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FOOD AND AGRICULTURE  
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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  
Sixteenth Session  
Surfer's Paradise, Queensland, Australia, 26-30 November, 2007**

**PROPOSED DRAFT APPENDIX TO THE CODEX GUIDELINES ON THE JUDGEMENT  
OF EQUIVALENCE OF SANITARY MEASURES ASSOCIATED WITH FOOD  
INSPECTION AND CERTIFICATION SYSTEMS  
(Comments at Step 3)**

**(Bolivia, Brazil, Costa Rica, European Community, Kenya, Mexico, New Zealand and Peru)**

**BOLIVIA**

In reference to the study document CX/FICS 07/16/03 Bolivia requests that consideration be given within the general scope of the document that the latter be applied in equivalence agreements between countries as described in the standards and between groups of regions, with groups of regions being understood to be the EU, MERCOSUR, CARICOM, CAN, etc.

3. Factors that may facilitate the equivalence determination of sanitary measures could include the following:

- a) The experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 17 below);
- b) The prior history in food trade between the importing and exporting countries;
- c) The level of compliance of the exporting country's food products with the importing country's requirements;
- d) The level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
- e) The extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);
- f) Being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
- g) Consideration of the relevance of any previous equivalence determinations made by the importing country.
- h) **[The existence of information exchange]**

**BOLIVIA suggests including the above sub-paragraph at this point given that the exchange of information between countries may be a factor in helping the application of equivalence**

- i) **[Transparency in the importing country's requirements]**

**BOLIVIA suggests including the above sub-paragraph as transparency between countries entering an equivalence process is a factor in achieving the joint objective.**

4. Preparatory steps, that should be considered include:

- a) Considering the benefits and cost/resource implications of an equivalence determination in comparison to other arrangements that meet the same outcome;
- b) Taking into account the considerations relating to setting priorities contained in Section 5, “Considerations before entering into bilateral or multilateral discussions”, of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999);
- c) Assuring that the importing and exporting countries have access to the necessary scientific and technical resources to carry out an equivalence determination, recognizing that a proposal for equivalence will need to be well considered and thoroughly documented;
- d) Where practicable the importing and exporting country should ~~at an early stage in the equivalence determination process~~ develop a clear plan containing, objectives, milestones, timelines and expected outcomes.

Bolivia suggests deleting this part of the text because when speaking of planning, it will form the starting point of the equivalence process.

## **GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION**

### **Scoping the equivalence determination**

5. The exporting country should appropriately scope the request for an equivalence determination by identifying the sanitary measures and food commodity combination to be submitted for consideration.

[Consideration should be given to special treatment for developing countries.]

**As contained in the MSF agreement, Bolivia suggest that within the scope of the equivalence agreement consideration be given to Special and Differentiated Treatment for developing countries.**

6. The exporting country must decide on which of the importing country’s measures it will meet by compliance and for which measures it will seek equivalence.

~~7. In some situations it will be clear as to the specific measure or group of measures that are the subject of the equivalence determination.~~

**Bolivia suggests removing this point, it being understood that in those situations where the specific measure for the application of the equivalence process is clear the process will continue as stipulated in that document.**

8. In ~~other~~ [the] situations the scope of the equivalence determination is not clear and categorization of sanitary measures as referred to in paragraphs 13 and 14 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003) may assist in determining the scope of the equivalence determination. Specifically categorisation assists with organising and carrying out side-by-side comparisons of sanitary measures and identifying which measures will be the subject of the equivalence determination

**Bolivia suggests the above rewording for consistency with the elimination of point 7.**

10. Experience, knowledge and confidence in an exporting country’s food inspection and certification system by an importing country includes the history of food trade between the two countries and the history of compliance of foods with the importing country’s requirements, particularly the food products involved in the equivalence determination. Other factors may include:

- a) general knowledge of the exporting country's food control system as demonstrated by, among other things, a side by side comparison;
- b) results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;
- c) knowledge of the exporting country's application and implementation of the risk analysis principles in their food control system;
- d) port of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
- e) agreements the importing country may already have with the exporting country, including equivalence agreements;
- f) bilateral or multilateral agreements on recognition **[and applicability]** of equivalence with other countries;

***Bolivia suggests including as a record the applicability of equivalence not just between countries that are in the process of applying an agreement but also processes undertaken for this purpose with third-party countries.***

- g) impact on food control systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;
- h) contingency plans for containing and mitigating the effects of food safety emergencies;
- i) food borne disease surveillance data associated with the food product;
- j) the degree to which industry in the exporting country uses appropriate processing controls;
- k) adequacy of the exporting country's legislation and, as appropriate, quality control systems;
- l) level/form of oversight of the food production system by the exporting country's certifying authority;
- m) acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country;
- n) any specific export control system in operation.

24. Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, ~~including~~ identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country

**Bolivia suggests removing the word "including" given that the submission package should necessarily identify the food products that are the subject of the equivalence measure.**

**27. Depending upon the nature of the OBC (see paragraph 18 of this appendix), exporting countries should provide the following information and data:**

- a) For a qualitative OBC, references to pertinent scientific information should be provided. The submission package should also contain a written analysis ~~by the exporting country's subject matter experts~~ explaining how they arrived at their conclusion that the exporting country's measures are equivalent to the importing country's measures.

**Bolivia suggest removing this text as it is understood that the exporting country would be working with experts when putting together the presentation package.**

- b) For a quantitative OBC, the submission package should include: the data used to assess the equivalence of the measure; the methodology used to obtain the data; the methodology used to assess the data including, as appropriate, the risk assessment models employed, and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis that clearly shows how the exporting country arrived at the conclusion that its measure(s) are equivalent to the importing country's measure(s).

31. Importing countries may undertake to judge equivalence based only on a review of the data and

information. ~~Some countries~~ **[or]** may also utilise on-site visits to clarify information provided by the exporting country. Subject matter experts in the importing ~~may~~ **[should]** also be utilised especially in reviewing the conclusions of the exporting country.

32. At any point in the process, ~~an~~ **[the]** importing country in consultation with the exporting country should be able to stop the process when **[justified]** evidence exists that equivalence is not possible.

