

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3 (a)

CX/FICS 05/14/3 – Add 1
November 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION
AND CERTIFICATION SYSTEMS

Fourteenth Session

Melbourne, Australia, 28 November – 2 December 2005

PROPOSED DRAFT APPENDICES TO THE GUIDELINES ON THE JUDGEMENT OF
EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD INSPECTION AND
CERTIFICATION

(N04-2004)

COMMENTS AT STEP 3

(Comments from Canada, India, Kenya, Malaysia, New Zealand and the United States)

CANADA

Canada thanks the United States for leading the Working Group and for preparing the revised draft appendices.

Canada is submitting its comments on the draft appendices with the understanding that the definitions, principles and footnotes in the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2001) will apply equally to these appendices.

Attachment 1 - Proposed Draft Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems - Documentation for Determination of Equivalence of Sanitary Measures*

General Comments

Canada has concerns with two important elements of this attachment. The first concern regards the scope of the document while the second relates to the use of the “experience, knowledge and confidence”.

Canada is of the opinion that the scope of this document is still too broad. We believe that this document should address documentation related to the latter half of paragraph 17 and paragraph 18 of the main document (CX/FICS 04/13/3), i.e., after initial discussions have taken place between exporting and importing countries and a preliminary review of each countries’ systems has been undertaken, including a side-by-side comparison as appropriate. This document should apply to activities that begin after a decision has been take by the exporting country to seek an equivalence determination for a measure (whether broad, e.g., infrastructure, or specific).

This restriction should eliminate the need for reference to exchange of documentation related to inspection and certification systems by the two countries and reference to the side-by-side comparison or other related information. It is Canada’s understanding that these activities would be the focus of a separate annex, i.e., Assessing which measures are to be the subject of an equivalence determination. This document should therefore focus on the more basic information related to the specific measure under consideration.

The Proposed Draft Appendix treats the idea of "experience, knowledge and confidence of an exporting country's food inspection and certification systems" in a manner different to how it is treated in the Guidelines on the Judgement of Equivalence of Sanitary Measures.

The Guidelines clearly indicate, in Section 8, paragraph 20, that "experience, knowledge and confidence of an exporting country's food inspection and certification systems" is but one element to be considered in the judgement of equivalence. Section 5, paragraphs 10-12 provide additional detail. The experience, knowledge and confidence that the importing country has regarding the food control measures of the exporting country will allow decisions to be made regarding the extent to which measures relevant to those being evaluated for equivalence must be considered. Nowhere do the Guidelines indicate that, on the basis of experience, knowledge and confidence alone, relevant measures of the exporting country can be determined to be equivalent.

The Proposed Draft Appendix, on the other hand, indicates that equivalence of certain measures can be based solely on experience, knowledge and confidence in the exporting country's systems while other measures must be the subject of an equivalence determination. This is seen in footnote 8 (the importing country determines which further relevant measures of the exporting country are equivalent based upon its prior experience, knowledge and confidence in the exporting country's systems the remaining measures are subject to the equivalence determination) and paragraph 12 (... determine the measures: which can be accepted by the importing country as equivalent based on knowledge, experience and confidence in the exporting country's systems; and which are to be the subject of the equivalence determination). As a result, the Proposed Draft Appendix implies that there are degrees of equivalence and, therefore, degrees of complexity in the process for determination of equivalence (i.e., more or less steps).

Canada is of the view that experience, knowledge and confidence can permit the importing country to categorize relevant measures; for example, as those with which the exporting country complies, those which exceed the requirements of the importing country, and those for which an equivalence determination has been previously conducted. Experience, knowledge and confidence can also facilitate and accelerate the procedure for determination of equivalence (e.g., there is no need to request information that is already available or to re-evaluate information that has been previously evaluated). However, the process for determination of equivalence of a measure (the sequence of steps) and the process for judgement of equivalence (elements to take into account) should be consistent, regardless of the knowledge, experience and confidence the importing country has regarding the food control systems of the exporting country.

Specific Comments

Canada provides the following specific comments with the understanding that some of these comments may be redundant should the concern raised regarding the scope of the document be adjusted as recommended in our General Comments.

