codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FICS 00/7 Add 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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

CANADA

INTRODUCTORY DIALOGUE

Although this text will not become part of the Guidelines, Canada wishes to correct a misrepresentation of the TBT Agreement to reduce the possibility of misunderstanding in the guidelines themselves.

Paragraph 5 - 3rd bullet
Although technical regulations are prepared, adopted and applied to fulfil the legitimate objective of protection of human health or safety, labelling of products which contain potential allergens is not an appropriate example. Labelling for allergens is an SPS measure. Annex 1 of the SPS Agreement defines sanitary or phytosanitary measures as including "packaging and labelling requirements directly related to food safety". A better example regarding public health would be those measures related to nutrition claims and concerns.

GUIDELINES

GENERAL COMMENTS

Canada notes that several terms are used which are either similar (e.g., technical requirements, legitimate requirements, requirements, relevant requirements) or appear to have the same intent (objectives, reason/purpose, outcomes). Consistent use of terms is encouraged to enhance common understanding. For example, care must be taken to clearly distinguish the use of "requirements" (as defined in the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Certification Systems* (CAC/GL 26-1997)) and "technical requirements" as defined in this document, since the meanings are quite different. Canada recommends that the above noted terms, and

their application in the guidelines, be scrutinized with the intent to identify those which will be used consistently in the document. Canada has made some suggestions for use under SPECIFIC COMMENTS.

SPECIFIC COMMENTS

Title

Canada suggests to revise the title by changing "Technical Regulations" to "Technical Requirements" to reflect the 2nd bullet under paragraph 5 of the Introductory Discourse (i.e., the use of the term "technical requirements" to encompass the technical regulations and conformance assessment systems under the TBT Agreement which are relevant to the application of the equivalence principle).

Preamble

Paragraph 2

In line with the decision of the 47th Session of the CCEXEC, Canada suggests the addition of the words "safety" and "conformity"; i.e., ... *as the means of achieving their desired level of safety, quality and conformity for domestically produced or imported food, ...*

Paragraph 4

The use of the word "requirements" in the first sentence is ambiguous. Is it intended to mean: 1) requirements (as defined in the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Certification Systems* (CAC/GL 26-1997)); 2) requirements as defined in this text (Technical requirements); or 3) objectives as used in the Equivalence definition or the TBT Agreement? Canada suggests using the word "objectives" since equivalence is the state whereby different technical requirements achieve the importing countries legitimate objectives; ie., *Application of the principle of equivalence ..... allow the importing country's legitimate objectives to be met.*

In the last sentence, the use of " technical requirements" is inaccurate. Harmonization is where exported food "meets the technical requirements of the importing country". Equivalence is where exported food "meets the objectives of the technical regulations of the importing country". Canada suggests to rewrite the sentence as: *"... while ensuring that exported food meets the objectives of the technical requirements of the importing country."*

Scope

Canada suggests that the second sentence be revised to more definitively reference the equivalence document for sanitary measures: The sentence would now read:

> *The technical requirements covered by this guideline do not include sanitary measures as defined in the [proposed draft] Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems; the determination of equivalence of sanitary measures is dealt with in that guideline.*

The text in square brackets acknowledges that the other document is still in development and the text would be deleted once the document has been adopted by the CAC.

Definitions

Equivalence
The proposed definition contains two paragraphs, one of which is consistent with the text adopted at the 23rd Session of the CAC when the Commission adopted the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems.* The second paragraph is helpful to clarify the definition for the purposes of this document but this should be made clear. Canada suggests starting the second paragraph as follows: *In the context of this document, equivalence is further defined as the state wherein technical requirements .....*

Technical Requirement
The text, *"...with which compliance is mandatory"* at the end of the definition appears to apply only to the "applicable administrative provisions" rather than applying to all regulations, rules, standards, codes or other criteria for food (as stated in the 2nd bullet, paragraph 5 of the Introductory Discourse). Canada suggests moving this phrase to the first sentence. As well, in the first sentence, Canada suggests deleting the phrase "a condition of importation". Under the principle of non-discrimination, technical requirements must apply equally to imported products and like products of national origin. Suggest the following rewrite: *"Any regulation, rule, standard, code or other criteria for food, not being sanitary or phyto-sanitary measures[3], set down by competent authorities, with which compliance is mandatory.*

Paragraph 8.4
A different technical requirement cannot achieve the importing country's technical requirement. As previously stated, equivalence is where the exporting country's technical requirements is capable of achieving the objective of the importing country's technical requirement.