**Bolivia suggests clarifying that the evidence the country submit must be justified.**

31. El país importador ~~quizás se comprometa~~ **[podría comprometerse]** a determinar... [change in Spanish with no effect on the English]  
Provision of Technical Assistance

37. The following expands on paragraph 7 (n) of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003), the principle relating to technical assistance, and provides additional guidance relating to the provision of technical assistance.

**Bolivia suggests retaining this text but in a separate paragraph from the above.**

~~It is possible that~~ **[T]**technical assistance may be needed by importing and exporting countries in carrying out equivalence determinations.

38. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:

- Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.
  - Appropriate areas for technical assistance associated with an equivalence determination could include:
    - assistance in evaluating which measures would be the subject of an equivalence determination;
    - assistance with the preparation of documentation, including the submittal package;
    - assistance in undertaking necessary risk assessments;
    - assistance with data analysis;
    - assistance in assessing whether measures meet the importing country's stated objective basis of comparison; and
- ~~[asistencia para evaluar si las medidas cumplen con la base objetiva de comparación;  
establecida por el país importador; y]~~

**Bolivia suggests including the above two sub-paragraphs as a single sub-paragraph**

- **[asistencia para evaluar si las medidas cumplen con la base objetiva de comparación; establecida por el país importador; y]**

**[Applicable only to the Spanish as the relevant two sub-paragraphs in the Spanish are already written as one in the English version, sub-paragraph 5 above.]**

- Exchange of technical expertise between the importing and exporting countries

## **BRAZIL**

Brazil thanks the effort of Codex Australia for coordinating the Working Group meeting held in Brussels, Belgium from 9-12 July 2007. We are of the opinion the *Additional Guidance to Assist Exporting and Importing Countries in Undertaking an Equivalence Determination of Sanitary*

*Measures* had been enhanced in many different ways. However, in order to make it clearer, Brazil would like to add few comments, **highlighted in bold**.

Paragraph 1 – This appendix relates to **the equivalence determination of** sanitary measures associated with a food inspection and certification system and clarifies certain aspects of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003).

**Brazil – In the way it is stated, it can lead to misunderstanding. The appendix refers specifically to the equivalence determination of sanitary measures and not to sanitary measures in general. The idea is to clarify the purpose of the document.**

Paragraph 10 g) – **negative impact on the food safety of the product** as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;

**Brazil – When organisational, structural or administrative changes occur in the exporting countries competent authorities, what matter to the importing country are the negative impacts on the food safety of the products. Adding the word “possible” at the beginning of the sentence reflects better this idea.**

Paragraph 18 – The objective basis of comparison (OBC) is a tool that can be formally (~~explicit~~) or informally (~~implicit~~) expressed by the importing country when undertaking an equivalence determination.

**Brazil – We suggest deleting the information placed between parentheses, since they can not be directly associated with the terms “formally” and “informally” and do not add significant value to the paragraph. The idea of using OBCs as a tool to reach an equivalence determination is fully covered by the expressions “formally” and “informally”.**

## COSTA RICA

Costa Rica is grateful for the opportunity to provide its comments on the document “Proposed Draft Appendix to the Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems”. Comments follow.

In paragraph 3 of the Attachment 1:

- a. Costa Rica considers that point 3a of the attachment should read as established within the context of the item’s application as follows: The experience, knowledge and confidence the importing country has with *[regard to the exporting country’s health measures associated with the food inspection and certification systems]* ~~food control system~~
- c. El ~~nivel~~ grado [change to Spanish only] de cumplimiento de los productos alimenticios del país exportador con las ~~requisitos~~ medidas sanitarias del país importador. [Change to Spanish text and proposed text change, “The level of compliance of the exporting country’s food products with the importing country’s health requirements.”]
- d. El ~~nivel~~ grado [change to Spanish only] de cooperación que exista entre las autoridades competentes ~~inocuidad~~ de inspección y certificación de los alimentos del país exportador con el país importador. [Change to Spanish text and proposed text change, “The level of cooperation that exists between the food ~~safety~~ competent inspection and certification authorities of the importing and exporting countries.”]
- e. The level of efficiency that the food safety measure inspection and certification systems achieve in providing the same results as demanded by the importing country (~~e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs~~).

Changes as well to the following paragraphs:

10.a general knowledge of the exporting country's food inspection and certification ~~control~~-system as demonstrated by, among other things, a side by side comparison

10.c. knowledge of the exporting country's application and implementation of the risk analysis principles in their inspection and certification ~~control~~-system.

10.g. impact on food inspection and certification ~~control~~-systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies.

10.h New proposal: Contingency plans for containing or mitigating the effects of food inspection and certification emergency situations.

10.i food borne disease surveillance data associated with and transmitted by the food product; statistics on residues and contaminants in foods.

10.j the degree to which industry in the exporting country ~~uses~~-applies appropriate processing controls and the competent authority's inspection method.

10.k ~~adequacy~~ of the legislation that supports the competent authority in exercising the food inspection and certification system and its application in the exporting country ~~and, as appropriate, quality control systems.~~

10. l ~~level/form~~-mechanisms or procedures of oversight of the ~~food~~ production systems by the exporting country's relevant food inspection and certification ~~certifying~~-authority

19. ... qualitative nature, e.g. the ability of food control legislation to achieve broad food ~~safety~~-health goals

35 c. To ask for information on: ~~improve~~-knowledge, experience and confidence in the exporting country's food inspection and certification ~~control~~ system

In the Spanish version of the text in paragraph 38, the sub-paragraphs 6 and 7 [sic, actually 5 and 6] should be joined together.

38.

[...]

- assistance with information and data analysis.

[...]

- exchange of technical experience ~~expertise~~ between the importing and exporting countries.

- assistance with the analysis and application of the exporting country's legislation with respect to the importing country in order to determine its equivalence.

### EUROPEAN COMMUNITY

The European Community and its Member States (ECMS) wish to commend the Working Group for the result achieved after the meeting held in Brussels in July 2007.

The ECMS are of the opinion that the text has been considerably improved and should therefore progress substantially in the Codex step procedure subject to some fine tuning.

