

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

COMMENTS AT STEP 3

ARGENTINA

Strikethrough indicates deletion. All corrections appear in bold and underlined.

PREAMBLE

1.- It is often the case that importing and exporting countries ~~operate~~ use different food inspection and certification systems ~~that incorporate~~ with the aim of assessing compliance of their different technical requirements incorporated into the technical regulations. 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 quality⁴ 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.~~

2.- Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an

⁴The *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.

ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued. (Art 2.4 of the TBT).

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.~~ **In particular, the flexibility given by equivalence determination to an exporting country lies in, through different technical regulations may adequately achieve the legitimate objectives of the importing country.** [Translator's Note The version provided by Argentina (in the Spanish language), in the last sentence of this paragraph has a missing noun and, thus, it could not be translated accurately].

SCOPE

4.- This document sets out principles and ~~processes available~~ **mechanisms** to facilitate the determination of **the** equivalence of technical requirements set out in the regulations ~~including systems and conformity assessment procedures~~ concerning food. ~~The technical requirements covered by this guideline are limited to technical regulations² and conformity assessment requirements as defined by the TBT Agreement³, 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 measures⁴.~~

The principles and mechanisms set out in these Guidelines serve as a legal framework for the determination of the equivalence of technical requirements and conformity assessment procedures, as defined by the Technical Barriers to Trade Agreement of the WTO.

AIM OF THE EQUIVALENCE DETERMINATION

5.- The general aim of equivalence determination is to facilitate the trading of products or groups of products which are subject to technical requirements, among those countries which have entered into equivalence agreements.

6.- The specific aim of said equivalence agreements is to reduce physical controls which seek to verify that products or groups of products entering the importing country's territory comply with the technical requirements set out by the importing country.

7.- DEFINITIONS

Technical Regulation

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is

² "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.*

³ 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.

⁴ 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.

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.

Technical Requirement

Technical requirement is **any requirement prescription set down by a technical regulation**, that is not a sanitary measure⁵, set down by the competent authorities, in order to fulfill 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.

Conformity Assessment Procedures:

Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. These include, *inter alia*, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

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.

A legitimate objective is, in relation to food, the prevention of practices which may lead to error on the part of the consumers and to fraud in commercial operations. (TBT)

Equivalence⁶

The state wherein technical requirements **and/or conformity assessment procedures** applied in an exporting country, though different from the requirements applied in **the requirements or procedures applied by** an importing country, achieves **adequately comply with** the importing country's stated **legitimate** objective for that technical requirement, **to the same extent achieved by the importing country.**

Determination of Equivalence

Mechanism through which an exporting country objectively demonstrates that its technical requirements and/or conformity assessment procedures adequately comply with the legitimate objective of the importing country, to the same extent achieved by the importing country.

⁵ As defined in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.

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

GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE

8.- Determination of the equivalence of technical requirements associated with food inspection and certification systems **and of food conformity assessment procedures** should be based on application of the following principles:

8.1.- An exporting country should recognise that an importing country has the sovereign right to apply **the** technical requirements **necessary to achieve its** legitimate objectives that protect consumers against health and/or deceptive or unfair trading practices.

8.2.- An objective basis must be established for the comparison of technical requirements and conformity assessment procedures so that the determination of equivalence becomes effective.

8.3.- An importing country ~~should~~ **must:**

Be able to describe the objective of its technical requirement(s) and the reason of said objectives.

Identify the legitimate objective its technical requirement seeks to achieve.

Demonstrate the sufficiency and necessity for the technical requirement to achieve its legitimate objective.

Clearly identify the risk of non-achievement of the legitimate objective which the technical requirement seeks to achieve.

Attach the scientific and technical evidence upon which the technical requirement is based.

Provide any additional information that may assist the exporting country in submitting an objective demonstration of the equivalence of its technical requirement and conformity assessment procedure.

8.4.- Equivalence may be accepted for a specific technical requirement or for requirements associated with a specific product or specific product category, or at the level of systems.

When so requested, Members shall attempt to accept the equivalence of a technical requirement associated with a specific product or specific product category.

Where necessary and appropriate, Members may attempt to enter into equivalence agreements that are broader or of a greater scope. The acceptance of equivalence of a technical requirement concerning a unique product may not necessitate the development of an equivalence agreement at the level of systems.

8.5.- 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.

8.6.- It is the responsibility of the exporting country to demonstrate that its technical requirement(s) including **and its** 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).~~ **Furthermore, an exporting country must provide access so that those conformity assessment systems which are the subject of equivalence determination may be inspected and evaluated, when so requested by the importing country's competent.**

8.6.- The judgement of equivalence by the importing country should be conducted using an analytical approach that is objective and consistent. **(ALREADY SET OUT IN ARTICLE 8.3.).**

8.7.- Countries should, upon request, promptly enter into consultations with the aim of achieving bilateral or multilateral recognition of the equivalence of specified technical requirements **and/or conformity assessment procedures.**

8.8.- ~~The conduct of the judgement process should not affect existing trade.~~ **The examination made by an importing country of a request submitted by an exporting country for the recognition of equivalence of its technical requirements and/or conformity assessment procedures in relation to a specific product or product, shall not constitute in itself sufficient reason to create obstacles to or suspend current imports of the product involved and originating from that country.**

8.9.- ~~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.~~ **(ALREADY SET OUT IN ARTICLE 8.3.).**

8.9.- Countries should ensure transparency in both the demonstration and determination of equivalence.