Introduction and Purpose

Paragraph 1

Canada is of the opinion that demonstration of the exporting country's legislative base and administrative systems for implementing and enforcing the alternative measures (point 3) is not exclusive to equivalence and applies even in the situation where the exporting country decides to comply with the importing country's measures. Demonstration of the ability of an exporting country to implement and enforce its measures is addressed in existing CCFICS texts (Guidelines for Food Import Control Systems (paragraph 32) and Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (Section 9)). Furthermore, the exporting country's legislative base and administrative systems are not addressed elsewhere in the Proposed Draft Appendix and, therefore, Canada proposes that this point be deleted.

However, Canada proposes that documentation should demonstrate the equivalence of the alternate methods with respect to both validation and verification. That is, the determination of equivalence should demonstrate that the alternate method has the ability to achieve the importing countries appropriate level of sanitary protection (i.e., validation) and that the alternate measure can be appropriately monitored to provide the same degree of confidence that is provided by monitoring the measure maintained by the importing country (i.e., verification).

Footnote 8

Canada is of the view that the footnote does not accurately paraphrase Section 5 of the Guidelines for the Judgement of Equivalence. Paragraph 13 of the Guidelines categorizes sanitary measures for the purpose of determining equivalence but it does not indicate that all these measures will be relevant to those being evaluated for equivalence. In addition, as noted under **General Comments**, the experience, knowledge and confidence that the importing country has regarding the food control measures of the exporting country will allow decisions to be made regarding the extent to which measures relevant to those being evaluated for equivalence must be considered. While certain relevant measures might be removed from consideration, this cannot be considered as a determination of their equivalence. Canada does not see how this footnote contributes to point 1 of paragraph 1 and, therefore, proposes that it be deleted.

Paragraph 2

Canada believes that there is another factor affecting the detail and extent of documentation to be provided and suggests to add the following as a 3rd point:

3) Extent to which knowledge of the technology, procedures and processes employed in the alternate measure are recognized and understood.

Documentation - An Initial RequestParagraph 5 - 3rd bullet

The extent to which the exporting country should submit information on its sanitary measures will depend on the rationale or purpose for the request for an equivalence determination. More information on sanitary measures related to a food product would likely be required for initiating trade than for changing processing technology for a product that is already being traded. Therefore, Canada suggests amending the 3rd bullet as follows:

The exporting country's sanitary measure(s) associated with a food product or group of food products for which determination or equivalence is sought, as appropriate for the rationale or purpose for the request for an equivalence determination;

Paragraph 5 - 6th and 7th bullets

In line with the General Comments that equivalence is determined through an established process (sequence of steps), Canada proposes to delete the 7th bullet and rewrite the 6th bullet as follows:

The exporting country's basis and rationale for proposing equivalence with the importing country's measures. Relevant measures that have previously been determined to be equivalent with those of the importing country or, as appropriate, with those of other countries, should also be identified.

Documentation - Submittal PackageParagraph 10

Canada has concerns with this statement. Documentation requirements will vary depending on the type of measure or measures for which an equivalence determination is requested. Documentation requirements should be less for an equivalence determination for a single measure related to a product that has been historically traded than for a system wide determination of equivalence. Documentation requirements should also vary depending on the purpose/reason for which an equivalence determination is requested (i.e., initiating market access versus facilitating trade of a specific commodity). Paragraph 10 is also inconsistent with paragraph 2 under Introduction and Purpose. Canada is of the opinion that this paragraph can be deleted.

Paragraph 11- 2nd bullet

Consistent with its **General Comments**, Canada suggests replacing the second sentence and the bullets under this paragraph with the following:

This side-by-side comparison, in conjunction with consultation with the importing country, should enable the exporting country to identify the measures:

- with which it and its exported products will comply;

- which have been determined by the importing country to be equivalent; and
- which are to be the subject of an equivalence determination.

Paragraph 12 - 2nd and 4th bullets

These two bullets appear to be repetitive. Canada suggests deleting the fourth bullet and rewriting the second bullet as follows:

- Results of the side-by-side comparison of the importing and exporting countries' pertinent sanitary measures for the commodity/hazard combinations, indicating the measures with which the exporting country will comply, those which have already been determined to be equivalent, and those which are the subject of an equivalence determination.

