

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 (b)

CX/FICS 06/15/4 Add 1

September 2006

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

Fifteenth Session

Mar de Plata, Argentina, 6-10 November, 2006

**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)

(Argentina, Australia, Canada, New Zealand, the United States and the OIE)

ARGENTINA

Argentina appreciates the efforts of the Working Group to develop this document, as well as the opportunity to provide these comments.

General comments

Argentina would like to point out that in the English version the paragraph numbering is incorrect, as paragraph 18 has been omitted, i.e. paragraph 19 comes immediately after paragraph 17. The Spanish version, however, is correct. Argentina's comments are therefore based on the paragraph numbering of the Spanish version, on the understanding that the omission in the English version should be amended.

Specific Comments

Struck out, bold text: wording proposed to be deleted.

Bold text: new proposed wording.

Text in italics: wording quoted from the original document.

ATTACHMENT 1**IDENTIFYING WHICH MEASURES ARE TO BE THE SUBJECT OF AN EQUIVALENCE DETERMINATION****Paragraph 5, second bullet point:**

“5. Before identifying measures to be the subject of an equivalence determination, the exporting country should consider its rationale or purpose for, and other factors that relate to, the proposed request for an equivalence determination. the exporting country may consider: (...)

- *Whether there is a need for facilitation of trade while ensuring the protection of health of consumers;”*

Argentina suggests the deletion of the phrase **“while ensuring the protection of health of consumers”**, as both in the case of the alternative measure for which equivalence has been requested and in the case of compliance with the standard of the destination country, consumer protection should always be ensured under the terms established by the destination country. The second bullet point would thus be redrafted as follows:

- *Whether there is a need for facilitation of trade;*

DOCUMENTATION FOR DETERMINATION OF EQUIVALENCE OF MEASURES**Submittal package****Paragraph 9, bullet point d):**

“Documentation provided by the competent authority of the exporting country to the importing country should:

d) Provide documentation on the existence of the exporting country’s legislative base and administrative systems for implementing and enforcing the alternative sanitary measure(s).”

Argentina suggests the deletion of the word **“administrative”** and the addition of the word **“inspection and certification”** before the word “systems”. The administrative system *per se* does not ensure the application of the sanitary measure(s). The administrative system is designed, in any case, according to the needs of the inspection system itself, since it is the one that performs the role of enforcing the nationally applicable sanitary measure(s) of which equivalence determination is requested. Bullet point d) would be redrafted as follows:

*d) Provide documentation on the existence of the exporting country’s legislative base and **inspection and certification** systems for implementing and enforcing the alternative sanitary measure(s)*

Argentina also suggests the addition of a new bullet point e) in paragraph 9, with the following wording:

e) Include, where the exporting country considers it appropriate, information on the historical trade background between both markets, associated with the product or group of products for which equivalence determination of (a) sanitary measure(s) is requested.

DETERMINING AN “OBJECTIVE BASIS OF COMPARISON”

Paragraph 12: Argentina suggests that the **Spanish version** of this paragraph be amended to more clearly reflect the issue concerned. The new wording for it would be as follows:

12. La base objetiva de comparación (BOC) es el instrumento por el cual una medida sanitaria o un grupo de medidas alternativas pueden demostrar que logran el mismo efecto para alcanzar el Nivel Adecuado de Protección del país importador, que las medidas sanitarias correspondientes aplicadas por el país importador, y que por lo tanto, pueden considerarse equivalentes.

MORE DETAIL ON THE PROCESS OF JUDGING EQUIVALENCE, INCLUDING TERMS FOR ON-SITE VISITS

Paragraph 22¹: As regards this paragraph, “*Experience, knowledge and confidence in an exporting country’s food inspection and certification system by an importing country may include 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 include:*”, Argentina suggests that the wording of the last sentence, “*Other factors include:*” , be amended as follows:

Other factors might include:

Argentina believes that the potentiality of the modal auxiliary “might” allows requiring some of the listed factors rather than compliance with all included items.

AUSTRALIA

Australia strongly 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 would like to thank the Working Group that developed the current draft under the leadership of the United States.

We believe the Committee needs to look again at the overall structure of the document especially the order of the specific sections and the content.

We could support progress of a document that avoids rephrasing the parent document, but promotes new and useful information that will assist in the determination of equivalence.