8.10.- ~~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.~~ **(ALREADY INCORPORATED INTO THE PROCEDURE)**

PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

9.- ~~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.~~

9.- An importing country shall make available to an exporting country, upon request, all details concerning its technical requirements and/or conformity assessment procedures, as identified in Article 8.3.

An exporting country should examine all the applicable technical requirements of an importing country concerning the food involved and identify the requirements and procedures that are being complied with and those which require the determination of equivalence.

Importing and exporting countries should utilize in such cases an agreed process for the exchange of relevant information so as to facilitate the determination of equivalence. This information should be limited to that which is necessary to this end, and minimize administrative burden on both parties.

10.- ~~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.~~

~~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.~~

10.- The importing country must speed up the procedure for the determination of equivalence in relation to the products or group of products which may have been traditionally imported from the exporting country.

Where there is no previous history of significant trading of the product or group of products which are the subject of equivalence determination, Members shall follow all the steps of the determination procedure as set out by these Guidelines.

11.- 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.

11.1.- The exporting country identifies the technical requirement **and/or conformity assessment procedure** of the importing country for which it wishes to apply a different requirement **and/or procedure**, and requests details of the technical requirement from the importing country.

~~11.2.- 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-fulfillment of the technical requirement elements of systems implemented to ensure compliance with the stated requirement.~~

11.2.- The importing country must:

- **Describe the objective of its technical requirement(s) and its reasons.**
- **Identify the legitimate objective its technical requirement seeks to achieve.**
- **Demonstrate the sufficiency and necessity for the technical requirement to achieve its legitimate objective.**
- **Clearly identify the risk of non-achievement of the legitimate objective which the technical requirement seeks to achieve.**
- **Attach the scientific and technical evidence upon which the technical requirement is based.**
- **Provide any additional information that may assist the exporting country in submitting an objective demonstration of the equivalence of its technical requirement and conformity assessment procedure.**
- **Identify the elements of those systems that have been implemented to ensure compliance with the stated requirement.**

11.3.- 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 **and conformity assessment procedures** has been expressed **established** *in a manner consisting of* the relevant principles set out in this document. [Translators note: the version provided in the Spanish language would read ‘in a manner which consists of’ as ‘consistente’ in Spanish is a false cognate and means ‘consisting of’ when used with the Spanish preposition ‘de’ and not ‘con’ as used here. The English original reads ‘in a manner consistent with’. Argentina will need to clarify/correct the meaning of this sentence.]

11.4.- The exporting country develops the submission to demonstrate that its different technical requirement(s) ~~is consistent with achievement of the importing country’s technical requirement,~~ **adequately complies with the legitimate objectives of the importing country’s technical requirement involved to the same extent achieved by the requirements of the importer,** and presents this submission to the importing country.

11.5.- If the importing country has any ~~concerns~~ **doubts** with the submission as presented, it should notify the exporting country ~~at the earliest opportunity~~ **as soon as possible** and should detail ~~the reasons for concern~~ **the reasons for said doubts**. If possible, the importing country should suggest how the concerns might be addressed.

11.6.- The exporting country ~~responds~~ **must respond** to such ~~concerns~~ **doubts** by providing further information as appropriate.

11.7.- The importing country determines whether the exporting country's technical requirements achieve the importing country's objective **to the same extent achieved by its requirements**.

11.8.- The importing country notifies the exporting country of its judgement within a reasonable period of time, **and indicates the reasons for its decision, should it arrive at the determination that the requirements or procedures of the exporting country are not equivalent to its own**.

11.9.- 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.

~~11.10. 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.-(ALREADY INCLUDED IN ARTICLE 11.8).~~

CONTINUATION OF THE JUDGEMENT PROCESS

[Translator's note: the version provided by Argentina in the Spanish language has a subheading which translated to English would read as "continuation of the judgement process" as opposed to the original English text "following the Judgement Process. This translated version reflects the original presented by Argentina.]

