

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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

Agenda Item 3(a)

CX/FICS 04/13/3 – Add 1
November 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Thirteenth Session

Melbourne, Australia, 6 – 10 December 2004

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

(N04-2004)

(Comments received from Argentina, Bolivia, Canada, Honduras, Mexico,
New Zealand, Norway and the United States)

Argentina

Argentina is thankful for the opportunity to make comments on the reference document.

Firstly, Argentina would like to point out that the proposed text has been prepared appropriately with each of the elements raised for future work, however, it would like to respond to several of the concerns raised for the governments.

Specific comments:

a) Paragraph 10: Argentina considers that once the procedure for the determination of equivalence has been completed, and the measure accepted by the importing country, the sanitary measure's equivalence must be maintained, except in certain situations (to be defined) that may require the measure's revision.

Without undertaking an exhaustive analysis, which should be the subject of consideration by CCFICS, Argentina proposes several of the situations that may lead to a revision of the measure, as follows:

- Change in the importing country's Adequate Level of Protection, on a scientific basis;
- A change in the importing country's sanitary status;
- Reliable proof of the lack of effectiveness in the level of control of a food's danger under the application of the equivalent sanitary measure accepted by the importing country.

The importing country should not initiate an equivalence revision procedure if none of the suspicions raised or any others that are the subject of consideration by CCFICS has occurred.

Should unforeseen situations arise, the revision of the equivalence should be made on the particular issue that has given rise to the change in the situation that pre-existed when the determination of equivalence was made. In this case, an abbreviated procedure should be implemented, taking into account the prior recognition that the importing country has made on the basis of the equivalence granted.

b) Paragraph 18: Argentina considers it appropriate to collect concrete examples of practical applications for use by countries as an objective basis for comparison, and which should be used to determine the equivalence of a specific sanitary measure by establishing its correlation (as indicated in paragraph 19) with the provisions in paragraphs 15 and 16 of Section 6 of the Codex Guidelines on the Judgement of Equivalence of Sanitary and Phytosanitary Measures Associated with Food Import and Export Inspection and Certification.

c) Argentina agrees that technical assistance sought cannot be considered as a mandatory prerequisite in determining equivalence. However, it considers that it would be relevant to emphasise that when an equivalence is requested by a developing country from a developed country, the latter should provide, insofar as possible, the measures available to it to respond to this request.

d) With regard to paragraph 23, we do not agree that the request for technical assistance should be made jointly with the initial request for the determination of equivalence. It should be possible for the request for technical assistance to be made at any stage in the analytical procedure for the equivalence, given that the disadvantages that may arise during the procedure may not necessarily be known at the outset of the procedure.

Finally, Argentina considers that future work cannot be carried out simultaneously. In this respect, we agree to separate the work items to be carried out into various stages.

The first stage should address the following work items:

- **New Work Item 1.** Assessing which measures are to be the subject of an equivalence determination
- **New Work Item 2.** Documentation for evaluation of submissions of requests for equivalence determinations
- **New Work Item 4.** Determining an “objective basis of comparison”

The remaining work items in the second stage:

- **New Work Item 3.** Terms for on-site visits by importing country authorities undertaking a determination of equivalence
- **New Work Item 5.** More detail on the process of judging equivalence
- **New Work Item 6.** Information relating to technical assistance to be provided by importing countries to exporting countries

This is based on the fact that prior to stipulating the terms for on-site visits, a clear idea of the “objective basis for comparison” will be needed in order to stipulate the effective need for carrying out the visits and, if they are needed, how to prioritise the actions and the form of assessment. Similarly, the aspects relating to the request for technical assistance should be considered once the remaining work items have been agreed in order to gain a more specific notion of the issues that may require technical assessment.

Bolivia

COMMENT No 1:

Bolivia agrees with the order of priority for the work items listed.

COMMENT No 2:

We fully agree with Peru and Korea with regard to the need to provide more information and include the documents requested.

COMMENT No 3:

With regard to New Work Item 1, paragraph 11 sub-paragraph a) Factors for exporting countries to consider when deciding whether or not to request an equivalence determination, should read as follows:

1. Rationale for undertaking equivalence (e.g., ease of using own system to qualify product for import, new technology replacing older control measure, etc.).
2. Are other lower cost means of meeting import country requirements equally effective (e.g., compliance, third party compliance, MOU)?
3. Technical capability to pursue an equivalence determination with respect to the measures selected.
4. Legal requirements of the importing country.

