

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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Agenda Item 3

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## 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

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

#### COMMENTS AT STEP 6

##### BANGLADESH

With reference to the above-mentioned subject the undersigned is directed to inform you that we would like to propose some modifications below may be incorporated in the drafts.

Page 1 “Sanitary measure: ..... additives, contaminants, toxins or disease-causing organisms” proposed modification “..... additives, contaminants, toxins, radio nucleotides or disease-causing organisms”

Page 2: “Hazard: a biological, chemical or physical agent....” proposed modification “a biological, chemical, radio active or physical agent....”

Page 4 13 c) “..(e.g. laboratory test for microbiological and chemical hazards)...” proposed modification 13 c) “..(e.g. laboratory test for microbiological radio active and chemical hazards)...”

##### BRAZIL

Brazil acknowledges that important improvements in the present document have been made. Brazil considers that the document incorporates its concerns expressed during the Oakland meeting and suggests the CCFICS to recommend its approval to the next step. With the purpose of overcoming the difficulties expressed by some delegations in the Draft Working Group related to the paragraph 15, Brazil presents the following suggestion:

§ 15 – {Since the sanitary measures applied by an importing country have the purpose of achieving its ALOP, an exporting country may demonstrate achievement of the importing country” ALOP by demonstrating that the measures it proposes as equivalent have the same effect, relative to the achievement of the importing country” ALOP, as the corresponding sanitary measures applied by the importing country by using an objective basis of comparison}, taking into account the internationally agreed Good Manufacturing Practices - GMP, Good Agricultural Practices - GAP and Good Hygienic Practices - GHP in the food chain.

**Justification:** Brazil would like to suggest this language with a view to accommodate the concerns expressed by some delegations that equivalence may be used to resolve problems related to inadequate processes of production.

## **CANADA**

Canada congratulates the Drafting Group on the redrafting of this document and is pleased to offer the following comments:

### **Paragraph 3 - Foot note 3**

The latter part of the last sentence of footnote 3 is an interpretation of the WTO, beyond the competence of Codex. Canada recommends that it be modified as follows:

*Such action by an importing country would be contrary to the principles of international trade ~~and in particular in violation of Article 2 of the WTO SPS Agreement.~~*

## **SECTION 2 - SCOPE**

### **Paragraph 5**

The semicolon after programme design should be changed to a comma.

## **SECTION 5 - THE CONTEXT OF AN EQUIVALENCE DETERMINATION**

### **Paragraph 8**

Canada recommends that the footnote 10 be amended to improve accuracy regarding the SPS Agreement.

*Article 3 of the WTO SPS Agreement ~~states~~ **recognizes**, inter alia, that WTO Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved **by measures** based on Codex standards, if there is a scientific justification, or as a consequence of the member's chosen level of protection. **Relevant provisions include that such measures ~~must~~** be based on a risk assessment appropriate to the circumstances.*

### **Paragraph 9**

To improve clarity, Canada recommends replacing the word “relevant” in the first sentence by “related” as follows:

*An equivalence determination can be sought for any sanitary measure or set of measures ~~relevant~~ **related** to a food product or group of food products.*

### **Paragraph 11**

To improve coherence, Canada recommends deleting the word “relevant” at the end of the paragraph as follows:

*When an importing country has prior experience, knowledge, and confidence in food control measures relevant to those being evaluated for equivalence and the countries agree that import requirements are being fully met, e.g. where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other ~~relevant~~ measures making up the food control system.*

## **SECTION 6 - OBJECTIVE BASIS OF COMPARISON**

### **Paragraph 15**

Canada recommends deleting the square brackets and maintaining the text.

### **FIGURE 1**

Canada notes a discrepancy between the numbering system used for the various steps in Figure 1 and the numbering system used in the text (para 18) - one being alphabetic and the other being numeric. In the final text, this should be corrected.

### **Importing country**

- Remove the arrow below Yes in the first evaluation for equivalence.
- Move the origin of the arrow pointing to “Possible resolution of different opinions...” from the “Yes” after the second evaluation for equivalence (18.8) so that it originates from the text box regarding “Importing country supplies reason for denial of equivalency”

### **EGYPT**

Section 1 – Preamble

We would apply our own measures when the situation requires strict application of our control measures, as in some cases the visual inspection reveals the presence of an infestation.

### **MEXICO**

Mexico wishes to commend the work of the Drafting Group.

We suggest as follows:

#### **Title of the Draft Guidelines**

We suggest replacing the term “on” with the word “for”.

#### **Throughout the text**

We suggest replacing the imperative “must” (“deberá”) with “should” (“debería”) so as to be in accordance with the recommendatory nature of the document and to be consistent with the English version.