Paragraph 12 - 3rd and 5th bullets

This paragraph addresses the information to be forwarded by the exporting country to the importing country. As it is the importing country that makes the judgement of equivalence, the most the exporting country can provide is its conclusion regarding equivalence of the alternate measure, based on the results of the analysis. Therefore, Canada suggests the following changes to the 3rd and 5th bullets respectively:

- The results of the analysis of the measure subject to the equivalence determination and the conclusion drawn by the exporting country as to whether the alternate measure is equivalent.
- For each alternate method that the exporting country has concluded to be equivalent, a summary of the scientific rationale as to why the measure is believed to be equivalent and detailed supporting information. (These would include...)

Paragraph 12 - footnote 13

The level of public health protection (ALOP) is, by definition and usage in the WTO SPS Agreement, against risks to human life or health. In addition, Objective Basis of Comparison is an inclusive term, which includes all the information necessary to permit the comparison of alternate measures. Therefore, the footnote should be rewritten as:

The analysis should demonstrate that the two measures will achieve the same level of public health protection against risk to human life or health consequential to the specified hazard in the commodity under consideration, employing, as appropriate, the objective basis of comparison.

Attachment 2 - Proposed Draft Appendix to the Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems - Determining an "Objective Basis of Comparison"

General Comments

In the *Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* Section 6 - Objective Basis of Comparison - treats the concept of objective basis of comparison in the singular, consisting of one or more qualitative and quantitative elements (Ref. footnote 11 of the Guidelines). For consistency, the same approach should be maintained in the Appendices to the Guidelines. In addition, consideration of the objective basis of comparison, or the elements of an objective basis of comparison, should always be in conjunction with the supporting information.

Canada is of the view that the Committee's discussion should focus on how best the Appendix should tie together the concept of objective basis of comparison, consisting of qualitative and/or quantitative elements, the supporting information that would be required in relation to the qualitative and/or quantitative elements of the objective basis of comparison, and how the elements and supporting information will be dependant on the category of the measure being subjected to an equivalence determination (i.e., where the measure is related to infrastructure, program design, implementation and monitoring, or specific requirements). Clear and precise examples of each situation would facilitate understanding.

Specific Comments

Paragraph 2

Consistent with the **General Comments**, Canada suggests revising the paragraph as follows:

Once the importing and exporting countries have agreed upon which measure(s) is to be the subject of an equivalence determination, the importing country, at the request of the exporting country, should provide the objective basis of comparison for the sanitary measure(s) together with appropriate supporting information. The elements of the objective basis of comparison may be elucidated in qualitative and/or quantitative terms.

Canada is of the opinion that judgement of the value of utilizing the objective basis of comparison is outside of the scope of this appendix and suggests deleting the last sentence of the paragraph.

Paragraph 3

With respect to the definition, Canada suggests the following:

An "objective basis of comparison" is a concept developed to allow the comparison of alternative measures or groups of measures with respect to their effect, relative to the achievement of an importing country's ALOP.

Paragraph 4

Consistent with the **General Comments**, Canada suggests revising the paragraph as follows:

Depending upon the nature and extent of the measures subject to an equivalence determination, the objective basis of comparison may need to include more than one element in order to effectively evaluate alternative sanitary measures or groups of sanitary measures. For example, more than one element may be required where a single measure applied by an importing country contributes in several different ways to the achievement of the ALOP, or where subsets of a group of measures for which an equivalence determination is sought make distinct contributions to the outcome.

Paragraph 5

Canada suggests deleting this paragraph as it repeats information that is already contained in paragraph 2 of this document. The footnote from this paragraph should be moved to paragraph 2.

Paragraph 6

As noted under **General Comments**, Canada believes that this paragraph is the crux of this appendix and should be further developed so as to more clearly show the correlation between the elements of the objective basis of comparison (qualitative and quantitative) and the supporting information, and how these are instrumental in determining the "Objective Basis of Comparison" for each of the categories of measures listed in paragraph 13 of the Guidelines. This would be further enhanced by the addition of examples.

Paragraphs 7 and 8

Canada suggests deleting these paragraphs as they are not pertinent to determining an objective basis of comparison and the concepts are addressed elsewhere; e.g., in the Guidelines and the Appendix: Documentation for Determination of Equivalence of Sanitary Measures.

Examples of Applying an Objective Basis of Comparison

Canada agrees with the intent to include a number of examples to enhance the utility of this attachment. Please refer to comments on paragraph 6.