The text is clarified in particular regarding the fact that it deals with the equivalence determination of a single sanitary measure or a set of sanitary measures making up a food control system associated with a certain type of food or group of foods;

The concept of objective basis of comparison is also clarified. It is now considered as an optional tool to be used when appropriate to facilitate the equivalence determination. The ECMS also support the deletion of the examples which can be perceived as limitations to the scope.

From a general point of view, the following points could still to be improved:

-The structure of the document could be better and could follow more closely the steps of the process. In order not to put into question at this stage all the structure of the document, the ECMS suggest to delete the two headings appearing in capital letters which do not bring any value to the document ("PRELIMINARY CONSIDERATIONS..." and "GUIDANCE ON UNDERTAKING"); the second level headings, which are directly related to the different steps of the process, would then become first level headings.

- The ECMS regret that maintenance of equivalence has not been dealt with. In particular the ECMS believe it would be useful to underline that the equivalence determination is mainly a documentary exercise and that implementation deficiencies should not put into question the result of the equivalence determination.

Some amendments in line with the general comments are included in the attached Annex.

### **ANNEX: Proposed amendments to the text.**

#### **APPENDIX: ADDITIONAL GUIDANCE TO ASSIST EXPORTING AND IMPORTING COUNTRIES IN UNDERTAKING AN EQUIVALENCE DETERMINATION OF SANITARY MEASURES**

1. This appendix relates to sanitary measures associated with a food inspection and certification system and **provides guidance on** ~~clarifies~~ certain aspects of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* (CAC/GL 53-2003 **referred below as "the Guidelines"**).

#### **PRELIMINARY CONSIDERATIONS RELATING TO UNDERTAKING AN EQUIVALENCE DETERMINATION**

2. There is a broad spectrum of circumstances where an exporting country may wish to seek an equivalence determination with an importing country. While each circumstance will likely need to be considered on a case-by-case basis, it can vary from seeking equivalence for a set of sanitary measures making up a food control system associated with a certain type of food or group of foods (e.g. dairy products) to seeking equivalence for a **single** sanitary measure (e.g. analytical method).

3. Factors that may facilitate the equivalence determination of sanitary measures could include the following:

- a) The experience, knowledge and confidence the importing country has with the exporting country's food control system (see paragraphs 9 to 17 below);
- b) The prior history in food trade between the importing and exporting countries;
- c) The level of compliance of the exporting country's food products with the importing country's requirements;
- d) The level of cooperation that exists between the food safety competent authorities of the importing and exporting countries;
- e) The extent to which importing and exporting countries' food control systems are similar (e.g., the similarity of food laws and regulations, the capabilities of professional staff and laboratories, the similarity of inspection and monitoring programs);

- f) Being well prepared to undertake an equivalence determination, including that the importing and exporting countries have access to the necessary resources such as the scientific and technical capabilities;
- g) Consideration of the relevance of any previous equivalence determinations made by the importing country.

### **Preparatory steps to undertaking an equivalence determination**

4. Preparatory steps, that should be considered include:

- a) Considering the benefits and cost/resource implications of an equivalence determination in comparison to other arrangements that meet the same outcome;
- b) Taking into account the considerations relating to setting priorities contained in Section 5, “Considerations before entering into bilateral or multilateral discussions”, of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999)*;
- c) Assuring that the importing and exporting countries have access to the necessary scientific and technical resources to carry out an equivalence determination, recognizing that a proposal for equivalence will need to be well considered and thoroughly documented;
- d) Where practicable the importing and exporting country should at an early stage in the equivalence determination process develop a clear plan containing, objectives, milestones, timelines and expected outcomes.

## **~~GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION~~**

### **Scoping the equivalence determination**

5. The exporting country should appropriately scope the request for an equivalence determination by identifying the sanitary measures and food commodity combination to be submitted for consideration.

6. The exporting country must decide on which of the importing country’s measures it will meet by compliance and for which measures it will seek equivalence.

~~7. In some situations it will be clear as to the specific measure or group of measures that are the subject of the equivalence determination.~~

8. In ~~other~~ situations **where** the scope of the equivalence determination is not clear, **and** categorization of sanitary measures as referred to in paragraphs 13 and 14 **of Section 5** of the *~~Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)~~* may assist in determining the scope of the equivalence determination. Specifically categorisation assists with organising and carrying out side-by-side comparisons of sanitary measures and identifying which measures will be the subject of the equivalence determination.

### **Experience, knowledge and confidence**

9. The following section expands on information presented in paragraph 10-12 **of Section 5** of the *~~Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)~~* and provides additional guidance relating to what constitutes experience, knowledge and confidence.

10. Experience, knowledge and confidence in an exporting country’s food inspection and certification system by an importing country includes the history of food trade between the two countries and the history of compliance of foods with the importing country’s requirements, particularly the food products involved in the equivalence determination. Other factors may include:



- a) general knowledge of the exporting country's food control system **and of its comparability with the importing country's food control system** as demonstrated by, among other things, a side by side comparison;
- b) results of audits/inspections/field examinations by the importing country, exporting country, other countries, or other officially recognized third party organizations;
- c) knowledge of the exporting country's application and implementation of the risk analysis principles in their food control system;
- d) **port point** of entry inspection and test results, including records of import rejections and alerts by the importing country as well as from other trading partners;
- e) agreements the importing country may already have with the exporting country, including equivalence agreements;
- f) bilateral or multilateral agreements on recognition of equivalence with other countries;
- g) impact on food control systems as a consequence of organisational/structural/administrative changes in the exporting countries competent authority/ies;
- h) contingency plans for containing and mitigating the effects of food safety emergencies;
- i) food borne disease surveillance data associated with the food product;
- j) the degree to which industry in the exporting country uses appropriate processing controls;
- k) adequacy of the exporting country's legislation and, as appropriate, quality control systems;
- l) level/form of oversight of the food production system by the exporting country's certifying authority;
- m) acknowledgement and evaluation of pre-existing certification systems conducted or carried out by the exporting country;
- n) any specific export control system in operation.