While a great deal of time and effort as been applied to the development of this draft, in Australia’s opinion it remains cluttered with information that is contained in the original document CAC/GL 53 -2003 and has the potential to confuse governments that may refer to the appendix for assisting determination of equivalence.

As the document is at Step 3, CCFICS has an opportunity to redress the approach and provide useful information that will assist governments in interpreting and using the parent document. Australia acknowledges that this may trigger procedural matters with CCFICS possibly having to notify the Codex Alimentarius Commission of its revised intentions.

The parent document describes the judgement of equivalence as an iterative process, where constructive dialogue between the exporting and importing countries occurs according to defined roles. For this reason we consider that the most helpful flow for the document would be to address upfront the framework of communication and cooperation between the exporting and importing countries that we see as an important prerequisite to a successful equivalency determination process.

Once this framework is established the question of experience, knowledge and confidence needs to be addressed (see the following points), the identification of the measures that will then pass through the full equivalency determination process including objective basis for comparison (OBC) and judgement.

There is a need for discussion on the extent to which experience, knowledge and confidence can be relied upon during the equivalency determination process and the subsequent judgement itself. We consider that a common understanding by the Committee of how experience, knowledge and confidence can be used by the importing and exporting countries during the equivalency determination process is a fundamental element to the document’s progression as it also relates to the question of ‘scope’ which arose throughout the discussion at the working group.

¹ This is the correct number of the paragraph. In the current document, this paragraph appears as paragraph 23.

Therefore, in our view the appendix needs to provide clarity on the role of experience, knowledge and confidence, how it can contribute to identifying which measures (or hierarchy/categories of measures) the importing country is already in compliance with (or equivalent to) and/or those measures that remain that need to progress through an equivalency determination process. The other gap in the text is a response to the proposition that the technical exchange of information can be offset (particularly in regard to the OBC) where the importing country has extensive experience, knowledge and confidence in the exporting country and wishes to place reliance upon it. Where reliance is placed on experience, knowledge and confidence there is also lack of clarity as to what such a process is called.

Whilst we are supportive of the single appendix being used to address all the areas of work, we do think that the Committee may wish to consider addressing the Appendix in two parts, part one covering; communication/cooperation, identifying and choosing measures for determination of equivalence (informed by experience, knowledge and confidence); determining the OBC and ultimately, the judgment of equivalence, with the second part covering the 'administrative' type procedures (documentation and technical assistance). These two parts could still be developed in parallel but through different processes.

CANADA

General Comments

Canada thanks the United States for leading the Working Group and notes the progress made with respect to this document. We are of the view the current draft is significantly improved with respect to scope and focus of the document.

However, we remain concerned that the use of the word "equivalence" by itself in this document leaves ambiguity with respect to whether or not the document is referring to "equivalence agreements" or "equivalence of sanitary measures". It is Canada's view that this document should focus specifically on equivalence of sanitary measures (as referenced in the title) and that all instances where "equivalence" is used by itself should be modified to read "equivalence of sanitary measures" (or "equivalence of measures" where the footnote clearly establishes that this refers to equivalence of sanitary measures). Similarly, where the phrase "equivalence determination" appears, we are of the view it should be replaced with "determination of equivalence of measures".

Canada is also concerned with the inclusion of reference to judgement of equivalence based on "experience, knowledge and confidence" in the inspection and certification system operated by the exporting country. The process described in the parent document is one which requires a specific review of the relevant measure of the importing country, the establishment of an objective basis of comparison for the purpose of judging equivalence, and a process whereby the judgement is made. It is our view that reference to "experience, knowledge and confidence" should be restricted to those measures which may be related to the measure for which equivalence is being sought, e.g., measures related to audits, testing, etc. which would provide assurance that the measure for which equivalence is being sought can be delivered in an appropriate fashion.

Specific Comments

Paragraph 19 - Examples of objective bases of comparison

Example - JUICE PROCESSING TO REDUCE BACTERIAL PATHOGENS

We recommend that reference to a 5 fold reduction in the numbers of the pathogen be changed to 5 log and that the word "fold" be added after 100,000. In addition, explanatory text in the section on Reason/Purpose of the sanitary measure should more clearly link the desire to address illness through the proposed pathogen levels. Hence, we propose the following changes to those sections:

Importing Country Sanitary Measure: Fruit juice processors are required to use processes that achieve a 5 log or 100,000 fold reduction in the numbers of the most resistant pathogen in their finished product compared to levels that may be present in the untreated juice.