#### **Section 1**

We suggest adding a new Paragraph, or adding text to Paragraph 3, to indicate that: “since an equivalence agreement is established for the convenience of the parties, current trade will not be restricted while equivalence is being determined. The absence of an equivalence agreement will not be a reason to restrict food trade.”

#### **Section 3**

In the note following the definition of “sanitary measure” we suggest replacing the word “end” (“acabado”) with the word “end”(“terminado”). Translator’s note: This amendment only applies to the Spanish version.

Replace the expression “Appropriate Level of Protection” with “Adequate Level of Protection” to indicate that the ALOP may be expressed in qualitative and quantitative terms, deleting this text from , point a).

## Section 4

Point b)- The English version reads “The measure applied in an importing country”, whilst the Spanish version reads “The measure applied in an exporting country”. If this refers to the importing country itself, as suggested by article 2.3 of the SPS Agreement, the text would need to be reworded and footnote 8 deleted.

Point n)- Delete the word “developing” because irrespective of the level of development, an importing country can provide technical assistance to the exporter, in order to facilitate the determination of equivalence process.

### Paragraph 13

We suggest replacing the term “performance”(“el rendimiento”) with “results”(“los resultados”).

## Section 8

Heading:

We suggest amending to “Final considerations” (“Consideraciones finales”) since “Equivalence” (“Equivalencia”) is ambiguous regarding the aspects of equivalence to which this Section refers.

### Paragraph 20

Point c).- We suggest replacing “strength of the relationship” (“...la estrechez de la relación...”) with “the degree of the relationship” (“...el grado de relación...”).

### Figure

Replace numbers by letters in accordance with Paragraph 18 which describes the procedure for the determination of equivalence.

## NEW ZEALAND

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

New Zealand would like to thank the other members of the drafting group for their support and assistance in revising the draft guidelines, we also wish to thank those member governments that provided comment to assist the drafting group in our deliberations.

New Zealand believes that the revision of the draft guidelines has address the matters raised in comments and during the last session of CCFICS. There is, however, one paragraph on which the drafting group was unfortunately not able to reach consensus, paragraph 15. New Zealand would suggest that the current paragraph 15 be deleted and replaced with a simple statement as follows:

"To determine if a sanitary measure is equivalent there must be an objective basis for comparison."

We make this suggestion noting that the WTO obligations of members are already referred to elsewhere in the draft guidelines, specifically in footnote 6 to *Section 4 -General Principles* (paragraph 7a).

New Zealand also notes that a small number of editorial corrections need to be made, including:

- in paragraph 5 where the semicolon after “...programme design” should be changed to a comma;
- Figure 1 needs to be aligned with the numbering for paragraph 18;
- there is an extra arrow in the centre right of the figure; and
- the arrow leading to “Possible resolution of...” needs to originate from “Importing country supplies...” not “Yes”.

With these changes to the draft guidelines New Zealand supports their progress to step 8 of the Codex process.

## **UNITED STATES**

### **GENERAL COMMENTS**

The United States appreciates the work of Australia in leading the Drafting Group in revising these important Guidelines. We believe the document is substantially improved and addresses the issues brought forward during discussion at the 10<sup>th</sup> Session of CCFICS. The United States was supportive of advancing the previous version of the Guidelines to Step 8. To promote a better understanding of equivalence, we nevertheless see the benefits of giving the document better structure, appropriate logic flow, more complete development of certain sections, and appropriate references. We strongly encourage the Committee to give every consideration to advancing this document in the Codex step process as we believe it will provide valuable guidance to countries in undertaking judgments of equivalence with respect to sanitary measures.

### **SPECIFIC COMMENTS**

The following specific comment is provided.

#### **Section 6- Objective Basis of Comparison**

Paragraph 15. The United States notes that the language within the brackets was not finalized at the drafting group session due to inadequate time and may require additional further work at this meeting of CCFICS. While the United States can be satisfied with the proposed wording of this paragraph, we look forward to hearing and considering comments on possible revisions to its wording.

Thank you for the opportunity to provide comments on these Draft Proposed Guidelines.

## **EUROPEAN COMMUNITY**

The European Community supports the “Draft Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification System”.

## **CONSUMERS INTERNATIONAL**

Consumers International (CI) thanks the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) for the opportunity to comment on the Draft Guidelines. CI regrets that resource constraints precluded it from participating in the Oakland, California workshop that produced the latest version of the draft Guidelines.