14. The importing country can apply such experience, knowledge and confidence at any point throughout the equivalence determination process: **and may draw the corresponding conclusions.**

15. Experience, knowledge and confidence may assist in facilitating familiarity with the information provided by the exporting country and therefore reduce the resources required to form a judgement of equivalence of the measures proposed.

16. Situations where experience, knowledge and confidence can assist include:

- a) in making a decision as to whether and how to proceed with a request for a judgement of equivalence;
- b) in setting priorities, as may be appropriate (reference should also be made to Section 5, "Considerations Before Entering into Bilateral or Multilateral Discussions", of the Codex *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999));
- c) in informing the process of comparing the exporting country's relevant sanitary measures with the importing country's sanitary measures;
- d) in reducing the number of sanitary measures that are to be the subject of a detailed examination;
- e) In reducing the extent of the scientific evidence required to determine equivalence.

17. In applying experience, knowledge and confidence to a determination of equivalence, transparency is essential so that the use and application of this information is clear to all parties.

### **Objective Basis of Comparison**

18. The objective basis of comparison (OBC) is a tool that can be formally (explicit) or informally (implicit) expressed by the importing country when undertaking an equivalence determination.

19. An ~~OBC objective basis of comparison~~ may be quantitative and/or qualitative in nature. The ~~OBC objective basis for comparison~~ of sanitary measures categorized as “infrastructure” is likely to be of a qualitative nature, e.g. the ability of food control legislation to achieve broad food safety goals. The ~~OBC objective basis of comparison~~ of sanitary measures categorised as “specific requirements” is likely to be quantitative in nature, e.g. a comparison of levels of hazard control achieved by the measure. The ~~OBC objective basis of comparison~~ of sanitary measures categorized as “programme” is likely to contain a mixture of qualitative and quantitative elements e.g. correct application of principles, and establishment of appropriate critical limits, in HACCP food control systems.

20. The following paragraph expands on information presented in paragraphs 15 and 16 **of Section 6** of the ~~Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53 2003)~~ and provides additional guidance relating to what constitutes the development of a formal ~~OBC objective basis of comparison~~. Depending on the scope of the equivalence determination there may be more than one OBC.

21. When developing OBC(s) the importing country should gather and assess scientific data and other information<sup>1</sup> and enter into a dialogue with the exporting country to seek agreement on the OBC(s). The OBC development process should, as appropriate:

- a) Ensure sufficient data to provide valid support for conclusions;
- b) Ensure the adequacy and accuracy of the data;
- c) Utilize risk assessments, as available; and
- d) Ensure sufficient knowledge and technical expertise of the subject matter experts

### **Information and Documentation Contained in Submissions for Evaluation of a Request for an Equivalence Determination**

22. The following section provides additional guidance on what information should be contained in a country’s submission for an equivalence determination.

23. Paragraphs 16-20 of Section 7, “Consultative process for equivalence agreements”, of the *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL-34-1999) provide guidance and the type of information that may need to be included in a submissions package.

24. Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country.

25. The submission package should specify the measure(s) for which equivalence is sought.

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<sup>1</sup> In the context of this appendix data is taken to mean both quantitative and qualitative data and other information

26. It may often be the case that a submission package is done in steps. For example the exporting country provides the measures for which an equivalence determination is sought. The importing country then provides the OBC if required.

27. Depending upon the nature of the OBC (see paragraph 18 of this appendix), exporting countries should provide the following information and data:

a) For a qualitative OBC, references to pertinent scientific information should be provided. The submission package should also contain a written analysis by the exporting country's subject matter experts explaining how they arrived at their conclusion that the exporting country's measures are equivalent to the importing country's measures.

b) For a quantitative OBC, the submission package should include: the data used to assess the equivalence of the measure; the methodology used to obtain the data; the methodology used to assess the data including, as appropriate, the risk assessment models employed, and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis that clearly shows how the exporting country arrived at the conclusion that its measure(s) are equivalent to the importing country's measure(s).

### Details on Judgement of Equivalence

28. The following expands on paragraphs 17-21 of Sections 7 and 8 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)*.

29. In the process of judging equivalence the importing country should focus on those measures or groups of measures which the exporting country and importing country have mutually agreed will be the subject of the equivalence determination.

30. Ongoing communication between the importing and exporting countries may assist with the judgement of equivalence process to, among other things, clarify technical points and respond to the need for additional information.

31. Importing countries may undertake to judge equivalence based only on a review of the data and information. ~~Some countries may also utilise on-site visits to clarify information provided by the exporting country.~~ *[this is the subject of para. 35]* Subject matter experts in the importing country may also be utilised especially in reviewing the conclusions of the exporting country.

32. At any point in the process, an importing country in consultation with the exporting country should be able to stop the process when evidence exists that equivalence is not possible.

33. A decision regarding the judgement of equivalence based on available information taking into account experience, knowledge and confidence can be made at any point in the process including:

a) At initial contact by the exporting country;

b) Following review of the submission package by the importing country, including the opinions of subject experts where necessary;

c) Following an assessment based on an OBC objective basis of comparison.

d) Following an assessment of the information gathered during onsite visits by the importing country;

e) Following the resolution of outstanding issues.

34. As agreed to between the importing and exporting countries, the importing country should provide to the exporting country a written report as to whether or not equivalence has been found. Where equivalence is not found, the reasoning for this should be given to the exporting country and should be

included in the written report with suggestions for solutions where possible.

### Use of On-site visits

35. To complement the documentary review by the importing country, the use of on-site visits may be beneficial in clarifying information provided by the exporting country. The rationale for on-site visits related to the determination of equivalence may include:

- a) To help clarify information provided by the exporting country relevant to its sanitary measures subject to the equivalence determination;
- b) To gather additional information on the exporting country's proposed measures that may be required by the importing country to undertake a judgement of equivalence;
- c) To improve knowledge and confidence in the exporting country's food control system<sup>36</sup>. In preparing for an on-site visit, both the importing and exporting country should consider:
  - a. Limiting the scope of on-site visits to the food product or group of food products and the associated sanitary measures that are the subject of the equivalence determination
  - b. The development of a protocol for the on-site visit.