Bolivia also considers that the following could be included:

5. Is there fluid trade for a similar product, for which the sanitary requirements fully comply and which might cover the requirements for the new product (in question)?
6. The sanitary requirements requested by the importing country ensure an ALOP that can be met by other sanitary requirements offered by the exporting country?

In section b) the wording does not make it clear whether equivalence measures can ONLY be requested for processes/products (for example, alternative technology) or also for certification systems (OFFICIAL ENTITY), so it is suggested this point be clarified.

COMMENT No 4:

With regard to New Work Item 3, in paragraph 16 sub-paragraph c) Protocols for on-site audit, an additional point could be included: 6. Visit and report language, ideally, time frames for responding after returning to their home country.

Visits to primary production buildings could perhaps be included in point 3.

COMMENT No 5

Bolivia considers that New Work Item 6. Information relating to technical assistance to be provided by importing countries to exporting countries should be retained.

Canada

Canada thanks the United States for leading the Working Group and redrafting the draft appendices. Canada is pleased to offer the following comments.

GENERAL COMMENTS:

Canada has concerns with Work Item 6 dealing with information relating to technical assistance to be provided by importing countries to exporting countries. Canada is of the opinion that Codex is not the appropriate forum for work relating to the provision of technical assistance. In our view, the proposed Work Item does not fall within the mandate of Codex, neither is it consistent with the Terms of Reference of the Codex Committee on Food Import and Export Certification and Inspection Systems (CCFICS).

With respect to suggested priority for undertaking the new work (Paragraph 6), Canada recommends that Work Items 1, 4 and 5 be undertaken as a matter of priority, and then to be followed up with the next two items (2 and 3). We believe that the issues of documentation required (Work Item 2), and terms for on-site visits required (Work Item 3), will depend on the process used to establish equivalence. We submit that selecting the measures to be addressed (Work Item 1), selecting the objective basis for comparison (Work Item 4) and establishing necessary principles around the technical process of determining equivalence (Work Item 5) should be logical first steps. Until a better understanding is reached around the process of equivalence determination, it is somewhat difficult to establish principles around documentation required, and on-site visits. Hence, decisions made regarding the first three topics (1,4 and 5) will likely have significant impact on discussions and decisions made regarding the last two topics (2 and 3).

Finally, Canada believes that the development of a number of Case Studies (theoretical or actual) would be beneficial to assist the Working Group and the Committee to develop this guidance and the rationale for such guidance.

SPECIFIC COMMENTS:**Work Item 1**

Canada believes that early discussion will be necessary to determine the appropriate level of detail required regarding the issue of prior knowledge. Canada believes that it may be appropriate to develop some very broad concepts within this Work Item. However, Work Item 5 would be a more appropriate section to develop more detailed guidelines for consideration.

Work Item 2

Canada would suggest the following change to keep the text in line with the title of the work item:

11. The purpose of ~~required~~ the documentation is to.....

Canada would also like to note that the reference to “legislative base and administrative system” should be made in Paragraph 14 e) in order to be consistent with paragraph 12 and thus provides the following change:

14 (e) Information on the exporting country’s food safety infrastructure....This may include relevant laws, decrees, regulations and other policy documents that demonstrate the country’s ~~legal basis~~ legislative base and administrative system for implementing and enforcing the alternative measure.

Work Item 3

Canada notes the importance that correct terminology be used in this document. The intent of the on-site visits needs to be clarified, i.e. to verify exporting country claims, to validate effectiveness of these claims, or to audit the program. We note a subtle shift within this Work Item from verification to auditing, complete with the development of an on-site audit protocol. We believe that there may be significant difference in the implications of these approaches when dealing with equivalence determination versus some other aspect of import/export control.

We believe significant discussion needs to take place under Paragraph 16 a) regarding where, in the equivalence determination process, on-site visits should actually occur. Canada would like full discussion on the following questions: Should equivalence first be established as a paper exercise to determine if the technical and program/infrastructure requirements are satisfied? If there is technical and operational equivalence, would it be appropriate to declare equivalence? What is the difference between equivalence on-site visit and ongoing country audits? If an exporting country decided to harmonize measures rather than seek equivalence, what would be the on-site visit requirements?