### **General Remarks**

At the 24<sup>th</sup> Session of the Codex Alimentarius Commission, CI was among those who spoke against using the accelerated procedure to adopt the Draft Guidelines at Step 8, despite a plea from the World Trade Organization Secretariat for the Commission to do so. The WTO Secretariat’s interest in having the Draft Guidelines adopted is clear: while there are no Guidelines, Article 4.1 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which calls for bilateral SPS equivalence agreements, remains without a framework for implementation. The pressure to adopt the Draft Guidelines at the 25<sup>th</sup> Session of the Commission will be very great, particularly as there continues to be great disagreement on other implementation issues, particularly the definition and implementation of Special and Differential Treatment.<sup>1</sup> The provision by Codex of a framework for the opportunity to negotiate equivalence agreements may be regarded as a sign of progress for the so-called Doha Development Agenda.

Our comment to the 24<sup>th</sup> Session stated, “Consumers International does not believe that the terms of the Proposed Draft Guidelines offer sufficiently specific guidance to convert the opportunity for equivalence agreements [in the SPS Agreement] into concrete agreements that would both protect consumer health and foster fair practices in the trade of food.” CI’s reasoning for this belief was based on the inability of CCFICS

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<sup>1</sup> e.g. “WTO Members Make Little Progress In Continue Discussion On S&D,” INSIDE U.S. TRADE, 11 October 2002.

to come to agreement in the Ninth Session on “the types of information to be taken into account in making a judgment of equivalence” (para. 88, Alinorm 01/30). Unable to come to agreement, CCFICS chose to delete the examples of types of information to be taken into account in making a judgment of equivalences. However, “[t]he Committee agreed that development of the examples of information to be taken into account could perhaps be developed in the future as an Annex” (para. 88, Alinorm 01/30). To date, unfortunately, there has been no development of such an Annex.

Apparently, to expedite the adoption of Guidelines and hence implement Article 4.1 of the SPS Agreement, CCFICS has agreed to avoid disagreement about “types of information to be taken into account in making a judgment of equivalence” by deleting the issue from the Draft Guidelines. To a very limited extent, paragraph 13 of the Draft Guidelines to be considered by the Eleventh Session points to some of the types of information to be documented and analyzed in a request for equivalence. However, that paragraph is too schematic to offer specific guidance to Codex members seeking common terms of reference upon which to make a request for a judgment of equivalence. If the Draft Guidelines were presented to the Commission in their present form, they might well provide a basis for satisfying the need of the WTO Secretariat to show the opportunity for progress on implementation issues. But such Draft Guidelines would not offer specific enough guidance to governments so that equivalence agreements protect consumer health. Indeed, if the Draft Guidelines offer no specific guidance to exporting and importing equivalence agreements members about the types of information to be taken into account in a judgment of equivalence, such judgments could conduce to trade disputes rather than to fair practices in food trade.

CI believes that to provide governments adequate guidance on this issue, CCFICS needs to develop three kinds of appendices or reference papers that would be a formal part of the Guidelines. The first kind would concern documentation requirements for the submission of a request for a judgment of equivalence. This appendix or reference paper would specify the kinds of information requested by importing country authorities to make and then maintain a determination of equivalence. It would also cover such vital, if mundane, matters as the translation of documentation. (Quite remarkably, judgments of equivalence have been made on the basis of documents in their language of origin, but “reviewed” by officials not competent in the language of the documentation submitted!) A second kind of appendix or reference paper would outline the terms for onsite visits by importing country authorities to inspection and certification systems, including exporting establishments, to verify how the exporting country’s application of SPS measures meets the importing country’s ALOP. A third kind of appendix or reference paper would specify the kinds of technical assistance to be provided by importing countries to exporting developing countries and economies in transition in order to satisfy importing country requirements for a submission to request a judgment of equivalence. It is our understanding that appendices pertaining to draft codes and guidelines do not authorize by the Commission as new work.

Despite the shortcomings of the present Draft Guidelines, CI wishes to note that some aspects of the Draft Guidelines have improved since the Ninth Session, particularly the section on what should be documented in a judgment of equivalence. CI still believes, however, that CCFICS should develop Guidelines that go beyond fulfilling the needs of the WTO Secretariat for implementation of the opportunity for equivalence agreements in Article 4.1 towards developing specific guidance for governments on this issue. With these caveats in mind, CI wishes to submit in *italics* proposed amendments to the present Draft Guidelines. Numbers preceding each CI comment correspond to the paragraph and/or sub-paragraph of the Draft Guidelines.