### Provision of Technical Assistance

37. The following expands on paragraph 7 (n) **of Section 4** of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification (CAC/GL 53-2003)*, the principle relating to technical assistance, and provides additional guidance relating to the provision of technical assistance. It is possible that technical assistance may be needed by importing and exporting countries in carrying out equivalence determinations.

38. Countries considering the need for technical assistance with respect to equivalence determinations or countries considering providing technical assistance, may wish to consider the following:

- Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.
- Appropriate areas for technical assistance associated with an equivalence determination could include:
  - assistance in evaluating which measures would be the subject of an equivalence determination;
  - assistance with the preparation of documentation, including the submittal package;
  - assistance in undertaking necessary risk assessments;
  - assistance with data analysis;
  - assistance in assessing whether measures meet the importing country's stated **OBC objective basis of comparison**; and
  - Exchange of technical expertise between the importing and exporting countries.

### Maintenance of a determination of equivalence

**39. The following section expands on information presented in paragraph 21 of Section 8 of the Guidelines and provides additional guidance to the maintenance of a determination of equivalence.**

**40. A determination of equivalence may need to be re-assessed on the basis of any amendment of measures of the importing or the exporting country that affects equivalence.**

**41. Both Parties shall inform each other of any proposal for amendment of its measures and the likely effect of the proposed measures on the equivalence. The importing country shall inform the exporting country whether or not equivalence would continue to be recognised on the basis of the proposed measure. Within a period to be agreed by the Parties, the exporting country shall have the right of providing additional assurances for addressing the importing country's concerns. The previously recognised equivalence should remain applicable until the end of this period or the legislative amendment process that had established the equivalence.**

**42. The status of equivalence can only be affected by a change of legislation or measures but not by implementation failures. In the case of a substantial safety hazard the importing country reserves the right of applying a safeguard measure. The status of equivalence shall however not be directly affected by such measure.**

## **KENYA**

Kenya thanks the working group led by the Chair of the CCFICS and supports the advancement of the document to the next stage. However, we propose in line with the initial Terms of Reference of the Working Group and concerns from several delegations as indicated in ALINORM 07/30/30 paragraph 51 & 52, that the guide includes examples as an extra appendix or annex to enhance clarity for member countries.

There is an error of numbers between page 6 & 7 as paragraphs 11-13 of CX/FICS 07/16/3 are missing.

Add the wording “- assistance in building capacity in equivalence determination” particularly in developing countries with special consideration to quantitative measures.

## **MEXICO**

Mexico is grateful for the opportunity to make the following comments:

**General comment.** Given the recommendatory nature of Codex documents, it is suggested replacing in the Spanish text, the imperative form of the verb “deber” with the conditional form “debería”, whenever the English version employs the word “should”.

**Paragraph 3.** Reword as follows: “Among the factors that may facilitate the equivalence determination of sanitary measures could are included the following”

- Change the words “food control system” with the words “food control system” in sub-paragraphs a) and e).
- Sub-paragraph b: “... entre el país importador ~~de~~ y el país exportador;” [correction to the Spanish]
- Sub-paragraph d: Change the text “...food safety competent authorities ...” with the words “...food control competent authorities ...”
- Sub-paragraph e: Change as follows: “la similitud de los programas de inspección y monitoreo ~~control~~);” [Change to Spanish text, “... the similarity of inspection and monitoring programs;”]
- Sub-paragraph g: Modificar: “... la pertinencia de ~~todo~~ cualquier determinación de equivalencia ...” [Change to Spanish text, “...the relevance of any previous equivalence determinations...”]

**Paragraph 4.-** Change the text as follows: “Las etapas preparatorias que ~~se deberán considerar~~ deberían ser consideradas incluyen:” [Change to Spanish text, Preparatory steps, that should be considered include:”]

- Sub-paragraph c: Change the word “thoroughly” with “sufficiently”
- Sub-paragraph d: Change the text as follows: “En la medida de lo posible, el país importador y el país exportador ~~deberán~~ deberían elaborar durante una etapa temprana del proceso de determinación de equivalencia un plan claro que contenga objetivos, hitos, plazos y resultados esperados, ~~durante una etapa temprana del proceso de terminación~~” [Word order change in Spanish, “Where practicable the importing and exporting country should at an early stage in the equivalence determination process develop a clear plan containing, objectives, milestones, timelines and expected outcomes.”]

**Paragraph 9:** Change “proporciona orientación adicional con respecto a ~~qué~~ lo que constituye experiencia, conocimiento y confianza.” [Change to Spanish text, “...provides additional guidance relating to what constitutes experience, knowledge and confidence.”]

**Paragraph 10:** Change as follows: “...especialmente los productos alimenticios ~~incluidos~~ involucrados en la determinación de equivalencia. Otros factores ~~incluyen~~ pueden incluir.” [Change to Spanish text: “particularly the food products involved in the equivalence determination. Other factors may include:”]

- Sub-paragraph b: “...u otras organizaciones de tercera parte oficialmente reconocidas” [Change to Spanish text to bring in line with English: “...or other officially recognized third party organizations;”]
- Sub-paragraph d: “resultados de pruebas e inspección en puerto de inspección de entrada y resultados de análisis, incluso...” [Change to Spanish: “...port of entry inspection and test results, including...”]
- Sub-paragraph f: “...on recognition of equivalence that the exporting country has with other countries;”
- Sub-paragraph g: “efecto ~~de~~ en los sistemas de control...” [Change to Spanish: “impact on food control systems...”]
- Sub-paragraph h: “planes ~~para situaciones imprevistas~~ de contingencia para contener...” [Change to Spanish, “contingency plans for containing...”]

Renumber paragraphs 14, as there is a jump in the numbering.

**Paragraph 16.** Change: “situaciones para las cuales ~~en las que~~ la experiencia, conocimiento y confianza...” [Change to Spanish: “Situations where experience, knowledge and confidence...”]