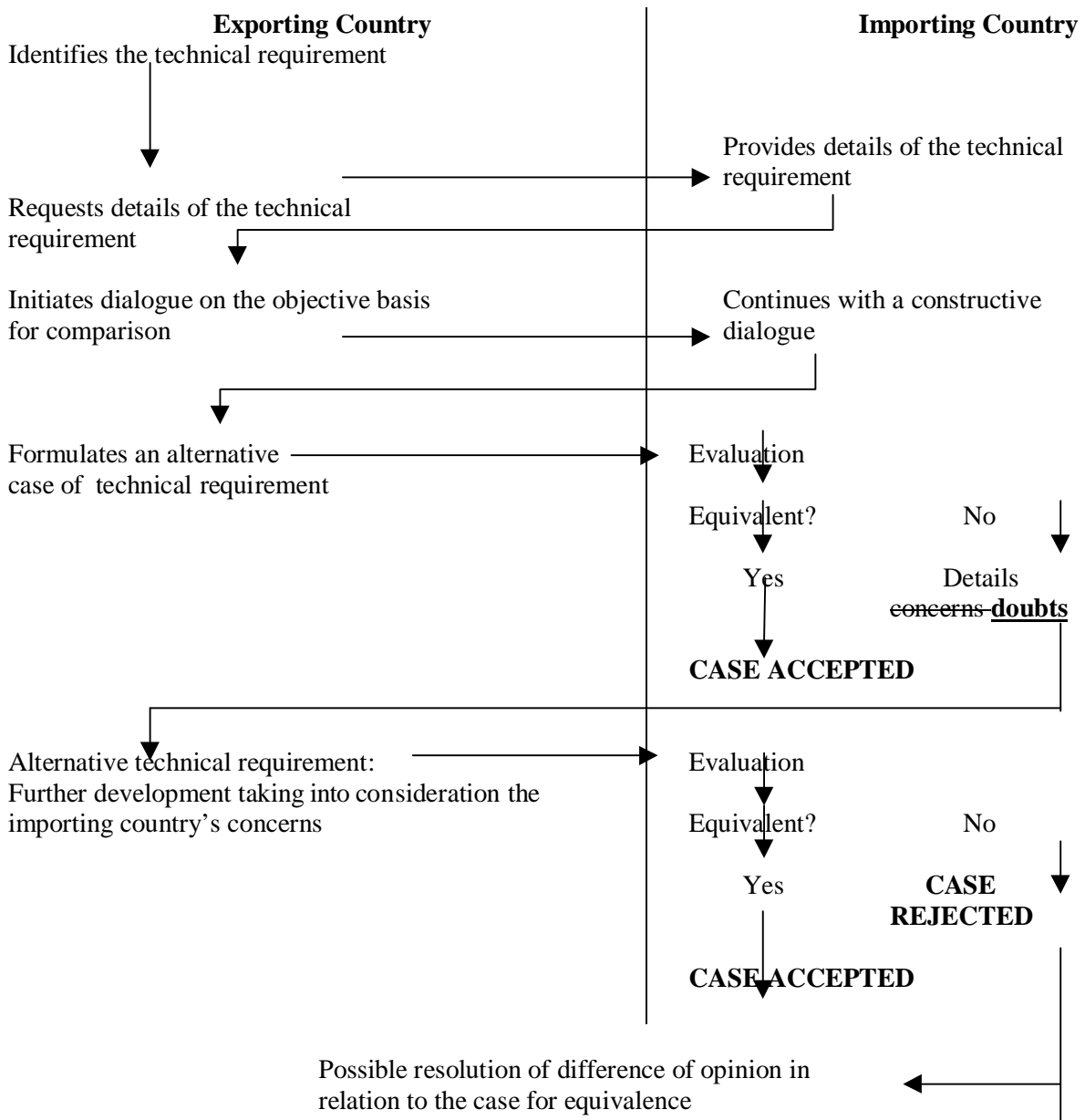
12.- When achievement of equivalence is ~~agreed upon~~ **recognised** by the importing country, the importing and exporting countries may enter into a formal agreement giving effect to that decision. Agreements should be established according to the *Codex Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems* (CAC/GL 34 1999).

13.- Exporting and importing countries, subsequent to a ~~successful~~ agreement in regard to equivalence of technical requirements **and/or conformity assessment procedures**, should advise each other of significant changes in their supporting programmes and infrastructure that may affect the original determination of equivalence.

14.- 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

Figure I: Simplified flowchart for the determination of equivalence
(some steps may be repeated)



BRAZIL

Brazil reiterates its support to the elaboration of this document and considers that, eventually, it should be unified with the document on equivalence of sanitary measures. Brazil emphasized, in several opportunities, that issues of technical regulations and sanitary measures are intertwined and the analysis or judgement of equivalence in such issues in a separate way is extremely difficult. In the text of this document some issues already reflect such connection, namely:

The definition of legitimate objective mentions the SPS Agreement and sanitary measures. In Paragraph 2, the term ‘quality’ is used in footnote 2, encompassing the issue of food safety Footnote 7 – Definition of “Technical Requirement” mentions health issues.

In paragraph 5.1 Brazil asks the meaning of the expression “health practices” to be clarified. We note once more the connection between the two issues above mentioned.