Reason/Purpose for the importing country's sanitary measure: to assure that fruit juices do not result in unacceptable levels of illness in consumers through the presence of food borne pathogens in excess of specified levels.

Example - SAMPLE COLLECTOR

We recommend changes to more clearly reflect the issue of integrity and reliability in the section on OBC by modifying the first sentence as follows:

- **OBC:** Controls to ensure integrity and reliability of sampling include measures related to competency and measures to ensure freedom from conflict of interest of sample collectors. For example.....

SECTION - Experience, Knowledge and confidence

Paragraph 22

This paragraph should be adjusted to reflect the fact that experience, knowledge and confidence comes from situations where trade already exists in the commodity or related commodities. Hence, we recommend changing it as follows:

22. Where trade already exists in the commodity or related commodities, judgement of equivalence of measures may be expedited by experience, knowledge and confidence in the food inspection and certification system of the exporting country, based on

Paragraph 24 – bullet f.

We recommend removal of the first part of the text in square brackets as experience, knowledge and confidence cannot establish equivalence of measures.

Hence, bullet f should be modified as follows:

- f. determine the necessity or scope of an on-site visit by the importing country of the exporting country's system;

SECTION - Decision regarding a Judgement of equivalence

Paragraphs 28 and 29

To reflect Canada's concerns regarding the need for appropriate information to make a judgement on the equivalence of sanitary measures, we commend the following changes:

28. A decision regarding the judgement of equivalence of measures could be made at several points provided adequate detail is available upon which to base such a judgement including:

- a. At initial contact by the exporting country;
- b. Following review of the submittal package by the importing country;
- c. Following onsite visits by the importing country;
- d. ~~Following an assessment based on experience, knowledge and confidence;~~
- e. Following an assessment based on an objective basis of comparison.
- f. Following further exchange of information that resolves any differences of opinion.

29. Equivalence of sanitary measures proposed by the exporting country should be granted by the importing country when:

- a. ~~The experience, knowledge and confidence of the importing country with the pertinent measures of the exporting country is such that the importing country can determine that measures are equivalent;~~
- b. The exporting country demonstrates, through the use of the objective basis of comparison, that its alternative measures are equivalent to those of the importing country. This comparison is facilitated with the use of quantitative data but also can be done on a qualitative basis.

NEW ZEALAND

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

General Comment

New Zealand strongly 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 have welcomed the opportunity to participate in the Working Group that undertook the development of an appendix to CAC/GL 53-2003 to achieve this. We also strongly support the objectives provided by CCFICS to the Working Group and believe that the technical issues therein must be specifically advanced if the Appendix is going to add significant value to the existing Guidelines – CAC/GL 53-2003.

New Zealand thanks the United States for the work they have done in leading the development of this document. Providing advanced technical guidance on equivalence is highly challenging and the Working Group made reasonable progress in advancing the draft document. However, New Zealand continues to have concerns. The new draft Appendix produced by the Working Group continues to cover a lot of ground and does so in a generic rather than a specific way. In particular it paraphrases a lot of material already present in CAC/GL 53-2003 and in some instances confuses issues that are already covered by carefully crafted original text.

CAC/GL 53-2003 is also careful to carry through overarching guidance on determination of equivalence relative to three broad categories of sanitary measures: Infrastructure, Programme Design etc., and Specific Requirements. We strongly suggest that a similar approach in developing the draft Appendix should be taken.

We believe that it is the key principles in CAC/GL 53-2003 that need expansion so as to provide practical guidance to countries on **how** they are to be applied. These are:

- further developing the context of different categories of measures and how this influences a choice of the measure(s) that will be the subject of a case for determination of equivalence;
- establishing an objective basis for comparison (OBC); and
- judging equivalence.

Further, the value to the importing country of “experience, knowledge and confidence” on sanitary measures in the exporting country as it affects all aspects of determination of equivalence is not clearly differentiated in the draft Appendix. Good guidance on identifying what is going to be the subject of equivalency and what is not in respect of an “inspection system” is the key and this needs to be fully developed as a starting point in the Appendix. “Experience, knowledge and confidence” of the exporting country is an essential contributor to this sorting process. It remains highly unlikely that a full inspection system will ever be contemplated for judgement of equivalence by an importing country unless the majority of “higher level” components can be accepted on the basis of “experience, knowledge and confidence”. Specific requirements (or measures in other categories) can then be put through the formal equivalence process. It is simply not practical on either side to work through a formal equivalence process for every element of an inspection system and judge the equivalence of each according to an OBC etc.