- Sub-paragraph a). “~~en~~ la toma de decisiones...” [Change to Spanish, “in making a decision...”]
- Sub-paragraph b: ~~establecer~~ el establecimiento de prioridades...” [Change to Spanish, “in setting priorities...”]
- Sub-paragraph c: “~~al preparar~~ la preparación de información para documentar el proceso...” [Change to Spanish, “in informing the process of comparing the...”]
- Sub-paragraph d: “~~al reducir~~ la reducción de la cantidad de medidas sanitarias ~~a ser~~ objeto de un análisis detallado;” [Change to Spanish, “in reducing the number of sanitary measures that are to be the subject of a detailed examination;”]
- Sub-paragraph e: “~~al reducir~~ el la reducción del alcance...” [Change to Spanish, “In reducing the extent of...”]

**Paragraph 18.** Change the words “oficialmente” and “extraoficialmente” to “formalmente” and “informalmente” [Change to Spanish.]

Include a paragraph with a definition of the Objective Basis of Comparison. “The Objective Basis of Comparison describes or represents the objective defined and backed by a health measure must be able

to reach the ALOP or contribute to reaching it in combination with other health measures.”

**Paragraph 19.** Change the word “hazard” to “risk”

**Paragraph 20.** Change as follows: “...con respecto a qué lo que constituye experiencia, conocimiento y confianza el desarrollo de una base objetiva de comparación formal...” [Change to Spanish in line with the English, “...relating to what constitutes the development of a formal objective basis of comparison.”]

**Paragraph 21.** Change as follows: “Al elaborar BOC(s)... para llegar a un acuerdo sobre la BOC(s) o BOCs. El proceso de elaboración de la ~~OBC~~ deberá BOC debería, según corresponda.” [Changes to Spanish, “When developing OBC(s) ... to seek agreement on the OBC(s). OBC development process should, as appropriate:]

- Sub-paragraph a: “~~Obtener~~ Asegurar suficientes datos ~~como~~ para acreditar...” [Change to Spanish, “Ensure sufficient data to provide valid support...”]
- Sub-paragraph b: “~~Garantizar~~ Asegurar la suficiencia...” [Change to Spanish: “Ensure the adequacy...”]
- Sub-paragraph c: “~~Utilizar~~ Utilizar evaluaciones de riesgos...” [Correct typo in Spanish, “Utilize risk assessments...”]

**Paragraph 24.** Change as follows: “... el país exportador ~~deberá~~ debería iniciar una solicitud oficial de determinación de equivalencia, ~~incluso identificar~~ incluyendo la identificación de los productos alimenticios o grupos de productos alimenticios en cuestión, y ~~deberá~~ debería haber iniciado el contacto apropiado con su homólogo en el país importador.” [Changes applicable to Spanish only, “Before forwarding a submission package to the importing country, an exporting country should initiate an official request for the determination of equivalence, including identifying the food products or group of food products concerned, and have made appropriate contact with its counterpart in the importing country.”]

**Paragraph 26.** Change as follows: “A menudo es el caso que un paquete de presentación ~~puede efectuarse se presentae~~ en etapas. Por ejemplo, el país exportador proporciona las medidas para las cuales se solicita una determinación de equivalencia. El país importador proporciona la BOC, de ser necesario. [Changes to the Spanish, It may often be the case that a submission package is done in steps. For example the exporting country provides the measures for which an equivalence determination is sought. The importing country then provides the OBC if required] (Paragraph 18 and Figure 1 of the Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems CAC/GL 53–2003)”

**Paragraph 27.** Sub-paragraph b: Change as follows: “y ~~las asunciones~~ los supuestos de riesgo efectuados y la naturaleza y alcance de la incertidumbre de las conclusiones. El paquete de presentación también ~~deberá~~ debería incluir un análisis... a conclusión de que su medida ~~es equivalente~~ o sus medidas son equivalentes...” [Changes to the Spanish, “...and the assumptions made and the nature and extent of uncertainty of the findings. The submission package should also contain a written analysis ... at the conclusion that its measure(s) are equivalent...”]

**Paragraph 29.** Change “...hayan acordado mutuamente ~~han de ser~~ que serán objeto de la determinación de equivalencia.” [Change to Spanish, “...have mutually agreed will be the subject of the equivalence determination.]

**Paragraph 30.** Change the Spanish word “asistir” to “ayudar”.

**Paragraph 31-** Modificar: “El país importador ~~quizás se comprometa a~~ puede determinar... También se pueden ~~Quizás se deban~~ usar los servicios de ~~los~~ expertos...” [Changes to the Spanish, “Importing countries may undertake to judge. ... Subject matter experts in the importing may also be utilised...”]

**Paragraph 33.** Change as follows: ~~En cualquier momento del proceso puede tomarse~~ una decisión

con respecto a la determinación de equivalencia en base a la información disponible, tomando en cuenta la experiencia, conocimiento y confianza, puede tomarse en cualquier momento del proceso, incluyendo: ~~incluse~~” [Changes to Spanish, “A decision regarding the judgement of equivalence based on available information taking into account experience, knowledge and confidence can be made at any point in the process including:”]

**Paragraph 34.** Change “...que determine si se ha hallado o no la equivalencia...” [Change to Spanish text, “...as to whether or not equivalence has been found...”]

**Paragraph 35.-** Sub-paragraph a) “Para ayudar a ~~verificar~~ aclarar la información proporcionada...” [Change to Spanish text in line with the English, “To help clarify information provided...”]

**Paragraph 38.-** First bullet point. “~~ninguna de las partes debería considerar que~~ la asistencia técnica no es un requisito obligatorio para ninguna de las partes al llevar a cabo una determinación de equivalencia.” [Change to Spanish text, “Technical assistance is not a mandatory pre-requisite by either party in undertaking a determination of equivalence.”]

Second bullet point, last two sub-paragraphs of English text:

“- asistencia para evaluar si las medidas cumplen con la base objetiva de comparación establecida por el país importador; y

~~—establecida por el país importador; y~~

[An additional return margin has been inserted in the middle of the fifth sub-paragraph, ie, join Spanish sub-para six to end of sub-para 5, as in English, “assistance in assessing whether measures meet the importing country’s stated objective basis of comparison; and”]

- intercambio de pericia ~~ténica~~ técnica entre el país importador y el país exportador. “ [Correct typo in Spanish]

## NEW ZEALAND

### **General Comment**

New Zealand supports the development of additional guidance in relation to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)* and we welcomed the opportunity to participate in the Working Group that develop the draft appendix to CAC/GL 53-2003 that CCFICS is considering under CX/FICS 07/16/3.