In paragraph 11, Brazil understands the text should take into consideration in the text the situation of an importing country asking the revision of the Agreement on Equivalence because of the detection of problems (fraud, etc.). In view of that, Brazil suggests the following text: “Likewise, when the importing country verifies that the given results do not reach the legitimate objectives previously agreed upon, that country could start the process of revising the existing Agreement.”

For the reasons pointed out above, regarding the connection between technical and sanitary requirements, Brazil favors documents CX/FICS 02/05 and Ap III – ALINOM 01/30^A to follow in the same pace, so that they may be integrated in one single document in the future.

CANADA

GENERAL COMMENTS

Canada believes that these guidelines should specifically address only those technical requirements which relate to the prevention of fraud and ensuring fair practices in the food trade. For those technical requirements which have as their objective the protection of the health of consumers, this document should specify that judgement of equivalence should follow the same process as outlined in the [Proposed Draft] Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.

Canada notes that examples of the application of the guidelines to the different types of technical requirements have not been included in the draft text as suggested by the Committee at its last session. Canada considers such examples important to illustrate the application of the guidelines and to facilitate their further development. As such, Canada encourages the Committee to reiterate the need for their inclusion.

Canada believes that this document should be more consistent in format and layout with the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated With Food Inspection and Certification Systems. For example, a section similar to “Section 4 - Sanitary Measures and the Determination of Equivalence” as found in the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures may be appropriate for this document.

SPECIFIC COMMENTS

Preamble

Paragraph 1

Canada suggests that the examples in the second sentence should be more in line with the definition of technical requirements. “Control of production and processing systems” has a safety connotation, since the phrase is generally used by Codex in relation to control of hazards (e.g., HACCP). The definition of technical requirements actually refers to processes and production methods related to product characteristics. Additionally, the definition refers to conformity assessment procedures, not systems. Hence, we suggest rewording this paragraph as follows: *It is often the case that importing and exporting countries operate different food inspection and certification systems which incorporate different technical requirements. These requirements may relate to matters such as the processes and production methods related to product characteristics, conformity assessment procedures, language(s) used to label products and mechanisms for prevention of fraud.*

Paragraph 3

The structure of the last sentence is confusing and appears to be incorrect. Equivalence does not mean that the technical requirements of an importing country can be met by the exporting country in the “most efficient and effective way”. Rather, equivalence is the meeting of an importing countries legitimate objective through technical requirements that differ from those of the importing country. Canada suggests that the paragraph be reworded as follows:

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. The flexibility afforded by the application of equivalence allows an exporting country, in the design and implementation of its technical requirements, to meet the importing country’s legitimate objective in the most efficient and effective way.

Scope

In the first sentence, unless there is a particular need to emphasize the inclusion of conformity assessment systems, the phrase “including conformity assessment systems” is redundant since conformity assessment procedures are already captured in the definition of technical requirement.

Since “technical requirement” is defined in the Definitions section, the second and third sentences are redundant. As well, the second sentence is not accurate since the definition of technical requirement in this document, which is intended to address Codex needs, is not identical to the definition of technical regulation in the WTO TBT Agreement. Canada would thus recommend that the second and third sentences, along with footnotes 3 and 4, be deleted. We suggest paragraph 4 be reworded as follows:

This document sets out principles and processes to facilitate the determination of equivalence of technical requirements concerning food which have been mandated by governments. This document does not cover judgement of equivalence of sanitary measures. ^[footnote]

New Paragraph to be included in the Scope

As noted in our General Comments, Canada believes that judgement of equivalence of technical requirements which have as their objective the protection of the health of consumers should follow the same process as outlined in the [Proposed Draft] Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems. Canada recommends the addition of a new paragraph in this section as follows:

The judgement of equivalence of technical requirements that are related to the prevention of fraud and ensuring fair practices in food trade should be conducted according to these guidelines. The judgement of equivalence of technical requirements which have as their objective the protection of the health of consumers should be conducted using the process outlined in the [Proposed Draft] Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems.

Definitions

Equivalence

Canada is of the opinion that footnote "6" should be part of the definition of Equivalence and that the new definition of equivalence should be clearly noted as applying only for this document. The definition of equivalence should be as follows:

Equivalence: The capability of different inspection and certification systems to meet the same objectives. In the context of this document, equivalence is further defined as the state wherein technical requirements applied in an exporting country,

Legitimate Objective

In line with our General Comments and other comments relating to Scope, we recommend deletion of the second sentence. Hence, the revised wording would be:

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.

Technical Requirement

Footnote "8" should make reference to the definition of Sanitary Measure as found in the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated With Food Inspection and Certification Systems.

The second sentence of the definition is confusing and duplicative. Canada recommends that it be modified as follows:

Technical requirements are: (1) product characteristics or their related processes and production methods, including applicable terminology, symbols, packaging, marking or labelling provisions; (2) product-related conformity assessment procedures (including sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval); and (3) applicable administrative provisions.