Attachment 3 - Proposed Draft Appendix to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems - Details on the Process of Judging Equivalence

Canada believes that providing elaboration on the bullet points found in Paragraph 20 of the main document represents a good starting point for the document; however, further discussion is necessary to establish the need for more practical advice regarding the actual judgement of equivalence.

Notwithstanding the foregoing, Canada is of the opinion that the additional details provided in the Proposed Draft Appendix go beyond the process of judging equivalence of sanitary measures and, instead, address numerous aspects related to food import control systems, and food import and export inspection and certification systems in general. Consistent with its comments on the Proposed Draft Appendix: Documentation for Determination of Equivalence of Sanitary Measures, Canada believes that determination of equivalence, including the process for judging equivalence, should be focussed on determining whether the alternate measure has the ability to achieve the importing countries appropriate level of sanitary protection (i.e., validation) and whether the alternate measure can be appropriately monitored to provide the same degree of confidence that is provided by monitoring the measure maintained by the importing country (i.e., verification).

For example, Canada does not believe that the section on on-site visits/audits is appropriate for this attachment. On-site visits/audits are not part of the initial judgement of equivalence, but rather would be part of the process of on-site verification that would follow the determination of equivalence. Equivalence determination is an analytical activity that examines the degree to which alternative measures can address (contribute to the achievement of) an importing country's ALOP. On-site verification is a process that establishes compliance with a country's measures and verifies that the inspection and certification system accomplishes its objectives. This process would be applied after the evaluation of the exporting country's system and would be applied whether the exporting country sought harmonization or equivalence with the importing country's system.

While a case could be made for on-site visits to gain greater understanding of a particular measure or approach to the control of a food safety hazard, this would be the exception rather than the rule.

Other details in the Proposed Draft Appendix would be more appropriate for consideration, by the importing country, in an initial evaluation of the potential for success of an equivalence determination. For example, a poor compliance history and incomplete or absent legislation and quality control system would reduce the degree of confidence that an importing country has in the food safety controls of the exporting country and could preclude further consideration by an importing country of a request by an exporting country for an equivalence determination. This is noted in paragraph 2 (i.e., applying known information to a decision whether to proceed with the request) but this decision should be made well in advance of the process of judgement of equivalence.

Canada suggests that, with respect to the step-wise approach to the development of the appendices, the scope of Appendix 1: Assessing Which Measures are to be the Subject of an Equivalence Determination, could be broadened to consider the minimum requirements that must be met before the process for determination of equivalence can commence.

INDIA

General

Equivalence determination is for measures that are different, the whole purpose being to determine equivalence of these measures with those of the importing country so as to meet its ALOP. The process of determination of equivalence therefore starts only after the exporting country has identified the measures that are different. This is also obvious from the definition of 'equivalence of sanitary measures' as given under clause 6 of CAC/GL 53-2003. This concept has also been clearly reflected under clause 17 and 18 a) of CAC/GL 53-2003.

The annexures are being developed to elaborate on certain parts of document **CAC/GL 53-2003** and not to change what has presently been reflected in this document. However, it has been observed at various places in Annexes 1 & 2 that these are conflicting with the original document in so far as the basic concept is concerned namely, are all the measures to be subject to equivalence determination or only those which are different, is it the importing or exporting country which carries out the initial exercise to assess which of the measures are the same and for which equivalence needs to be determined, the steps involved in determination of equivalence as elaborated at Sl no 18 of **CAC/GL 53-2003**.

Annex Attachment 1

Clause 4

Following to be added at the end:

‘...that are different from the importing country measures’.

This addition is necessary as the measures that are different and for which an equivalence determination is required have already been identified and so obviously the importing country’s sanitary measures are already available with the exporting country.

Clause 5

4th bullet to be brought after the *2nd bullet* as the sequence would be to first identify the importing country’s measures for which equivalence is being sought and only after that will the exporting country be in a position to identify which of its measures has to be judged as equivalent. Further, the words ‘and the rationale’ to be deleted as these are already covered in the *2nd bullet*.

A new bullet as follows, to be added after the fourth bullet:

‘A request for the reason or purpose of the measure if considered necessary’

This would bring it in line with clause 18 a) of **CAC/GL 53-2003**’

5th bullet – This is not relevant in an equivalence determination and may be deleted

6th bullet – Delete the 1st sentence as this is already included in the *2nd bullet*.