Canada, also, questions whether the purpose of the on-site visits as suggested in Paragraph 15 is one that is applicable to any imported product regardless of whether the exporting country’s system is equivalent or the same as that of the importing country. Canada recommends close examination of CCFICS Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997). The Guidelines have an Annex entitled “Guidelines on procedures for conducting an assessment and verification by an importing country of inspection and certification systems of an exporting country”, that discusses the issue of “On-site verification”. Hence, Canada suggests that this Work Item might best be addressed by the Committee within a broader terms of reference, i.e., on-site visits for the evaluation of import and export inspection and certification systems.

Work Item 5

Greater clarity around the intent of Paragraphs 20 c) & 20 e) is required. Canada believes it would be more appropriate to actually develop mechanisms or simply establish some broad concepts around the issues of evaluating data packages and dealing with data uncertainty rather than develop specific mechanisms for this purpose.

Specific to Paragraph 20 c) and in keeping with our general comments regarding priority, Canada believes that if ~~that~~ this Work Item is dealt with prior to Work Item 3, then there would be an opportunity to establish some broad principles / approaches regarding the requirement for and application of on-site visits. These could then be further elaborated in Work Item 3.

As mentioned in the general comments, this Work Item would benefit considerably from the use of Case Studies (theoretical or actual) to elaborate on the application of these mechanisms or approaches.

Work Item 6

Canada is of the opinion that this proposed Work Item does not fall within the mandate of Codex, neither is it consistent with the Terms of Reference of CCFICS. Issues related to the provision of technical assistance are more appropriately addressed by other international organizations.

The WTO SPS Committee has undertaken work on equivalence within its role of administration of the SPS Agreement. The Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (G/SPS/19/Rev.2) specifically addresses technical assistance with respect to equivalence. As well, the SPS Committee has instituted a process whereby there is a standing agenda item on Technical Assistance and Cooperation at each meeting of the Committee, where information on technical assistance activities is provided by the Secretariat, Members and Observer Organizations. Members also have the right to bring specific requests for technical assistance to the attention of the Committee at any time.

Furthermore, the FAO operates a Technical Cooperation Program and has developed Guidelines for its implementation. The main features of the Program are its flexibility and practical orientation, and that it is directed to urgent and specific problems or needs, is limited to a particular sector or area, and involves practical action with well-defined objectives and expected results.

Consequently, given the apparent consensus that technical assistance requirements are determined on a case-by-case basis to address specific identified needs of the recipient country, it is not practical to attempt to identify "one-size-fits-all" information related to technical assistance, to be provided by importing countries to exporting countries. Canada believes that issues regarding technical assistance should remain with the WTO, FAO and other organizations that have taken on or been assigned the responsibility, and Codex should continue to focus on work within its mandate.

Honduras

We are pleased to forward our reply to the circular letter CX/FICS04/13/3 of August 2004, regarding the Request for Comments on the **“Proposed Draft Appendices to the Sanitary Measures Associated with Food Inspection and Certification Systems”**- to be examined at the 13th Meeting of the Codex Committee on Food Import and Export Inspection and Certification Systems in Melbourne, Australia, 6 - 10 December 2004.

Honduras thanks the Codex Committee on Food Import and Export Inspection and Certification Systems and the Australian Government for their hospitality and the opportunity to express our position.

Comments

The National Codex Committee, the Technical Secretary through its Official Contact with the Codex Alimentarius Commission (CAC), has read and analysed the document that refers and has no comments thereto, and accepts the approach presented.

Mexico

The Government of Mexico supports the production of appendices that provide additional information for the practical application of the guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification.

The following are its comments regarding the proposed nine work items:

Work Item 1.- Assessing which measures are to be the subject of an equivalence determination.

Par.11.a.- Clarification of the text "...for the import..." is requested, given that it refers to one of the factors that must be considered by the exporting country when deciding whether to request an equivalence determination.

The statement that in some cases it is possible that an equivalence determination may be required for an entire inspection system should be assessed given that the equivalence determination should specifically refer to those factors regarding the product(s) when requesting an equivalence agreement, including cases in which the importing country has little knowledge or experience of the exporting country's system (Sec. 5, paras. 9 and 12 of the Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification).

In general terms, the equivalence should not alter or modify the standards requirements that an importing country may establish on the basis of a risk analysis, even if it has to allow for the recognition of alternative measures applied in the system's various components, such as, procedures for the checking inspection, sample and analytical methods are being fully met; the technology of alternative procedures that result in equivalent levels of protection; organisational structures that provide sufficient authority and operability, etc.

Further, prior experience and knowledge of a system for which an equivalence is being judged, should be considered objectively, in order to avoid erroneous or ambiguous assessments.