General Principles for Determination of Equivalence

Paragraph 5.1

It would appear that some words are missing in this sentence since Codex does not want to “protect consumers against health”. Suggest to reword the latter part of this sentence as follows:

..... to achieve legitimate objectives that protect consumers from risks to public health and/or deceptive or unfair trading practices.

Paragraph 5.4

As noted in our comments under Scope, since “conformity assessment procedures” are part of the definition of technical requirements, we question the inclusion of this phrase in this paragraph as it appears to be redundant.

Canada suggests that the word “can” be deleted from the 1st sentence and the word “meet” be changed to “meets” in this sentence since the exporting country needs to demonstrate that its technical requirement actually meets the importing country’s legitimate objective.

In the 2nd sentence, Canada suggests to add the words “relevant aspects of the” prior to “program design”. The sentence would read:

... the importing country should take into account relevant aspects of the program design, implementation and monitoring that operate in the exporting country

We also believe that the 2nd sentence may more appropriately belong under the section Procedure for the Determination of Equivalence.

Paragraph 5.5

Consistent with the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated With Food Inspection and Certification Systems, Canada suggests adding to the sentence as follows:

... using an analytical approach that is objective and consistent, and includes consultation with all interested parties to the extent practicable and reasonable.

Paragraph 5.6

Since the words “bilateral or multilateral” may imply that unilateral recognition is excluded, Canada suggests that they be deleted. We suggest that this paragraph be reworded as follows:

Countries should, upon request, enter into consultations with the aim of achieving recognition of the equivalence of specified technical requirements.

Paragraph 5.7

Canada suggests to augment this statement as follows:

The conduct of the judgement process should not be in itself a reason to disrupt or suspend existing trade.

Procedure for the Determination of Equivalence

Paragraph 6

Codex standards and guidelines should not include presumptions. Suggest to rewrite in a more factual manner, as per the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated With Food Inspection and Certification Systems; i.e.

The importing country should make available details of its technical requirements to the exporting country on request. The exporting country should review all applicable technical requirements of the importing country for the food involved and identify those for which it seeks a determination of equivalence.

Paragraph 8

Canada recommends that the word “countries” be replaced by “the importing country” and “each other’s” be replaced by “the exporting country’s” in the first line. The word “relevant” should be linked to the judgement of equivalence and thus we recommend that it be deleted prior to “conformity assessment programs” and be inserted prior to “system elements”. The revised wording for this paragraph would be as follows:

Where the importing country lacks extensive experience with, or detailed knowledge about the exporting country’s control systems or 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 relevant system elements.

Paragraph 9

Canada suggests that the word “both” prior to “exporting and importing countries” be deleted as it is redundant.

Paragraph 9.4

A different technical requirement cannot achieve the importing country’s technical requirement. As previously stated, equivalence is where the exporting country’s technical requirement is capable of achieving the objective of the importing country’s technical requirement. Suggest to reword the sentence as follows:

The exporting country develops the submission to demonstrate that its different technical requirement(s) is capable of achieving the legitimate objective established by the importing country.

CZECH REPUBLIC

Thank you very much for your circular letter CL 2001/25-FICS in which you request us for comments on matters arising from the Codex Committee on Food Import and Export Inspection and Certification Systems. After carefully reading up and receiving references from our experts on the topic in discussion we are sending you the following notes:

Comments on the proposed draft guidelines for the judgement of equivalence of technical requirements associated with food inspection and certification systems (Step 3).

Paragraph 4

The sentence “these mandatory technical regulations are defined as technical requirements in this document” does not seem to be necessary. What do technical requirements covered by this guideline mean is already defined in the previous sentence.

Definitions

Equivalence

We suggest changing the last part of the sentence into the plural form so that it better corresponds with the beginning of the sentence.

“...,achieve the importing country’s stated objectives for those technical requirements.”

Legitimate objective

We suggest adding the underlined connection in the 1st sentence of the definition similarly as mentioned in other parts of the document:

“..., of a technical requirement intended to protect the health of consumers and/or prevent deception or fraud in relation to food trade.”

Paragraph 5.1

The word “risk” is missing: “.... against health risks and/or deceptive....”

Paragraph 5.3, 9.7

Before the word “objective” insert word “legitimate” according to the definition.

Paragraph 5.4

Complete the end of the 1st sentence with: “.....legitimate objective(s).....” We suggest inserting the underlined text into the 2nd sentence. The text will better correspond to other parts of this guideline (eg paragraph 8).

“...the importing country should take into account a food control or relevant conformity assessment program design, implementation....”

Paragraph 5.6

In order to coincide with other paragraphs of the document we suggest putting the underlined text at the beginning of the sentence:

“Exporting and importing countries should....”

Paragraph 5.9

In order to coincide with other paragraphs of the document we suggest putting the underlined text at the beginning of the sentence:

“Exporting and importing countries should....”

Paragraph 8

We suggest inserting the underlined text to specify context of the paragraph: “Where exporting or importing countries lack extensive experience...”