7th bullet – Delete as already covered in *6th bullet*

In view of the above comments, the proposed text of Clause 5 is as follows:

“**5. The** exporting country should submit the following basic information with the initial request:

- Contact information for the submitting competent authority (e.g. contact person, address, phone, email, FAX);
- The rationale or purpose for the request for an equivalence determination (e.g., desire to begin exporting a specific commodity; new technology providing an alternative control measure, resolution of an existing trade difficulty etc.);
- The importing country measure(s) which is the subject of the equivalence determination, where such has already been identified;
- The exporting country’s sanitary measure(s) associated with the food product or group of food products for which determination of equivalence is sought;
- A request for the reason or purpose of the measure if considered necessary;
- Where relevant measure(s) that have previously been agreed as equivalent with the importing country and/or where relevant with other importing countries should also be included.

Clause 7 - The word ‘pertinent’ in the first line may be substituted by the word ‘relevant’

Clause 8

This clause basically addresses clause 16 of **CAC/GL 53-2003**. It should therefore either cover all the points raised therein or only give a reference to this clause. The clause should therefore, be reworded as follows:

‘When the exporting country deems necessary/appropriate, it may ask for additional supporting information as given under a) – e) of clause 16 of **CAC/GL 53-2003**.’

or alternatively

When the exporting country deems necessary/appropriate, it may ask for additional supporting information including the reason/purpose for the sanitary measure including identification of the specific risk that the measure is intended to address; how the sanitary measure achieves or helps to achieve the ALOP; the scientific basis for the sanitary measure including risk assessment where appropriate; and any additional information that the exporting country may need to assist in presenting the objective demonstration of equivalence and the importing country should supply this information

Clause 9 – Delete the words ‘as appropriate’.

Clause 11 - It may once again be pointed out that the issues raised in the three bullets have already been done prior to a decision on the measures for which a judgement of equivalence is required. This may therefore be deleted and clause 11 modified as follows:

“A useful method for determining the information that needs to be submitted is to carry out a side-by-side comparison of pertinent sanitary measures of the importing country which are related to the judgement of equivalence. This side-by-side comparison in conjunction with consultation with the importing country, should enable the exporting country to present which of the sanitary measures achieves the ALOP of the importing country.”

Clause 12 - Second bullet to be deleted.

Third bullet to be deleted as this is covered in the fifth bullet.

Clause 14 - The following to be added at the end:

“..... along with suggestions for addressing the gaps”.

ATTACHMENT 2

Clause 5 - The words ‘...to the extent possible,’ in the second line may be deleted.

Clause 7 - This para does not correctly reflect the situation. The first and second sentences are contradictory. In case all measures are to be the subject of an equivalence determination as reflected in the first sentence, then the second sentence is incorrect as it indicates that measures with which the exporting country cannot comply will be subject to an equivalence determination. The para may therefore be modified as follows:

“Initially all sanitary measures (infrastructure, programme design, implementation, monitoring and specific requirements) pertaining to control of a hazard in a food may be subject to a comparison. The exporting country will determine which measures and/or its exported goods/products are different and will thereby be subject to an equivalence determination.”

KENYA**CX/FICS 05/ 14/3 Attachment 1****Annex Proposed Draft Appendixes to the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems on Documentation for Determination of Equivalence of Sanitary Measures****INTRODUCTION AND PURPOSE****Clause 1****Kenya proposes that;**

- The word “**appendix**” in the introductory statement in clause 1 be substituted with the word “**annex**” for uniformity.

DOCUMENTATION**Clause 3****Kenya supports the statement and proposes that;**

- The brackets be deleted and the words in the brackets be retained as is.

Clause 5 an Initial Request**Kenya supports the statement and proposes that;**

- The brackets in bullets number five and seven of clause 5 be deleted and the words in the brackets be retained as is.

Attachment 2

Annex Proposed Draft Appendix to the Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems on Determining an “Objective Basis of Comparison”

Comments**Clause 3****Kenya proposes that;**

- The word “Means” to be adopted in the statement for it to be meaningful.