Work Item 2.- Documentation for evaluation of submissions of requests for equivalence determinations

It is important that the exporting country provide documentary support for the request for equivalence, and the benefits it hopes to obtain. However, it should first be considered that it is the importing country, which, at the exporter's request, should provide information about how its own measures achieve appropriate levels of protection. On this basis, the exporter can then provide information about the alternative measures it requests be recognised and the corresponding supporting data.

Work Item 3.- Terms for on-site visits by importing country authorities undertaking a determination of equivalence

It is believed that the visit to the country requesting the assessment of equivalence would make it possible to confirm that the measures described are applied appropriately and ensure the appropriate level of protection is met.

It is requested that it be possible to achieve the determination of equivalence without the need for prior visits, given the appropriate and sufficient nature of the information provided by the exporting country, which shall not limit post-visits by the authorities of the importing country.

Work Item 4.- Determining an “objective basis of comparison”

Determining an objective basis of comparison is fundamental to the process of recognising alternative measures as being equivalent.

Work Item 5.- More detail on the process of judging equivalence

Clarification is requested in this regard as it would seem that the work involves the development of methods for the assessment of information considered in Work Item 2, which could perhaps be addressed in a single work item that includes the documentation required and the considerations and criteria for its appropriate assessment.

Work Item 6.- Information relating to technical assistance to be provided by importing countries to exporting countries

This is considered as basic in maintaining adequate trade openness with all World Trade Organisation and Codex Alimentarius member countries. It should be stated that the WTO Agreement on Sanitary and Phytosanitary Measures refers to technical assistance and, as a result, this document could be quoted in this Work Item.

With regard to the order in which the Work Items should be addressed, given the probable sequence of requests in developing equivalence agreements, we propose the following:

1. Documentation for evaluation of submissions of requests for equivalence determinations and considerations for its assessment.

2. Assessing which measures are to be the subject of an equivalence determination
3. Determining an “objective basis of comparison”
4. Terms for on-site visits by importing country authorities undertaking a determination of equivalence
5. Information relating to technical assistance to be provided by importing countries to exporting countries

New Zealand

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

New Zealand supports the development of additional information to assist member countries to utilise the *Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems (CAC/GL -/2003)*.

We agree with the comments in paragraphs 4 and 5 of CX/FICS 04/13/3 that the matters raised by the Republic of Korea and Peru at the 26th session of the Codex Alimentarius Commission can be addressed as part of the work areas identified in the Project Document and elaborated in CX/FICS 04/13/3.

New Zealand would like to make the following comments on the Recommendations: -

Recommendation 1 – Will the elements specified for each new work item, when fully elaborated, fulfil the need for additional guidance?

New Zealand suggests that the information presented in CX/FICS 04/13/3 for work items 2, 3 and 6 provides sufficient additional guidance for member governments. We propose that the Committee consider recommending that these items be progressed in the Codex Step process. This would provide opportunity for any fine tuning of the text to occur and allow the Committee to focus resources on the further work required for elaboration of the other work items.

The information provided under work items 1, 4 and 5 provides a good basis for further elaboration.

Recommendation 2 – Priority order for work items

New Zealand suggests that work item 4 (Determining an ‘objective basis of comparison’) needs to be given a higher priority.

After deciding which measures are to be the subject of an equivalence determination (work item 1), the next logical step is to determine an objective basis of comparison (work item 4) and then finalise the documentation as necessary (work item 2). As proposed above New Zealand suggests that sufficient information has been provided in CX/FICS 04/13/3 for work items 2, 3 and 6 to commence progress through the step process.

Based on the above logical sequence of activity and our previous comments New Zealand suggests that the priority order for further work should be:

- Assessing which measures are to be the subject of an equivalence determination (work item 1);
- Determining an objective basis of comparison (work item 4);
- Process of judging equivalence (work item 5)

Recommendation 3 – Extending electronic working group

New Zealand supports continuation of the electronic working group. New Zealand wishes to continue as a member of the working group and would welcome any new members who may wish to participate.

Other comments

New Zealand would also like to make the following comments on the proposal in paragraph 10 under ‘Considerations Relating to the Proposed Areas of Work’.

In paragraph 10 the need to maintain and/or re-verify a determination of equivalence is raised. The Committee is asked to consider whether this area should be incorporated into the proposed new work. New Zealand agrees that maintenance and review are important aspects of any equivalence agreement. We note that the Appendix ‘Contents of ‘Equivalence Agreements’ to the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999), lists both ‘assessment and verification provisions’ and ‘review, modification and termination’ as information that should be included in equivalence agreements.

