

# codex alimentarius commission



FOOD AND AGRICULTURE  
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**Agenda Item 6**

**CX/FICS 00/6 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**

**Perth, Australia, 11 – 15 December 2000**

#### **COMMENTS ON THE PROPOSED DRAFT GUIDELINES ON THE JUDGEMENT OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND CERTIFICATION SYSTEMS**

##### **CANADA**

Canada is pleased to offer the following comments on the *Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems, CX/FICS 00/6*

##### **Preamble**

##### **Paragraph 3**

While Canada concurs with this statement, there may be some value in expanding this paragraph to give one or two examples of the mutual benefits.

##### **Definitions**

##### **Sanitary measure**

Canada recommends the removal of the text in square brackets. Regardless of the ultimate source of a hazard entering the food chain, the importing country will establish measures designed to protect human health. The text “*or feedstuffs*” is redundant.

##### **Appropriate level of protection**

Canada suggests removing the square brackets and retain the text: *This can otherwise be referred to as the “acceptable level of risk”*.

##### **Equivalence**

To maintain consistency with the definition in CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Certification Systems (CAC/GL 26-1977), Canada suggests modifying this definition as follows:

*“Equivalence is the capability of different inspection and certification systems to meet the same objectives. [add footnote referencing above document] In the context of this document, Equivalence is further defined as the state wherein .....”.*

### **[Sanitary Measures Involved in the Determination of Equivalence]**

Canada suggests that the square brackets around this title (immediately preceding paragraph 6) be removed, and that the title be modified as follows “*SANITARY MEASURES AND THE DETERMINATION OF EQUIVALENCE*”. The Sanitary measures are not directly involved in the determination of equivalence; rather the equivalence process is designed to determine the equivalence of the sanitary measures. This section (paragraphs 6-9) really just elaborates further on how the term Sanitary Measures is used in this document.

#### **Paragraph 9(b)**

Canada would suggest adding the words, “*i.e., how the sanitary measures achieve, or contribute to the achievement of the ALOP*” to the end of this paragraph. This establishes a more direct link between paragraph 9(b) and the following paragraph 10.2

#### **Paragraph 9(d)**

Canada suggests deleting the words “and available”. Equivalence determinations would generally be requested when sanitary measures are not based on international standards. In those cases, the WTO SPS Agreement requires that those measures be based on an assessment of risk to human life or health.

#### **Paragraph 10**

Canada suggests removing the text in square brackets in the title immediately preceding Section 10. Demonstration of equivalence by the exporting country is but one element of the process leading to the final determination (or judgement) of equivalence by the importing country. Therefore, “*Determination*” is more appropriate.

#### **Paragraph 10.1**

As importing country is in the singular, the last part of this para should read “*...level of protection it deems appropriate in relation to its food supply.*”

#### **Paragraph 10.2**

Canada suggests that the square brackets be removed and the text be retained without change.

#### **Paragraph 10.3**

Add the word “country” after “importing” in this para, i.e., “*An importing country should ....*”.

#### **Para 10.6**

Canada suggests adding a new paragraph after paragraph 10.6 to reflect the responsibility of the importing country to make a determination based on science; i.e.,

*“It is the responsibility of the importing country to determine on a scientific basis whether or not the exporting country’s sanitary measures can meet the importing country’s ALOP.”*

#### **Paragraph 10.8**

Canada suggests that the square brackets be removed and the text be retained without change.

### **Paragraph 10.9**

Canada suggests that the text in the square brackets be removed. The purpose of this principle is not clear. The WTO SPS Agreement stipulates that sanitary measures shall be applied only to the extent necessary to protect human health, whether or not such measures are the subject of an equivalence determination.

### **Guidelines for the Determination [Assessment] of Equivalence**

Canada suggests that the text in square brackets in this title be removed. The reasoning is similar to that provided for the previous title. “*Determination*” is more appropriate.

### **Paragraph 13**

Canada recommends that the text in the square brackets be removed. If it remains, Canada suggests that the words “agreed upon” be replaced with “determined” to more accurately reflect the process outlined in these guidelines, i.e., “*Where achievement of equivalence is determined by the importing country.....*”.