Sorting and acceptance of "surrounding components" based on "experience, knowledge and confidence" may be on the basis of replication of the importing countries requirements for some components/measures (already being carried out), or "mutual recognition" of some differences on the basis that they are likely to produce similar food safety outcomes, even though judgement has not been via a formal OBC / judgement process.

Having isolated measures that do need to be judged formally, we proceed through the equivalence determination as in CAC/GL 53-2003. This underpins current so-called "equivalence" agreements in the real world.

In its current form the draft presents little new material on a core tenet of CAC/GL 53-2003 - "analysis of the strength of the relationship between the exporting country's specified sanitary measure and the achievement of the Appropriate Level of Protection (ALOP) of the importing country as reflected in the OBC". An important part of this should be providing guidance on the different expressions of ALOP that can be used to anchor different expressions of an OBC.

While New Zealand acknowledges that the Working Group was asked to develop additional guidance on documentation, on-site visits and technical assistance, and further that CCFICS-14 instructed the Working Group to combine all the requested information into one Appendix, we are very concerned that this 'administrative' guidance is preventing the development of guidance on the key principles on how to actually select measures for a determination of equivalence and how to actually judge equivalence New Zealand, therefore suggests that CCFICS might consider focusing on only three sections of the Appendix in the first instance. These would be:

- Section 1: Identifying and choosing measures for determination of equivalence, to be read in conjunction with Section 5 of CAC/GL 53-2003
- Section 2: Determining an objective basis for comparison, to be read in conjunction with Section 6 of CAC/GL 53-2003
- Section 3: Judging equivalence, to be read in conjunction with Section 8 of CAC/GL 53-2003

Specific Comments

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

INTRODUCTION AND PURPOSE

Paragraph 2 is covered under Section 5 in CAC/GL 53-2003. The current text in the draft Appendix paraphrases what is more appropriate generic text in paragraph 9 of CAC/GL 53-2003 i.e. "an equivalence determination can be sought for any sanitary measure or set of measures relevant to a food product or group of food products".

Paragraphs 3 and 4 are covered under Principle 7f, and Section 7 of CAC/GL 53-2003, where it is identified that importing and exporting countries should use an agreed process for exchange of relevant information. Paragraph 4 does add that information may be exchanged... "using tools, such as a questionnaire, that facilitate an organized compilation of material" but in fact dialogue will be iterative and will differ case-by-case (see Paragraph 16 of CAC/GL 53-2003).

IDENTIFYING WHICH MEASURES ARE TO BE THE SUBJECT OF AN EQUIVALENCE DETERMINATION

This Section appears to cut across several parts of CAC/GL 53-2003 but the main context is provided by Section 7, paragraph 18a. Paragraph 5 provides a series of bullets to assist the exporting country exercising its SPS right to choose any measure of an importing country for the determination of equivalence. However, most of these bullets are already covered in CAC/GL 53-2003. Paragraph 6 paraphrases text in the Principles, Section 7 and the flow chart (Figure 1) in CAC/GL 53-2003. Paragraph 7 discusses the use of a

“side-by-side comparison of measures between systems”. This is covered in Section 7 of CAC/GL 53-2003 – “the exporting country should review all applicable sanitary measures of the importing country” etc.

More importantly, the Section misses out expansion of the key issue presented in Paragraphs 11 and 12 and summarised in paragraph 14 of CAC/GL 53-2003 relative to choosing measures for judgement of equivalence i.e. “allocation of measures to a particular category may assist countries in simplifying the extent of the equivalence determination relative to other sanitary measures making up the food control system”.

The key issue for this Section of the draft Appendix should be the chance of success, and efficiency of process. When contemplating a submission for equivalence, an exporting country needs to mount a robust case (so needs good data and technical resources as mentioned) and needs to be confident that the importing country will apply appropriate resources in a timely manner. The choice of measures put forward should reflect this (see general discussion above).

It is suggested that the current material in this Section could be improved by text to the effect: “*When selecting a measure for judgment of equivalence, an exporting country should be satisfied that sufficient scientific data is available to support the case and there are sufficient technical and administrative resources available to see the equivalence process through to completion*”.