## **Section 1 – Preamble**

2. Although the (SPS Agreement) does make the Codex Alimentarius into a kind of technical appendix to the SPS Agreement, the mandate and authority of the Codex Alimentarius is not co-terminous with that of the SPS Agreement. Trade facilitation is the proper ambit of the WTO Agreements. However, until such time as the Codex Commission decides to change the first Article of the CAC statutes from “ensuring fair practices in the food trade” to “facilitating trade” Codex members should refrain from blurring the mandates of the WTO Agreements and the Codex Alimentarius. Sanitary and phytosanitary measures taken to ensure fair trade in food may have trade facilitatory effects, but it may happen that SPS measures are applied fairly to traded foods, but have the result of denying trade, at least temporarily. The protection of consumer health

is not an incidental effect of equivalence agreements that “facilitate trade” but is a purpose that should be acknowledged in the Preamble as important as ensuring fair practices in the trade of food.

Therefore, CI would redraft the second clause of this paragraph to read, “In such circumstances, and in order to *ensure fair practices in the food trade, and to protect the health of consumers from any harm that might result from such trade . . .*”

3. Regarding “to facilitate trade,” see our comment in paragraph 2, as the comment should apply here also. The paragraph states as a matter of invariable fact what is an aspirational goal of the Guidelines. Therefore, CI would redraft the paragraph as follows: “Application of the principle of equivalence *should have mutual benefits for both exporting and importing countries. The application of the principle should protect the health of consumers, ensure fair practices in food trade, and minimize . . .*” The footnote to this paragraph reads like a legal interpretation of the SPS Agreement by the WTO Secretariat. Codex has neither competence in nor mandate to interpret the actions of WTO members and hence the footnote should be deleted.

4. This paragraph does not belong in a Preamble, as it is injunctive and prescriptive, not a description of the purpose of the Guidelines and what is hoped to be achieved with their application. The paragraph as drafted is confusing. “Importing countries should avoid the application of unnecessary measures when they have already been carried out by the exporting country.” What is an “unnecessary” measure? Is it “unnecessary” in the sense of being not “least trade restrictive” or “unnecessary” in the sense of not being needed to protect the health of consumers? Presumably “they” does not refer to “unnecessary” measures carried out in the exporting country, even though “unnecessary measures” is the grammatical antecedent of “they.” But what does “they” refer to? This paragraph should be deleted from the Preamble.

A paragraph should be added in the Preamble to stress that “*A judgment of equivalence should not reduce or qualify the responsibility and authority of the importing government to protect consumer health from trade-related food borne hazards, nor should it transfer such responsibility to the exporting country.*”

## **Section 4 – General Principles for the Determination of Equivalence**

7. CI proposes the following additional Principles and amendments to the Principles: First, in continuation of c): “*The importing country should also describe measures for sanitary procedures where scientific data to devise objective regulatory criteria evaluated in the determination of a judgment of equivalence are incomplete and/or of uncertain validity.*”

CI proposes that the following new principle should be added between the current Principles 7e) and 7f): “*An equivalence agreement may be based on certification by the importing country of establishments in the exporting country that comply with the sanitary standards and provisions of the importing country.*”

Principle 7j) outlines a wide-open process for determination of equivalence – “take into account any knowledge it has of the food inspection and certification systems in the exporting country” while insisting that the determination be done as “quickly and efficiently as possible.” CI believes that to protect consumer health, evaluation of documentation and on-site inspections of exporting facilities must be done as thoroughly as possible, rather than “as quickly and efficiently as possible”. Because the determination of equivalence should be made on the basis of information furnished by the exporting country in its request for equivalence, the importing country cannot act fairly on “any knowledge.” If the exporting country is not forthcoming with all information requested by the importing country or if the exporting country does not ensure timely and complete access for importing country authorities to exporting establishments, including inspection and certification systems, then equivalence can be fairly and duly denied.

Therefore, CI would substitute for the present 7j) the following: “*The competent authority of the importing country should affirm or deny a request for a judgment of equivalence based upon a thorough analysis of information supplied by the competent authority of the exporting country, including information specifically requested by the importing country.*”

CI proposes to amend Principle 7k) as follows: “*Upon request of the food control authorities of the importing country, the exporting country should provide timely and complete access to its inspection and certification systems, including those of establishments, which are the subject of the evaluations that are used to affirm or deny a request for a judgment of equivalence.*”

CI proposes to amend Principle 7l) as follows: “All judgments of equivalence should *state the requirements and criteria for maintaining that judgment of equivalence.*”

For sub-paragraph 7m), there should be a footnote or additional sentence to give examples of how all interested parties will be consulted “to the extent reasonable and practical.” There should be another footnote or additional sentence to illustrate criteria to demonstrate that discussions about an equivalence determination are carried out “in a cooperative way.” While adherence to the procedures outlines in the “simplified flow chart” (figure 1) may indicate cooperation, CCFICS may wish to specify other criteria for cooperation.