Paragraph 9.4

We propose amending the sentence as follows:

“...that its different technical requirement(s) is capable of achieving the legitimate objective of the importing country technical requirement,...”

Paragraph 9.8

We suggest altering the end of the sentence as underlined: “...of its judgement as soon as possible.”

Reason: This could cause more incentive effect for the importing country as for period of time when notification of judgement should be delivered to the exporting country.

Paragraph 11

We suggest adding the underlined text so that it is more comprehensive:

“...should advise each other of significant changes in their supporting programmes and infrastructure and of changes in the technical requirements that may affect the original determination of equivalence.

We hope that our comments are acceptable for you and can help in further development of the draft Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems. We would also like to participate on the preparation of CAC documents more actively than we have done so far.

FRANCE

PRELIMINARY REMARK

France’s comments at the working group which were sent to Australia have not been taken into account. France also regrets there has been no exchange about the comments made by the other members of the working group.

GENERAL REMARK

The title, and of course references to it in the text, illustrate the whole ambiguity of the subject, which does not clearly distinguish between the comparison of technical specifications and the control means implemented to ensure their observance. It was noted in the report of the 47th session of the Codex Alimentarius Commission Executive Committee, Alinorm 01/3, that the document should highlight the requirements of the systems.

The title could, therefore, be reworded as follows:

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

PREAMBLE

Paragraph 1'

In the 1st sentence replace “that incorporate” by “to ensure the observance of”.

In the 2nd sentence replace “may” by “always”.

Paragraph 1 thus reads : “It is often the case that importing and exporting countries operate different food inspection and certification systems to ensure the observance of different technical requirements. These requirements always 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.”

Paragraph 3

With reference to the general remark, it is requested that paragraph 3 be deleted.

SCOPE

Paragraph 4

Insert “of conformity to” after “determination of equivalence”.

With reference to the general remark, delete “including conformity... food”.

Delete the 2nd and 3rd sentences, as this is a Codex text. It seems to us no reference should be made to the TBT, especially when the references are infinitely variable. The technical requirements are defined in the following section. Furthermore, we cannot talk of equivalence with regard to many technical requirements, particularly when they relate to product characteristics (e.g., fat content, vitamins...). We should talk of mutual recognition of provisions and equivalence of control means. In conclusion, there are two aspects in mastering the technical requirements with the mutual recognition options and the efficiency of the control means. One should be aware that the former is tantamount to claiming that Codex standards are completely devoid of interest, which is a paradox.

Paragraph 4 thus reads : “This document sets out principles and processes to facilitate the determination of equivalence of conformity to technical requirements. This document does not cover judgement of equivalence of sanitary measures ⁵.”

DEFINITIONS

Equivalence

The same term cannot be used for two different definitions. The text of footnote ‘6’ should be reworded : “Capability of inspection and certification systems to meet the same objectives” and completed by “These objectives may be expressed by technical rules (which may be mutually recognized if they are different)”.

Legitimate objective

In the 1st sentence insert “*inter alia*” after “in relation to”. The 2nd sentence should be deleted as it rewrites the TBT Agreement based on the SPS Agreement. The definition thus reads : “The clearly stated purpose, that is both genuine and achievable, of a technical requirement intended *inter alia* to protect the health of consumers or prevent deception or fraud in relation to food trade.”.

Technical requirement

Footnote ‘8’: change it to : “as defined in the proposed draft guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems.”

GENERAL PRINCIPLES FOR DETERMINATION OF EQUIVALENCE

Paragraph 5

With reference to the general remark, delete “technical requirements associated with”, and insert “associated with technical regulations” after “certification systems...” The paragraph thus reads : “Determination of the equivalence of food inspection and certification systems associated with technical regulations should be based on application of the following principles:”.

Paragraph 5.1

Insert “*inter alia*” after “legitimate objectives that protect”. The paragraph thus reads : “An exporting country should recognize that an importing country has the sovereign right to apply technical requirements in order to achieve legitimate objectives that protect consumers, *inter alia*, against health and/or deceptive or unfair trading practices.”.

Paragraph 5.3

Equivalence of means is not automatic, so in the 1st sentence replace “may be capable of achieving” by “may be achieved” and end the sentence at “its technical requirements”. After this 1st sentence, add “This objective may be achieved by different technical rules which may be mutually recognized, and the implementation of which may be the subject of a request for equivalence determination by an exporting country.”.

The paragraph thus reads : “An exporting country should recognize that the objective of its technical requirement may be achieved by different means. This objective may be achieved by different technical rules which may be mutually recognized, and the implementation of which may be the subject of a request for equivalence determination by an exporting country.”

Paragraph 5.4

In the 2nd sentence, replace “programme ... monitoring” by “monitoring ... procedures”. The paragraph thus reads : “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 monitoring design, implementation and procedures that operate in the exporting country and underpin consistent achievement of equivalence of the importing country’s technical requirement(s).”.

Paragraph 5.6

After “bilateral or multilateral recognition”, insert “means for observing the”.