Attachment 3

Annex Proposed Draft Appendix to the Guidelines on The Judgement Of Equivalence of Sanitary Measures Associated With Food Import and Export Inspection and Certification Systems on Details on the Process of Judging Equivalence

Comments**Clause 1 (e)****Kenya proposes that;**

- The word “Point”/ to be added before the word port of entry to justify for the country for the country which does not have a Port of entry. The statement to read as follows;

Point / port of entry inspection and test results.

Clause 2**Kenya proposes that;**

- A semi-colon to be added at the end of the last statement on page 9 for it to make more sense

Clause 2 Note**Kenya proposes that;**

- The word “to” in the statement be substituted with the word “so”.

The Note to read as follows;

Note: Transparency in the application of experience, knowledge and confidence is essential **so** that the use and application of this information is clear to all parties.

Clause 3 (f)**Kenya proposes that;**

- The word “iterative” in the statement be substituted with the word “interactive” for proper grammar.

MALAYSIA**General Comments**

Malaysia is of the opinion that determination of equivalence should be a process that facilitates trade. As such documentation should be minimized to the extent necessary that would allow the process of judgment of equivalence. Hence though necessary the following requirements should not result in administrative delays.

Para 5 Bullet 5 - which requires exporting country to present results of comparison

Para 7 – which requires the importing country to provide written or electronic copies of all pertinent sanitary measures relating to: infrastructure; program design, implementing and monitoring; and specific requirements for the same products, as relevant to the request from the exporting country.

Para 12 Bullet 2 - which requires results of side by side comparison of importing and exporting countries' measures.

NEW ZEALAND

New Zealand supports the development of the draft appendices to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems* CAC/GL 53-2003 and has welcomed the opportunity to participate in the working group that developed the three attachments to CX/FICS 05/14/3.

We believe that work on Attachment 1 (Proposed Draft Appendix on Documentation for Determination of Equivalence of Sanitary measures) and Attachment 2 (Determining an 'Objective Basis of Comparison') has made good progress but there remains some further work to be done to ensure the attachments fully address the questions asked in the project outlines. Appendices to CAC/GL 53-2003 need to add value to the base guidelines and be clear and concise. We believe that the current drafts still contains a level of repetition and paraphrased text from the base guidelines which is redundant.

New Zealand is also concerned that the current draft of Attachment 1 (Proposed Draft Appendix on Documentation for Determination of Equivalence of Sanitary measures) does not focus strongly enough on Documentation but rather provides guidance that will be more appropriate in the yet to be developed Appendix *Assessing which measures are to be the subject of an equivalence determination* or in the Appendices relating to *Objective Basis of Comparison* or *Judgement of Equivalence*. What the documentation appendix needs to focus on is what should be exchanged:

- at the time of initial contact;
- after initial contact but prior to submission of a request for an equivalence determination;
- at the submittal stage
- on the decision regarding judgement of equivalence

The Documentation appendix should not extol the benefit or usefulness of specific tools (for example the side-by-side comparison) or stages such as reaching agreement on an Objective Basis of Comparison. These are either addressed in the main guideline or will be covered in other appendices.

Attachment 3 (Details on the Process of Judging Equivalence) requires substantial work and would benefit with being referred back to the working group for further elaboration. New Zealand also question if the title of this attachment is appropriate and it may be better to rename this appendix as 'Elements or criteria relating to the Judgement of Equivalence of Sanitary measures'.

New Zealand is working on specific suggestions for amendments to the text of the draft appendices and expects to offer these at the 14th Session of CCFICS.

UNITED STATES**Comments**

The United States appreciates the assistance of the Working Group in developing the first three appendices to the *Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)*.

The United States recognizes that the current work is the first step in developing a comprehensive set of appendices to provide countries with further guidance in implementing the provisions of CAC/GL 53-2003 and that extensive further work will be needed, both on some of the current draft appendices and the additional appendices that await development.

The United States supports the development of the three appendices: 1) Documentation for Determination of Equivalence of Sanitary Measures; 2) Determining an “Objective Basis of Comparison”; and 3) Details on the Process of Judging Equivalence. We also support the development of the two appendices on which work was deferred: a) Assessing which measures are to be the subject of an equivalence determination; and b) Terms for on site visits by importing country authorities undertaking a determination of equivalence.