We would also note, however, that in the case of an equivalence agreement such ‘assessment or verification provisions’ would be expected to relate to the mechanism for checking that the process or system covered by the agreement continues to deliver the required outcome. It is the outcome of these processes or systems that is determined to be equivalent to the outcome required by the importing country. Therefore while it is entirely reasonable for an importing country to want to check from time to time that the system(s) or process(es) covered by the equivalence agreement continue to deliver the required outcome we do not see this as a re-verification of the actual determination of equivalence.

At this time we are not convinced that work on re-verification of a determination of equivalence is necessary. We hold this view based on two factors. Firstly, the term verification is currently under debate in Codex and until such time as a consensus view is reached on this term we do not think it should be used in relation to development of additional guidance on the judgement of equivalence. Secondly, the Codex Guidelines on Judgement of Equivalence (CAC/GL -/2003) provide under section 7 – Judgement (para 17) for parties to an equivalence agreement to advise each other of significant changes that may affect the original determination of equivalence. If the Committee were to recommend that new work on the ‘maintenance’ of a determination of equivalence was necessary it could be undertaken in relation to the process of judging equivalence (new work item 5).

New Zealand proposes that new work in the area of ‘maintenance of a determination of equivalence’ should be considered at a later time once the work now before the Committee has been progressed.

Norway

Norway welcomes the proposals of the drafting group found in CX/FICS 04/13/3 regarding which main topics to elaborate on as appendices to the recently adopted “Guidelines on the Judgement of Equivalence of Sanitary Measures associated with Food Inspection and Certification Systems”.

In our opinion, the two overriding objectives of an assessment of equivalence are to ensure that

- a) Food is produced in a way to meet the level of protection of the importing country, and
- b) The performance of the food export inspection and certification system is trustworthy, in order to build confidence between the competent authorities of the exporting and importing countries

In line with article 10 and 11 of the recently adopted guidelines on judgement of equivalence, CX/FICS/04/13/3 states that:

“That the importing country’s prior experience, knowledge and confidence may permit a determination of equivalence of certain measures (e.g. legislation, program design, implementation, monitoring) without further consideration.”

Articles 52 and 53 of CAC/GL 26-1997, “Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems” state that:

52. A national system should be subject to audit separate from routine inspection. Inspection and certification services should be encouraged to carry out self-evaluation or have their effectiveness evaluated by third parties.

53. Self-assessment or third-party audits should be carried out periodically at various levels of the inspection and certification system, using internationally-recognized assessment and verification procedures.

To our knowledge, none of the internationally-recognized assessment and verification procedures are tailor-made to fit official food export inspection and certification authorities in order to create confidence and trust, and at the same time being as cost-effective as possible.

In order to avoid that complicated internationally-recognized assessment and verification procedures are forced upon exporting countries by their importing counterparts, there seems to be a need for guidance on quality assurance of export inspection and certification authorities. Such guidance may serve as basis for 5 of the 6 work items proposed in CX/FICS 04/13/3.

CCFICS may wish to discuss whether work on quality assurance of food export inspection and certification systems shall be included in the topics discussed under this agenda item, or to be discussed under item 8 – Other Business and Future Work, as new work of the committee.

United States

The United States supports the development of implementing appendices to the *Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Import and Export Inspection and Certification Systems*. We believe that the appendices presented as Work items 1, 2, 3, 4 and 5 will, when developed as outlined, provide additional information to that contained in the *Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* that will be useful to countries undertaking equivalence determinations. We believe that the order in which the Work Items are presented in the document is appropriate. The U.S. observes that these five work items, if undertaken, respond to the issues raised by the Republic of Korea and Peru.

The United States suggests that the Committee reconsider Work Item 6, Technical Assistance. We note that Principle “n” in Section 4 of the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification* states that “An importing country should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of an equivalency determination”. We believe that this principle clearly presents the fundamental approach to technical assistance that ought to be provided between countries undertaking an equivalence determination. It could be helpful to more fully specify the areas in which technical assistance would be beneficial (e.g., preparation of data packages, assessing measures against an objective basis of comparison), but these points also could be made by amending the existing text rather than creating an appendix.

The United States supports the continuation of the electronic working group to accomplish the work needed to elaborate the various appendices to the *Codex Guidelines on the Judgement of Equivalence of Sanitary measures Associated with Food Inspection and Certification*.