### **Paragraph 15**

This is an exact duplication of paragraph 11 and should be removed.

### **Paragraph 21 - 4<sup>th</sup> bullet point**

Correct the typographical error near the end of the point - “*control of hazards in foods is not quantified.*”

### **Figure 1: Flow chart for the determination of equivalence**

Editorial changes made to the last step in the exporting country side have resulted in a minor error that should be corrected. The word “of” is now superfluous and it should read “*Alternative sanitary measures ....taking into account importing country concerns*”.

## **CZECH REPUBLIC**

### **General principles for determination (demonstration) of equivalence**

Paragraph 10, 10.3 - after the word „importing“ insert the word country

Reason: the word is missing

### ***Guidelines for the determination (assessment) of equivalence***

Paragraph 11 – the text is the same as that at part „Steps“, paragraph 15 - we suggest to think about the change of paragraph 15 or to delete it

## **INDIA**

Under Definition of Appropriate Level of Protection, to ensure that level of appropriateness does not result into non-tariff barrier it is necessary that it is supported by scientific justification. In view of this, the following should be added

“With Scientific justification” after the word “appropriate”

**Point No. 7** Under (c) “methods of sampling and inspection” the following to also be included.

Guidelines for determination (assessment of equivalence).

In **Point No. 11**, it is indicated that determination of equivalence presumes that the exporting country has already reviewed all sanitary measures applicable in the importing country. however, at times all sanitary measures may not be available to the exporting country. It is therefore proposed that the following point be added before Point no. 11.

“It is the responsibility of the importing country to make available details of its sanitary measures to the exporting country.”

In view of the above, point No. 11 to be modified as follows:

“Once the exporting country had reviewed all applicable importing country’s sanitary measures for the food involved, and has identified those it will meet and those for which it seeks determination of equivalence, the next stage would follow.”

**Point No. 13** the following words to be added at the beginning:

“The importing country should first make available clearly its requirements for equivalence. The exporting country should then \_\_\_\_\_.”

**Point No. 16 and also Figure 1**

The first point would be “he importing country provides its sanitary measures to the exporting country”.

## **NEW ZEALAND**

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

New Zealand thanks the other members of the drafting group for their contribution to the development of these draft guidelines.

New Zealand supports the further development of these guidelines and their advancement in the step process.

## **UNITED STATES**

### **General Comments**

The United States supports the effort to develop guidelines on the judgement of equivalence, and appreciates the fine work of the drafting group.

### **Specific Comments**

#### **Preamble**

**Paragraph 2:** The reference to the SPS Agreement should reflect that equivalence is an obligation of WTO Members. We would suggest that this can be addressed by adding the following phrase to the end of the last sentence of paragraph 2 “which is an obligation of signatories to the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures”. The footnote could then be deleted.

### **Sanitary Measures Involved in the Determination of Equivalence**

**Paragraph 9 (c):** Delete the reference to “food safety objective”. Given that the text has excluded all references to food safety objectives, it would be confusing to make such a reference.

**Paragraph 9 (d):** Replace with the following: “the scientific basis for sanitary measure under consideration, including risk assessment where appropriate and available”

### **General Principles for Determination (Demonstration) of Equivalence**

**Paragraph 10.3.** Insert “country” after “importing”. Also, replace “are” with “can” and add “be found” before “equivalent”. The revised sentence would then read: “An importing country should recognize that sanitary measures different from its own may be capable of achieving its ALOP, and can therefore be found equivalent.”

**Paragraph 10.8:** Replace with the following: “Where it is available and appropriate to use risk assessment in the demonstration of equivalence, the exporting country should explain the methodologies applied.”

**Paragraph 10.9:** Delete. This statement is unclear, and does not articulate a principle for determining equivalence.

**Paragraph 10.11:** Replace with: “Countries should ensure transparency in both the demonstration and judgement of equivalence.”