DOCUMENTATION FOR DETERMINATION OF EQUIVALENCE OF MEASURES

Paragraph 8 is covered in several parts of CAC/GL 53-2003 e.g. Principles, paragraphs 17, 18. Similarly, are the first three bullets of Paragraph 9. The fourth bullet of Paragraph 9 asks for documentation “on the existence of the exporting country’s legislative base and administrative systems for implementing and enforcing the alternative sanitary measures” yet the need for this type of documentation will vary on a case-by-case basis e.g. Section 5 of CAC/GL 53-2003 says that this is not needed when the importing country has “prior experience, knowledge and confidence” etc. Paragraphs 10 and 11 are paraphrases of the same content in CAC/GL 53-2003.

DETERMINING AN OBJECTIVE BASIS FOR COMPARISON

This is an essential part of the Appendix and has been identified as such from the commencement of this work by CCFICS. However, this section of the current draft fails to provide substantive additional guidance on developing an OBC. Much of the draft repeats or paraphrases CAC/GL 53-2003 text or when new material is introduced this is not expanded upon.

In illustration, Paragraph 12 repeats Paragraph 15 in CAC/GL 53-2003. Paragraph 13 indicates that there may be more than one “objective basis of comparison” (OBC) needed for a determination. This is new material and should be enlarged on rather than just stated.

Paragraph 14 states that an OBC may be quantitative or qualitative. If so, clear examples of both should be supplied. Paragraph 15 adds little e.g. stating that a quantitative OBC “may require data gathering and statistical analysis”.

Paragraph 16 addresses some inputs to developing an OBC. As stated in CAC/GL 53-2003, the importing country primarily establishes this, in consultation (and hopefully reaching agreement) with the exporting country. However, the current text appears to focus more on providing guidance to the exporting country on developing a case for judgement of equivalence, than on guidance to the importing country on setting an OBC e.g. an importing country certainly is not bound to “utilize side-by-side comparisons of the data developed by the importing and exporting countries associated with the same or alternative measures” in setting an OBC.

The chapeau to Paragraph 17 repeats text from CAC/GL 53-2003. The lists of examples mirror the examples provided in CAC/GL 53-2003.

It is concluded that this important Section does not expand CAC/GL 53-2003 on developing an OBC to any real extent and needs considerable new content if it is to provide additional guidance. Reworked examples (quantitative and qualitative) that illustrate application of the new guidance material are needed. It should be noted that a central tenet of CAC/GL 53-2003 is the relationship between the OBC and the ALOP of the importing country but this is not extended into practical guidance in the draft Appendix.

MORE DETAIL ON THE PROCESS OF JUDGING EQUIVALENCE, INCLUDING TERMS FOR ON-SITE VISITS

Judgement is again an essential part of the Appendix and has also been identified as such from the commencement of this work by CCFICS. This Section of the current draft also fails to provide substantive additional guidance and mixes in elements belonging to the second section of the current draft Appendix – guidance on choosing sanitary measures for judgement.

Paragraph 22 provides a list of sources that contribute to experience, knowledge and confidence in the exporting country's measures so that a "judgement of equivalence of measures may be expedited". However, the draft Appendix does not address the important concept in CAC/GL 53-2003 (Paragraph 10) that this knowledge primarily contributes to circumscribing the extent of the equivalence determination and states that "where trade experience exists, determination of the equivalence of sanitary measures may be made without further consideration of those other relevant measures making up the food control system". This step precedes judgement of a 'specific measure(s)', and is clearly presented as such in CAC/GL 53-2003. The language used is also important ("other relevant measures") and should remain consistent in both CAC/GL 53-2003 and the Appendix.

In respect of measure(s) at the Specific Requirements level (Paragraph 13 of CAC/GL 53-2003), once the importing country can accept the 'other relevant' or surrounding measures – such satisfaction having been achieved by any combination of the factors listed in Paragraph 22 of the draft Appendix – judgement of the specific measure(s) that is the focus of the equivalence determination proceeds. It is likely that the consideration of the specific measure(s) that have been identified for judgement of equivalence will then involve a quantitative or qualitative OBC and be based on science to the extent practicable.

Where the measure(s) identified for judgement of equivalence are at either the Infrastructure or Programme Design, Implementation and Monitoring levels (Paragraph 13 of CAC/GL 53-2003), then "experience, knowledge and confidence" will come into play directly in the judgement of equivalence of any measure(s) in either of these categories. In this case Paragraph 22 of the draft Appendix provides a useful list of factors that may apply in this respect but does not explore how this knowledge may expedite judgement, including how simplified OBCs for these levels can be developed from this knowledge.