Principle 7n) states “An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalence determination.” CI is unclear about the meaning of “positive consideration” and “successful completion of an equivalence determination”. For the sake of clarity, CI proposes the following amendments to 7n): “An importing country should give *favorable* consideration to a request by an exporting developing country *or economy in transition* for appropriate technical assistance that would facilitate the completion of *an application requesting* an equivalence determination.” An importing country should provide technical assistance to exporting developing countries and economies in transition to ensure that an application for a determination of equivalence is complete in terms of supplying the information requested by the importing country. However, importing country authorities cannot guarantee apriori that an application so completed will be granted an affirmative determination of equivalence.

## **Section 5 – The Context of An Equivalence Determination**

8. There needs to be an addition to this paragraph or the creation of an additional paragraph to take into account those situations in which Codex standards and related texts have not been adopted into the legislation and regulations of the WTO members that are negotiating an equivalence determination. There likewise needs to be provision made in the Guidelines for situations in which equivalence is sought concerning application of SPS measures for which there is no agreed Codex standard or related text or for where the application of Codex standards or related texts to different food products appears to be contradictory or unclear. CI will not propose language for these situations at this time, but will be ready to do so at CCFICS if the committee agrees that there is a need for these provisions.

10. The term “extent” in “The extent of the equivalence determination will depend . . .” needs clarification. If by “extent” nothing else is meant other than “*the number of food products covered under an equivalence determination,*” then it should be so stated. If something more or something else is intended, then it would be helpful to specify what is entailed in the term “extent.”

11. The substitution of “trade experience” for verification by the competent authority of the equivalence of SPS measures is an invitation to circumvent regulatory prudence. Current “trade experience” is based on a trade system in which individual plants are certified by the importing country. Few Codex members, if any, have any experience in certifying food safety systems in another country. Such certification would require harmonization on horizontal issues, such as harmonized recall procedures, that are not yet part of the Codex agenda. To extrapolate from current “trade experience” regarding certification of individual export establishments towards broader certification “without further consideration of those other relevant measures making up the food control system” undermines the requirement of “an objective basis for the comparison” of SPS measures as the basis for a judgment of equivalence. “Trade experience” will likely expedite a determination of equivalence but it cannot preclude the need to require an objective demonstration of equivalence. This paragraph should be deleted.



12. This paragraph should likewise be deleted, since it implies that only when trade is being proposed for the first time, should the consideration of all relevant SPS measures form a part of an equivalence determination.

15. This paragraph appears to repeat the content of paragraph 2. If something other than the Preamble's content is intended, the paragraph needs to be redrafted, so as to reveal the intended content. Otherwise, it may be deleted as redundant to paragraph 2, preferably as paragraph 2 has been amended by CI.

## **Section 7 – Procedure for the Determination of Equivalence**

17. The last sentence of this paragraph is “This information [supplied and requested for the determination of equivalence] should be limited to that which is necessary for this purpose.” This sentence should be deleted, as it provides a formal basis for challenging the good faith of the equivalence agreement parties in a complaint to the WTO. Codex has no mandate or competence to provide the basis for such a challenge. The phrase “that which is necessary” can be interpreted to mean “that which is least trade restrictive,” and hence would undermine the ability of the competent authority to determine what information is needed in order to make a determination of equivalence that will protect consumers from food hazards and food-borne illness.

18f) The last sentence of the sub-paragraph is “If possible, the importing country should suggest how the concerns might be addressed.” In accordance with sub-paragraph 7n), as proposed for amendment by CI, we would like this sentence to be continued as follows: “*and provide such technical assistance to exporting developing countries and economies in transition as is needed to address these concerns.*”

18i) In the event of a dispute about a request for a judgment of equivalence what needs to be resolved are not “differences of opinion” as stated in the present draft, but “*differences in the interpretation of the documentation required by the importing country for judgment of a submission, whether interim or final.*”

## **Section 8 – Judgment**

20. CI would amend this paragraph to read “Judgment *or denial of judgment* of the equivalence of sanitary measures should *document that the following factors have been taken into account*:

20a) CI proposes that this sub-paragraph would read: “experience and knowledge of an exporting country’s food inspection and certification systems, *including reports by importing country authorities of visits to exporting country establishments (see Sections 4 and 5)*”

In conclusion, CI wishes to thank CCFICS Members and Observers for their consideration of these comments.