In the 2nd bullet, Canada suggests replacing "outcomes" with "objectives".

In the 4th bullet, given the objectives of technical regulations include more than food safety (eg., composition, quality, packaging), risk assessments to justify technical regulation are not always necessary. Canada suggests replacing "presented" with "appropriate"; i.e., *Reference to Codex risk assessment methodologies where available, if risk assessments are appropriate.*

NEW ZEALAND

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

New Zealand is supportive of further development of these draft guidelines, recognising the fact that the common thread joining judgement of the equivalence of sanitary compared with technical measures is an objective basis for comparison. However, the basis presented in this paper for such judgements in the case of technical regulations is strongly weighted towards the material presented in Agenda item 00/6, and this may not be entirely appropriate.

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS

The International Association of Consumer Food Organizations (IACFO) wishes to make the following comments on the Proposed Draft Guidelines For The Judgement of Equivalence of Technical Regulations Associated With Food Inspection And Certification Systems (hereinafter "draft guidelines"), prepared by Australia with the assistance of France, South Africa, and the United States.

General Comments

The proposed draft guidelines fail to ensure that equivalency agreements will not lead to a lowering of consumer protection standards in order to facilitate trade. We urge the Codex Committee on Food Import and Export Inspection and Certification Systems (hereinafter "the committee") to make the following amendments to the draft guidelines in order to correct this problem. Such changes will be necessary to prevent equivalency agreements from undermining public confidence in imported foods and from diminishing public support for further liberalization of policies regarding the international food trade.

Specific Comments

In paragraph 6.4, change the phrase "*involve all interested parties"* to "*involve non-governmental organizations and other members of the public."* This change will make it clear that the judgement on equivalence is not merely between governments.

In paragraph 6.9, change "*all parties*" to "*nongovernmental organizations and other members of the public*." This change will make it clear that governments are not the only parties with an interest in transparency.

Paragraph 6.9 fails to specify the means by which transparency can be assured in the equivalency judgement process. To correct this problem, we urge that the following sentence be added to the end of paragraph 6.9:

"The exporting country must provide the importing country and other interested non-governmental parties access to adequate information about its regulatory activities in order to facilitate an initial determination of equivalence and verification of an ongoing equivalency agreement."

We urge that a new paragraph 6.11 be added to the draft guidelines specifying mechanisms that can be used to verify equivalency determinations. After an equivalency agreement is reached, on-going verification is essential to ensure that the exporting country continues to administer and enforce the measures that were found to be equivalent. We thus urge that a new paragraph 6.11 be added as follows:

"6.11 All judgements of equivalence must specify mechanisms by which the importing country can verify that the exporting country continues to administer and enforce the measures that form the basis of such agreement. Such measures may include, but are not limited to, on-site audits and evaluation of the exporting country's facilities, end product testing, periodic reviews, and if necessary, re-negotiation of the agreement."

Paragraph 8.8 should be deleted. Despite the draft guidelines' recognition in paragraph 6.1 of an importing country's right to make its own equivalency determination, paragraph 8.8 undercuts that fundamental right by providing that "any bilateral differences of opinion" can be resolved by using "an agreed upon mechanism to reach consensus." Because a finding of equivalence should be based on the importing country's judgement -- not on the judgment of an outside committee of experts -- we believe this paragraph should be deleted. If this paragraph is not deleted, a sentence should be added at the end to clarify that "*an importing country has an absolute right to determine whether the exporting country's measures are equivalent to its own."*

Paragraph 8.9 fails to ensure than equivalency determinations are made in an open and transparent manner that will build public confidence in the safety of imported foods. The paragraph should be re-worded as follows:
"8.9 Judgement of equivalency by the importing country should be based on an analytical process that is objective, *consistent and transparent. Governments should receive input from all interested non-governmental parties at both the initial stages of the development of an equivalency agreement and again before a final determination is made. The final determination should take into account comments received from interested non-governmental parties and when announced, should contain an explanation of why the responsible national authority accepted or rejected the comments from interested non-governmental authorities. Failure to comply with this provision shall constitute adequate grounds for denying a determination of equivalency."*

In paragraph 9, add at the end *"All equivalency agreements should contain an expiration date no more than five years from the date of the initial determination of equivalency."* This requirement will compel governments to periodically review and update agreements to take account of changes in infrastructure, regulatory procedures, and other matters that may affect the original determination of equivalency.

IACFO believes that these changes will help address criticisms of the equivalency process and ensure that equivalency agreements, while facilitating trade, do not lower consumer protection standards. We urge the committee to consider them fully.