Paragraph 23 primarily presents guidance on factors affecting the choice and extent of a submission for judgement of equivalence and is therefore out of place in this Section. It also ascribes this activity to the importing country when in fact this will be done together with the exporting country in most cases. Further, the likely prioritisation of a submission for judgement should be communicated to the exporting country early in the process so that the exporting country does not waste resources on preparing a case that will be lowly prioritized by the importing country. Thus the guidance currently provided in this Section of the draft should be incorporated into the section of the draft dealing with *Identifying which Measures are to be the subject of an Equivalence Determination*, taking into account our comments above on that section.

Paragraphs 25 and 26 addresses on-site visits as a means to assist judgement but does not provide guidance relative to the broad category of the measures involved. This needs to be developed.

Paragraph 27 presents bullets on making decisions at several possible "points" in the equivalence process but the relevance of this paragraph is unclear. Particularly as CAC/GL 53-2003 clearly describes the overall process.

It appears that Section 8 in CAC/GL 53-2003 more directly addresses judgement of equivalence than the current draft Appendix itself. The latter does not mention "analysis of the strength of the relationship between the exporting country's specified sanitary measure and the achievement of the ALOP of the importing country as reflected in the OBC" which is a core tenet of CAC/GL 53-2003 and which should be considerably extended if the draft Appendix is to provide the additional guidance CCFICS has asked for.

Paragraphs 28 and 29 also repeat text presented in CAC/GL 53-2003.

It is concluded that this important Section needs further work to clarify and extend on the above points.

Paragraph 30 on technical assistance is still under discussion and is not commented on here.

UNITED STATES

General Comments

The United States expresses its thanks to the Working Group for its efforts in revising the document.

We note the recommendation of the 14th Session of CCFICS to prepare a single Annex containing additional guidance on key aspects of the determination of equivalence including: identifying which measures are to be the subject of equivalence; documentation including the submittal package; the process of judging equivalence and terms for on-site visits; and, the use of an Objective Basis of Comparison. The United States supports a single annex approach as certain elements of each section are needed to understand the others and, in a determination of equivalence, these five areas are often linked.

The United States also supports the inclusion of a limited section on Technical Assistance in the Appendix and believes that the section as currently proposed provides the appropriate guidance and correct amount of information on this subject for this document.

The United States believes that all sections of the document, with the exception of the section on Objective Basis of Comparison (OBC), are reasonably well developed. We believe, however, that as further described below, additional work is needed on the OBC section.

The United States notes the many key items considered by the Working Group, particularly on the scope of the document and associated points (i.e., process of undertaking an equivalence determination, using experience, knowledge and confidence in the exporting country's systems and products to assist in determining which measures would be subject to equivalence). The U.S. recognizes that a food safety system consists of a wide range and, in most cases, a large number of measures, and that it likely will be necessary for countries to work through a consideration of these measures in undertaking an equivalence determination. Further in this regard, we believe that an importing country may be able to, employing subject matter experts, use its' knowledge, experience and confidence of an exporting country's pertinent food safety system to determine precisely which measure(s) will be the subject of an equivalence determination.

Regarding the Objective Basis of Comparison (OBCs), the United States believes that the use of examples is helpful in understanding both the concept, and application of, OBCs. We suggest that the examples encompass both: 1) the use of quantitative and qualitative OBCs; and, 2) the various types of measures for which an OBC may be necessary (e.g., infrastructure; program design, implementation and monitoring; and, specific requirements). In this regard, the U.S. believes that substantive work remains to be done on this section of the document.

Specific Comments

Determining an Objective Basis of Comparison

Paragraph 19. The United States recommends that examples should be both quantitative and qualitative OBCs, and that the examples should also include the use of OBCs with respect to the different types of measures (e.g.: infrastructure; program design, implementation, and monitoring; specific requirements). If this is done, it may be helpful to so indicate this in either an additional sentence to the paragraph 19 or as a footnote added to "examples".

More Detail on the Process of Judging Equivalence Including Terms for On-Site Visits

Paragraph 24(f). The United States believes that experience, knowledge, and confidence can be used, in combination with the judgment of subject matter experts, to determine equivalence of sanitary measures. This will most likely be applicable to measures associated with infrastructure, and program design, implementation and monitoring. We therefore recommend that the square brackets be deleted.