New Zealand thanks the United States for the work they have done in leading the development of this document. The draft appendix that CCFICS now has before it has, in our opinion, been much improved by the extensive and detailed discussion and revision undertaken by the Working Group. New Zealand suggests that with some editorial amendments this draft can be significantly progressed in the Codex step process.

New Zealand acknowledges and supports the decision of the Working Group to clarify that the scope of the Appendix reflects and is defined by the scope of the main document CAC/GL 53-2003. New Zealand does however consider it is important that the record of the CCFICS 16 consideration state clearly that although the guidance provided by CAC/GL 53-2003 and this appendix is confined to dealing with the judgement of equivalence of specific *sanitary measures* this is in no way intended to suggest that countries can not enter into discussions or agreements relating to the equivalence of food control systems should they so wish.

### ***Specific Comments***

In support of our general comments above New Zealand makes the following specific comments in respect of the current draft Appendix.



Use of the phrase ‘equivalence determination’ – this phrase is currently used in two ways throughout the draft Appendix. Sometimes it is used in reference to a ‘process’ and at other times it is used in reference to a ‘decision’. New Zealand suggests that it may be clearer to use the phrase only in reference to the decision and to use another term or phrase when referring to the process. In support of this comment specific suggestions are made in relation to particular paragraphs below.

Title of the Appendix – New Zealand suggests that the title be amended to more clearly reflect the content and intent of the Appendix. The Working Group was clear in its decision that the Appendix is linked to the scope and content of the parent document CAC/GL 53/2003. New Zealand notes also that the parent document has a strong link to the SPS Agreement and we suggest that the title of the Appendix could reflect that link, particularly as it relates to the role of consultations between the exporting and importing countries, this would also assist in making a distinction between the process for determining equivalence and the decision or judgement. An amended title could be:

‘Additional guidance to assist exporting and importing countries ~~in undertaking an~~ **entering into consultations with the aim of achieving recognition of** equivalence ~~determination and~~ **for importing countries in arriving at judgements on the equivalence of specified** sanitary measures’

Similarly the first major heading should be amended. New Zealand suggests that it may be simpler and improve clarity to shorten the heading. An amended heading could be:

**PRELIMINARY CONSIDERATIONS RELATING TO ~~UNDERTAKING AN EQUIVALENE DETERMINATION~~**

**Paragraph 3** – there are two instances in this paragraph when the phrase ‘equivalence determination’ is used in reference to the process that leads to a determination of equivalence. New Zealand suggested that it would improve clarity to use different text in these two instances. Amended text could be:

‘Factors that may facilitate **consultations on the recognition of** the equivalence ~~determination~~ of **specified** sanitary measures could include the following:

- f) The **preparedness and availability of appropriate resources in both** ~~Being well prepared to undertake an equivalence determination, including that~~ the importing and exporting countries for the consultations including ~~have access to the~~ **any** necessary ~~resources such as the~~ scientific and technical capabilities;’

**Paragraph 3 bullet e)** – New Zealand suggests that the word ‘inspection’ be replaced with the word ‘verification’. ‘Inspection’ is an older terms that does not reflect modern usage and interpretation. We acknowledge that the term is defined in the main document and that definition does imply verification, however we suggest that it is clearer and more helpful to use the modern term ‘verification’.

Sub-heading before paragraph 4 – in line with our earlier comment New Zealand suggests that this sub-title be simplified and amended as follows:

‘Preparatory steps ~~to undertaking an equivalence determination~~

**Paragraph 4 bullets a), c) and d)** – the phrase ‘equivalence determination’ when used in these bullets refers to the process and New Zealand suggests it be replaced to improve clarity. Amended text could be:

- a) Considering the benefits and costs/resource implications of ~~an~~ **requesting consultations with the aim of achieving recognition of the** equivalence **of specified sanitary measures** ~~determination~~ in comparison to other arrangements that meet the same outcome;
- c) Assuring that the importing and exporting countries have access to the necessary scientific and technical resource to carry out an **assessment of the** equivalence ~~determination of the specified sanitary measures~~, recognising that a proposal for equivalence ...
- d) Where practicable the importing and exporting ~~country~~ **countries** should at an early stage in the ~~equivalence determination~~ process develop a clear plan ...

**Paragraph 4 bullet d)** – This bullet is the last in a list of ‘Preparatory steps’. New Zealand suggests that this bullet should be a separate short paragraph. It is not really a preparatory step but was identified during the Working Group discussions as a good idea that needed a place in the document. Development of a plan with objectives, milestones etc is something that would occur after the decision to proceed with an equivalence determination is made and could not be developed without having scoped what the determination will include. Its inclusion within the list of ‘Preparatory steps’ is therefore confusing, however as a separate paragraph it can be seen for what it is – a piece of useful advice that may assist the overall process.

Major heading ‘**GUIDANCE ON UNDERTAKING AN EQUIVALENCE DETERMINATION**’ – New Zealand suggests that this heading be shortened and reworded as:

**UNDERTAKING A DETERMINATION OF EQUIVALENCE**

Sub-heading before paragraph 5 – the word ‘scoping’ is being used as a verb this is incorrect English. New Zealand suggests that the sub-heading be reworded as:

‘Establishing the scope’

**Paragraph 5** – the word ‘scope’ is being used as a verb again this is incorrect English. New Zealand suggests that the paragraph be revised as follows:

‘The exporting country should appropriately **consider and identify which** ~~scope the request for an equivalence determination by identifying the~~ **specified** sanitary measures and food commodity combination(s) **they wish to request an equivalence determination for to be submitted for consideration.**’

**Paragraph 7** – the phrase ‘equivalence determination’ is being used to refer to the process. Also for consistency the term ‘sanitary measures’ should be used the first time it occurs rather than just ‘measures’. New Zealand suggests that the paragraph be reworded as follows:

‘In some situations it will be clear as to the specific **sanitary** measure or group of measures that are the subject of the **request for the** equivalence determination.’