The paragraph thus reads : “Countries should, upon request, promptly enter into consultations with the aim of achieving bilateral or multilateral recognition of means for observing the equivalence of specified technical requirements.”.

PROCEDURE FOR THE DETERMINATION OF EQUIVALENCE

Paragraph 7

In its current wording the paragraph is hard to understand. It may be clarified by changing “*L’expérience et la connaissance détaillée qu’un pays exportateur a des systèmes d’inspection et de certification des denrées alimentaires...*” to “*L’expérience et la connaissance détaillée par un pays importateur des systèmes d’inspection et de certification des denrées alimentaires d’un pays exportateur...*”

[Translator’s comment : the rewording of this sentence is an attempt to clarify and improve the translation stylistically – it does not change the meaning of the English original nor of the French translated version .]

- replace “in itself be sufficient to allow” by “serve as a basis for”.

The paragraph thus reads : “Experience and detailed knowledge of an exporting country’s food inspection and certification systems may serve as a basis for objective judgement of equivalence by the importing country.”.

Paragraph 9.2

Delete the 2nd bullet, the wording of which is unsuitable as the risks are included in the objective.

The paragraph thus reads : 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

elements of systems implemented to ensure compliance with the stated requirement.”

Paragraph 9.10

Replace “A final judgement of equivalence” by “A final judgement on equivalence”. Insert “and its implementation” after “the proposed technical requirement”.

The paragraph thus reads : “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 and its implementation are deemed not equivalent.”

FOLLOWING THE JUDGEMENT PROCESS

Paragraph 10

Replace “When achievement of equivalence is agreed upon” by “If equivalence is recognized”. The paragraph thus reads : If equivalence is recognized 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 Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification systems (CAC/GL 34 1999)*.”

Paragraph 11

Insert “of the implementation” after “in regard to equivalence”.

Replace “their supporting programmes and infrastructures” by “their programmes for the implementation of technical requirements or their control infrastructure”.

The paragraph thus reads : “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 programmes for the implementation of technical requirements or their control infrastructure that may affect the original determination of equivalence.”

NEW ZEALAND

The New Zealand Government would like to make the following comments:

General

New Zealand supports advancement of this draft within the Codex system taking into account our specific comments. New Zealand believes that this document should take a separate path through the Codex process and any discussion, debate or amendment of this draft should not delay the progress of the Proposed Draft Guidelines for the Judgement of Equivalence of Sanitary Measures also being considered by this committee.

Specific Comments

Definitions – Legitimate Objective

The first sentence of the definition should be reworded as follows:

‘The clearly stated purpose, that is both genuine and achievable, of a technical requirement intended to protect the health or safety of consumers or prevent deception or fraud in relation to practices in food trade.’

This wording better reflects the wording in the Agreement on Technical Barriers to Trade. The second sentence should be deleted it is confusing to refer to the Agreement on the Application of Sanitary and Phytosanitary Measures when these guidelines are applicable to the Agreement on Technical Barriers to Trade. The second sentence is also commentary on implementation or assessment of the term being defined rather being an actual definition.

General Principles for Determination of Equivalence

Paragraph 5.1 – to maintain consistency with the definitions and the Agreement on Technical Barriers to Trade this principle should be reworded as follows:

‘An exporting country should recognise that an importing country has the sovereign right to apply technical requirements in order to achieve legitimate objectives for the protection of human health or safety, or prevention of deceptive or unfair trade practices.

Paragraph 5.2 – this principle seems redundant and should be deleted. The definition of a ‘legitimate objective’ already stated that it is a ‘clearly stated purpose’ and the principle in paragraph 5.8 states that the objective of a technical requirement should be expressed in a way to facilitate comparison.

Paragraph 5.3 – the word ‘legitimate’ should be added before ‘objective’ so as to make a clear link to the defined term.

Paragraph 5.4 – this paragraph contains two principles, one related to the exporting country (1st sentence) and the other related to the importing country (2nd sentence). Each should be in a separate paragraph. The second principle is also currently focused on the process the importing country should apply rather the principle that underlies the process. We suggest that this second principle be reworded as follows:

When evaluating the equivalence of technical requirements the importing country should take into account any information it has of the exporting country’s systems and the performance of those systems.

Paragraph 5.5 – this principle should be reworded as follows:

‘The determination of equivalence by the importing country should be conducted in an objective and consistent manner.’

Paragraph 5.7 – this principle should be reworded as follows:

‘The conduct of a determination of equivalence process should not affect existing trade.’

Paragraph 5.8 – the word ‘legitimate’ should be added before ‘objective’ so as to make a clear link to the defined term.

Paragraph 5.9 – the concept of transparency should be built into the principles of demonstration (1st sentence of current 5.4) and determination (current 5.5) in which case the need for a separate principle. However, if the principle is intended to reflect a wider concept then it needs to include the aspect of consultation with interested parties, in which case the principle should be amended by adding at the end ‘consulting all interested parties to the extent practicable and reasonable’.

