assurance of conformity with technical regulations through different conformity assessment procedures applied by importing and exporting countries are illustrated.

SUMMARY

23. An importing country should give consideration to the potential equivalence of the technical regulation or conformity assessment procedures of an exporting country if it is specifically requested to do so. No guidance exists within the TBT Agreement as to the procedures that should be followed to facilitate the judgement of equivalence. However, it may be presumed that the initiative of an exporting country in seeking an equivalence determination would be supported by technical and other evidence concerning the performance of its technical regulation, or, confidence provided by conformity assessment procedures.

24. Since the importing country must satisfy itself that the regulation(s) of the exporting country will adequately fulfil the objectives of its own regulation(s) it may be further presumed that the importing country should have a clear understanding of the purpose of the regulation (this may be distinct from the legitimate objective as in Article 2.2) and how its regulation(s) actually contribute to the achievement of the stated purpose. If an exporting country is to show that its regulations are equally effective in achieving the same purpose, then it must also be informed of the purpose. Furthermore, the demonstration of equivalence will be greatly facilitated if the importing and exporting countries use an objective basis for comparison of the performance of their technical regulations.

25. There follows the parallel line of reasoning for conformity assessment procedures. Where an importing country conducts procedures to achieve a certain level of assurance that technical regulations comply, an exporting country must be informed of the required level of confidence, and relevant technical information to enable demonstration of equivalence of its conformity assessment procedures, using an objective basis for comparison

RECOMMENDATIONS

26. That CCFICS note that an advanced stage has been reached in the formulation of guidelines for judgment of equivalence of sanitary measures, which are within the scope of the SPS Agreement and that work should remain a priority for the Committee.

27. That the Committee note the distinction that the TBT Agreement makes between technical regulations and the conformity assessment procedures that are used to demonstrate compliance with technical regulations.

28. That the Committee consider its future work program, including whether guideline material should be developed for the application of equivalence as stipulated by the TBT Agreement and related to food inspection and certification.

29. If CCFICS decides that a guideline should be progressed, then it may consider examining for relevance, the elements included in the *Draft Guidelines for the Judgement of Equivalence of Sanitary Measures*.

HYPOTHETICAL EXAMPLES OF THE APPLICATION OF EQUIVALENCE/ RECOGNITION FOR TECHNICAL REGULATIONS OR CONFORMITY ASSESSMENT PROCEDURES

EXAMPLE 1

Technical regulation of Country IM:

Broccoli shall be harvested, processed, transported and distributed so as to minimise deterioration of quality, including nutritional characteristics.

Legitimate objective

Consumer expectation of quality products and “protection of human health or safety”, on basis of the preservation of nutritional value.

Formulation of technical regulation

The regulation is specified in accordance with Article 2.8 of the Agreement. It is not specifically linked to existing Codex standard for broccoli, (Codex Standard 110 – 1981), which refers to quick frozen product (there is no Codex Standard for fresh broccoli).

Scenario for application of equivalence

Country EX has a large fresh vegetable industry and processes broccoli in accordance with the Codex standard for quick frozen broccoli. Country EX also processes fresh broccoli where procedures include pre-cooling, packaging that is designed to maintain modified atmosphere, procedures to minimise storage delay including rapid transport in refrigerated vehicles.

Considerations to determine equivalence

In this case the technical regulations are specified in terms of performance rather than direct compositional characteristics. The demonstration of conformance, rather than equivalence of Country EX’s approach, with the technical regulation of Country IM, should be more significant in obtaining or maintaining market access.

EXAMPLE 2

Technical regulation of Country IM

Jam must contain minimum fruit content of 50% of final product.

Legitimate objective

“Fair trading and prevention of deceptive practices” on the basis that, according to country IM, its consumers expect that “jam” will have a certain minimum fruit content.

Formulation of technical regulation

This technical regulation is not based on an international standard, nor is it expressed in terms of performance.

Scenario for application of equivalence

Country EX wishes to export to Country IM, a product, as defined by Codex Standard for Jams (Fruit Preserves) and Jellies 79 – 1981, and labelled as jam. The product contains 45% fruit.

Considerations to determine equivalence

The two products in this example are different when considered in light of Country IM’s technical regulation.

The application of Article 2.7 of the TBT Agreement is not simply applied in this case.

Facilitating trade of “jam” from Country EX into Country IM, will require Country EX to apply for equivalence, not on the basis of a direct comparison of technical regulations, but on the basis of whether Country IM considers that the technical regulation of Country EX adequately fulfils the objective of their own regulation.

Even though Country EX’s product is prepared according to an international standard, if the legitimate objective stated by Country IM requires jam to have 50% or more of fruit content, determination of equivalence can only proceed if the objective can be achieved with fruit content of jam of 45%.

The negotiations may turn on what the objective of the technical regulation addressed, and how the 2 differing technical regulations fulfilled the objective.

[NOTE: The risk of non fulfilment of the legitimate objective may well be a factor in consideration for market access, however this point is not about equivalence as per Article 2.7, but addresses issues that arise in Article 2.2 of the TBT Agreement. These are not within the mandate provided to CCFICS.]

EXAMPLE 3

Technical regulation of Country IM

Foods labelled as “organic” must be grown, harvested and prepared according to Codex Guideline GL 32-1999, Rev 1 – 2001.

Legitimate objective

Prevention of deceptive practices.

Formulation of technical regulation

The technical regulation is similar to that of Example 1, i.e. based on international standard, and framed to address one of the legitimate objectives listed in Article 2.2. of the agreement. The important difference here is that the conformity assessment procedures are vital in assuring that the technical regulation is achieved.

Scenario for application of equivalence

Country EX wishes to export “organic” dairy products to Country IM, stating that its own technical regulations are based on GL 32-1999, Rev 1 – 2001, and the conformity assessment is achieved through the use of certification bodies that conform with relevant ISO guidelines.

Considerations to determine equivalence

In this case Country EX is looking to negotiate recognition of its conformity assessment procedures as per Article 6, rather than Article 2.7 of the TBT Agreement. Article 6.1 notes a number of factors that may be necessary to “*arrive at a mutually satisfactory understanding....*” such as adequate and enduring competence of the relevant conformity assessment bodies in the exporting member.

EXAMPLE 4

Technical regulation of Country IM

Products described as “low in sodium” shall have no more than 1.2g/kg of sodium.

Legitimate objective

Protection of human health.

Formulation of technical regulation

Based on international standards (Codex standard for special dietary foods with low-sodium content (including salt substitutes) 53-1981 (amended 1983).

Scenario for application of equivalence

Country EX has adopted the same technical regulation together with requirements that manufacturers who wish to make “low sodium” claims conduct analysis on such products, using independent accredited laboratories working to internationally accepted method of analysis.

Country IM samples and analyses samples from every shipment of low sodium products from Country EX, at the expense of the exporter.

Country EX applies for recognition of conformity assessment procedures and thus reduction of sampling and analysis upon importation.

Considerations to determine equivalence

The scenario here is not about determination of equivalence of technical regulations (Article 2.7 of the TBT Agreement), but about recognition of conformity assessment procedures providing equivalent assurance of conformity of the technical regulation (Article 6.1 of the TBT Agreement).