We would note that, while the Appendix on *Details on the Process of Judging Equivalence* provides explanatory information on Section 8 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification*, similar information relating to Section 7 (Procedure for the Determination of Equivalence) is not provided and we would inquire of the Committee whether the development of an appendix elaborating on Section 7 would be helpful. As a related note, paragraph 7 (3rd sentence) of the Background Section of the Paper, we believe that the difference between determining equivalence and judging equivalence is unclear. We suggest deleting “of determining equivalence” and inserting “issues” so that the phrase will read: “.....*focused more on process issues rather than on judging equivalence and revised the Appendix....*”

The following comments are provided on the various appendices (attachments).

Attachment 1: Documentation for Determination of Equivalence of Sanitary Measures

The United States provides the following specific comments on Attachment 1 and supports the advancement of this Attachment in the Codex Step Procedure.

Paragraph 5, 2nd bullet

In the parenthetical statement, replace the semi-colon after “commodity” with a comma.

Paragraph 5, 4th bullet

Place a comma after “identified”. Additionally, insert “for the measure” at the end to make the statement more clear.

Paragraph 5, bullets 5, 6 and 7

The United States believes the provisions contained in these bullets are correct and the brackets can be removed from the last 3 bullets.

Paragraph 5, 6th bullet

Replace the word “included” at the end of the sentence with “considered” as a better choice of words.

Paragraph 8

Revise the first phrase of the sentence to read: “*When appropriate, the exporting country may ask for additional information....*”.

Paragraph 12, 3rd bullet

We suggest deleting this bullet as it contains the same information as given in the 5th bullet.

Paragraph 12, 5th bullet

Delete “found to be equivalent” and insert “for which equivalence is sought” to reflect that the exporting country does not make the determination of equivalence. The sentence would then read: “*For each alternative measure for which equivalence is sought, a summary of the scientific rationale as to why the measure is equivalent and detailed supporting information.*”

Attachment 2: Determining an Objective Basis of Comparison

The United States supports the development of a definition for an “objective basis of comparison” and believes the definition appearing in paragraph 3 is a good starting point for discussion.

The United States strongly believes that the annex on the determination of an OBC should contain detailed examples and that the examples should reflect the broad extent of measures which may need to be compared, e.g., infrastructure; program design, implementation and monitoring; and specific requirements). We believe the examples should also reflect both the quantitative and qualitative nature that OBCs can have.

The United States provides the following specific comments on the introductory text.

Paragraph 3

We suggest the term “means” be used and the brackets be deleted.

Paragraph 5

We suggest consideration be given to deleting this paragraph because it is redundant with the base document (Sect. 6, paragraph 16) and does not relate to developing an objective basis of comparison.

Paragraph 6

We suggest creating a footnote in paragraph 6 that references Section 5, paragraph 13 of the base document addressing the different categories of sanitary measures that may be the subject of an equivalency determination. These categories of sanitary measures combined with the quantitative and qualitative types of objective basis of comparison would encompass all of the different basic forms an objective basis of comparison might take. This paragraph will also form the basis for the detailed examples that will be elaborated in the future. The footnote could read: “*Refer to Section 5, paragraph 13, of the main document for categories of measures*”.

Paragraph 6

The United States observes that the spectrum of an Objective Basis of Comparison extends from being entirely quantitative to being entirely qualitative. We believe, that while, the forms of an OBC expressed in paragraph 6 are correct, the paragraph does not adequately express the full range of OBCs, particularly those that are qualitative in nature. We suggest that the Working Group, in its further elaboration of this Attachment, revise this paragraph to reflect this range of OBCs and clarify the concepts. Similarly, the examples chosen be reflective of this range and should illustrate OBCs that are entirely quantitative in nature, those that are entirely qualitative in nature, and those that include both quantitative and qualitative aspects.

Paragraphs 7 and 8

For more appropriate placement, we recommend moving these two paragraphs up to between paragraphs 1 and 2.

Attachment 3: Details on the Process of Judging Equivalence

The United States supports the approach proposed for the development of the Appendix on *Details on the Process of Judging Equivalence*. We believe that the elements presented in the outline are generally correct and recognize that, while some of the elements are self-explanatory, many of the proposed elements may require explanatory text to be developed.

The United States looks forward to continuing leading the Working Group in the further development of these appendices.

Thank you for the opportunity to provide these comments.