New Zealand also suggests that the principles in paragraph 5 need to be reordered so there is a better flow of logic, for example the current 5.8 would be better placed before 5.4; and the current 5.6 should come before 5.5.

Procedure for the Determination of Equivalence

Paragraph 8 – this paragraph is the correct place to make reference to the elements of the importing country’s systems that need to be considered. This information is currently contain in paragraph 5.4. We suggest that paragraph 8 be amended by adding at another sentence at the end as follows:

Such a comparison should take into account programme design, implementation and monitoring that occur in the exporting country and underpin consistent achievement of the importing countries technical requirements for which equivalence is being sought.

Paragraph 9.9 – this paragraph should end after ‘an agreed mechanism’. Stating that an attempt to resolve will ‘reach consensus’ implies that there will be positive resolution of a difference of opinion when this may not be the case. Even with discussion a difference of opinion may not be resolved and a request for determination of equivalence may in the final event be

MEXICO

General Comments:

For the Spanish language version, we suggest the use of “requisitos técnicos” (‘technical requirements’) in the title of the aforementioned document appearing in the front cover page.

We suggest the incorporation of the following considerations throughout the document⁷.

That the technical requirements set down comply with the Codex objectives (protection of human health and fair trading practices) and that they do not become obstacles to trade.

- That the parties establish the process of equivalence determination upon agreement.
- That it shall not restrict any trading schemes or mechanisms already in place or that their implementation be agreed upon as soon as equivalence is determined.
- The absence of an equivalence agreement shall not constitute reason to restrict the trading of products.
- That the process of determination of equivalence must be agreed to upon a broad basis for negotiation and must not be the result of a unilateral decision through which the exporting country is a mere provider of information.
- That the negotiation process implies an open dialogue between the importing country and the exporting country, with the presentation of arguments, questions, debate, presentation of evidence, joint evaluation and agreed determination, taking into account throughout the process, where possible and reasonable, the opinion of all interested parties.
- That in order to facilitate the process of determination of equivalence of sanitary measures, and to prevent the process from becoming an obstacle which restricts food trade, the decision to evaluate solely those elements within the inspection and certification system associated with the product intended for trade should be considered, elements which enable the determination whether the ALOP being provided through the application measures is at least the ALOP established by the importing country.

Paragraph 2

We suggest an amendment to the wording: “The relevant prerequisite HACCP plans should be operating...” to “The prerequisite HACCP programmes should be operating...”

We suggest an amendment to the wording: “The HACCP steps correlate in this annex with elements...” to “The HACCP steps relate here to the elements...”

Title in the table:

We suggest this be amended to read: “The following table presents a summary of elements of a quality assurance system described in the present document, within which the HACCP steps of Codex may be documented”.

Table:

Training Policy is repeated in bullets 2 and 3.

⁷ Consideration must be given to Mexico’s comments on the “Appendix III Draft Guidelines for the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems”.

Point 7 – add the following elements: identification and analysis of factors to be monitored and monitoring measures for the minimisation or elimination of factors that may compromise quality.

Point 10 – and the following element: monitoring measures for the minimisation or elimination of factors that may compromise quality. Replace the term “plaza” with “mercado” (market). Consider that the elements: Structure of defined management with specification of responsibilities and a training policy which are mentioned in each HACCP step, consider a more specific relationship between these two steps and the elements of a quality assurance system.

- That countries define, within the context of the agreement under consideration, those elements of the inspection and certification systems which may be relevant for examination and evaluation in order to determine equivalence.

Furthermore, we suggest an amendment to the procedure for equivalence determination so that the process becomes an act of balanced negotiation amongst the parties.

UNITED STATES

Thank you for the opportunity to comment on the Draft Guidelines on the Judgment of Equivalence of Technical Regulations Associated with Food Inspection and Certification Systems.

The United States notes that, as contrasted with the development of the companion document on the judgment of equivalence of sanitary measures, CCFICS has not had the opportunity to consider specific examples of how the judgment of equivalence could be applied to technical regulations/requirements. Governments would benefit from a focused discussion that would seek to identify the problems this document is intended to address. The value of this document has yet to be examined in practical terms and such a discussion of real-life examples would assist in this regard.

The Committee should consider the manner and extent of application of these guidelines and what needs of countries will be met by their application. Thus, countries may be asked to propose specific practical examples of TBT-related equivalence determinations that might be considered. Such an exercise will help to clarify for countries how the guidelines might be applied in practice, and could help in evaluating the correctness of the principles and steps presented in the guidance. Also, it would help to clarify those areas that have both safety and non-safety elements (e.g., product labelling) and that may have applicability to both this document and the document on the judgment of equivalence of sanitary measures.

The United States would not support advancement of the document in the Codex Step Procedure until this discussion occurs and the Committee has an opportunity to consider the results of the discussion.

The United States may provide additional comments on the document prior to the 10th Session of CCFICS.