**Paragraph 8** – New Zealand suggests that the points made in the last sentence be reversed, this would clarify that the main benefit from categorisation is to help identify the measures that will be the subject of the request for a determination. We do not consider the use of the term ‘side-by-side comparison’ as helpful. As currently drafted it appears that this is the only way in which an assessment can be undertaken. The revised sentence would be:

‘Specifically categorisation assists with organising ~~and carrying out side-by-side comparisons of sanitary measures~~ and identifying which **sanitary** measures will be the subject of the **request for an** equivalence determination’.

**Paragraph 10** – the phrase ‘equivalence determination’ is being used to refer to the process. For clarity New Zealand suggests that the sentence be amended to:

‘... particularly the food products involved in **the request for** the equivalence determination. Other factors may include:’

**Paragraph 10, bullet a)** – in line with our comment on paragraph 8 we suggest that this bullet be amended to clarify that a side-by-side comparison is not necessarily required. New Zealand would suggest that the phrase be deleted and the bullet stop after ‘food control system’, if the phrase is to remain then the revised bullet should be:

- a) general knowledge of the exporting country’s food control system, **which may be as** demonstrated by, among other things, a side-by-side comparison;

**Paragraph 16 bullet b)** – New Zealand suggests that the readability of the bullet could be improved by making the link to CAC/GL 34-1999 clearer, by including in the main sentence the reference currently in round brackets. A revised bullet would be:

- b) in setting priorities, as may be appropriate, ~~(reference should also be made as~~ **referred to in** Section 5, “Considerations .....

**Paragraph 19** – this paragraph now includes the full text of footnote 11 from CAC/GL 53-2003, it is not however referenced as such. In developing the Appendix care was taken to not duplicate or paraphrase the original text. To maintain this approach New Zealand suggests that rather than repeat the footnote text an explicit referral to that text is made. A revised paragraph would be:

19 An objective basis of comparison may be quantitative and/or qualitative in nature.  
**The information in CAC/GL 53-2003 Footnote 11 is particularly relevant in explaining this point and provides some useful examples.**

**Paragraph 20** – to reinforce the connection to Footnote 11 made in paragraph 19 New Zealand suggests that a reference is also made in the first sentence of this paragraph. The last sentence of the paragraph again uses the phrase ‘equivalence determination’ without being clear about what it means. A revised paragraph would be:

20 The following paragraphs expand on information presented in paragraphs 15 and 16 **and footnote 11** of the *Guidelines on the Judgement* ... Depending on the scope of **the request for** the equivalence determination there may be more than one OBC.

**Paragraph 24** – New Zealand suggests that it is appropriate to again link the language to the parent document and the SPS Agreement by including a reference to entering consultations. A revised sentence would be:

‘Before forwarding a submission package to the importing country, an exporting country should initiate an official request **to enter consultations** for the determination of equivalence, including .....

**Paragraph 25 and 26** – These paragraphs could be seen as a paraphrase of information contained in the parent document CAC/GL 53-2003 – paragraph 18 a) to d). The Working Group and previous discussions by CCFICS has been clear that such paraphrasing is to be avoided to the maximum extent possible. New Zealand suggests that it may be of greater assistance to Codex members for this Appendix to make a clear reference to relevant paragraph in CAC/GL 53-2003. Revised text would be:

~~25 The submission package should specify the measures(s) for which equivalence is sought.~~

26 It may often be the case that a submission package is done in steps. **Paragraph 18 a) to d) of CAC/GL 53/2003 identify steps in the preparation of a submission package and the consultation and exchange of information that can occur in identifying** ~~For example the exporting country provides the measures for which an equivalence determination is sought and provision of~~ **The importing country then provides the OBC if required.**

**Paragraph 27** – the back reference should be to paragraphs 18 and 19, it is paragraph 19 that specifically mentions quantitative and qualitative. A revised first sentence would be:

27 Depending upon the nature of the OBC (see paragraphs 18 **and 19** of this appendix), exporting .....

**Paragraph 27 bullet a)** – New Zealand suggests that ‘regulatory’ as well as scientific information may be pertinent for qualitative OBCs. An amended bullet would be:

a) For a qualitative OBC, references to pertinent scientific **and regulatory** information should be provided. The submission package ... ‘

**Paragraph 31** – the word ‘country’ is missing from the last sentence. Amended text would be:

‘Subject matter experts in the importing **country** may also be utilised especially in reviewing the conclusions of the exporting country.’

**Paragraph 35 bullet a)** – the phrase ‘equivalence determination’ is used to identify the process. A revised bullet could be:

- a) To help clarify information provided by the exporting country relevant to its sanitary measures subject to the **request for an** equivalence determination;

**Paragraph 36 bullet a)** – the phrase ‘equivalence determination’ is used to identify the process. A revised bullet could be:

- a) Limiting the scope of on-site visits to the food product or group of food products and the associated sanitary measures that are the subject of the **request for an** equivalence determination;

**Paragraph 37** – the phrase ‘equivalence determination’ is used in the last sentence to identify the process. A revised sentence could be:

‘It is possible that technical assistance may be needed by importing and exporting countries in carrying out **the necessary work to prepare for and respond to a request for an** equivalence determinations.

**Paragraph 38** – the phrase ‘equivalence determination’ is used several time in this paragraph and the following bullets. New Zealand suggests the text is amended to clarify the meaning and also to ensure consistence with the rest of the Appendix. Amended text could be:

38 Countries considering the need for technical assistance with respect to **preparing for and responding to a request for** equivalence determinations or countries considering providing .....

- Technical assistance is not .....
- Appropriate areas for technical assistance associated with **preparing for and responding to a request for** an equivalence determination could include:
  - Assistance in evaluating which **specific sanitary** measures would be the subject of **the request to enter consultations with the aim of achieving** an equivalence determination;

## PERU

Peru is grateful for the opportunity to express its opinion regarding the information requested.

It is suggested considering the importance of stating in the present Proposed Draft that importing and exporting countries establish timelines of activities with milestones that lead to establishing these equivalences.