### **Guidelines for the Determination (Assessment) of Equivalence**

**Paragraph 11** is identical with paragraph 15. We suggest deleting paragraph 15.

**Paragraph 13:** The bracketed text should be moved further down in this section, perhaps as a new paragraph following paragraph 16 (including its sub-points).

**Paragraph 14:** Place this paragraph before paragraph 13.

**Paragraph 16.3:** Delete. This step is adequately addressed in paragraph 17. The basis for comparison needs to be objective, but it is inappropriate to identify a step that suggests the importing and exporting parties must agree, i.e. negotiate how the importing country will undertake its basis of comparison.

**Paragraph 18:** Change the word “should” to “may” on line four.

**Paragraph 19:** Insert the word “may” after “under consideration” on line three.

**Paragraph 21:** Change “should” to “may” on the first line. Also:

- In the second bullet point, add “as appropriate” after “other sanitary measures”.
- Delete bullet point three.

### **Figure I: Flow Chart for the Determination of Equivalence**

Third point under exporting country: Delete “on objective basis for comparison”.

## **INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS**

The International Association of Consumer Food Organizations (IAFCO) wishes to make the following comments on the Proposed Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (hereinafter “draft guidelines”), prepared by New Zealand with the assistance of Argentina, Australia, Canada, France, Japan, the United States, and the European Union.

### **General Comments**

The proposed draft guidelines fail to ensure that equivalency agreements will not result in a lowering of public health 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 the safety of imported foods and from diminishing public support for liberalization of policies regarding the international food trade.

### **Specific Comments**

In the first sentence of paragraph 4, change “human health” to “human life or health.” This change makes the scope of the draft guidelines consistent with the scope of the SPS Agreement.

In the definition of Sanitary measure in paragraph 5, change the phrase “protect human health” to “protect human life or health.” Again, this change is necessary to make the definition consistent with the language of the SPS Agreement.

In the definition of “Risk management” in paragraph 5, change the phrase “in consultation with all interested parties” to “in consultation with non-governmental organizations, and other members of the public.” This change will make it clear that the consultation is not merely between governments.

In the definition of “Appropriate level of protection” in paragraph 5, change “human health” to “human life or health.” This change will make this definition consistent with Annex A of the SPS Agreement.

In the definition of Equivalence in paragraph 5, remove the brackets around “as demonstrated by the exporting country.” This is an essential change that is necessary to make this definition consistent with Article 4 of the SPS Agreement, which squarely places this responsibility on the exporting country.

Paragraph 7(a) should be amended to include the state of the transportation infrastructure in an exporting country. The following specific language should be added immediately before the end of that section, “and transportation infrastructure;”

Section 10.11 of the draft guidelines 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 section 10.11:

“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 section 10.12 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 sanitary measures that were found to be equivalent. We thus urge that a new paragraph 10.12 be added to section 10 as follows:

“10.12 All judgements of equivalence must specify mechanisms by which the importing country can verify that the exporting country continues to administer and enforce the sanitary 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.”

In addition, all equivalency agreements should contain an expiration date no more than five years following the establishment of the agreement. 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. We specifically recommend that a new paragraph 10.13 be added to section 10 “General Principles for Determination [demonstration] of Equivalence as follows:

“10.13 All equivalency agreements should contain an expiration date no more than five years from the date of the initial determination of equivalency.”

Paragraph 16.8 should be deleted. Despite the draft guidelines’ recognition of an importing country’s right to make its own equivalency determination, this paragraph 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 sanitary measures are equivalent to its own.”

Paragraph 17 fails to ensure that 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 reworded as follows:

“17. 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.”

Paragraph 21 of the draft guideline fails to adequately account for the impact that environmental, climatic and other factors may have on an exporting Country’s sanitary measures. Thus, the following sentence should be added at the end of the Paragraph:

“ - the impact that climatic, environmental, labor relations and other relevant factors may have on the adequacy of an exporting country’s sanitary measures.”

IACFO believes that these changes will help address criticisms of the equivalency process and ensure that equivalency agreements protect public health while facilitating trade. We urge the committee to consider them fully