

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4

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

Twenty-fourth Session

**AMENDMENT TO PROJECT DOCUMENT FOR NEW WORK ON GUIDANCE ON THE USE OF SYSTEMS
EQUIVALENCE**

Prepared by New Zealand, Chile and United States of America

Agenda Item 4

CX/FICS 18/24/4 para 22 of Agenda item 4 contains several recommendations. With respect to the first recommendation, the co-chairs are in agreement that this existing work should continue to progress expeditiously as a separate document, taking into account the comments of the Committee.

With respect to the second set of recommendations in para 22 (iii) following further consideration the co-chairs recommend Option B and have provided a revised project document for the Committee to consider.

PROJECT DOCUMENT FOR THE DEVELOPMENT OF GUIDANCE ON THE USE OF SYSTEMS EQUIVALENCE AND SUBSEQUENT CONSOLIDATION OF EXISTING EQUIVALENCE GUIDANCE

Revised Proposal for new work to develop guidance on the use of systems equivalence and subsequent new work to consolidate all the equivalence guidance.

1. Purpose and scope of the proposed standards

The purpose of the work is to provide guidance to competent authorities of importing and exporting countries on the use of systems equivalence recognition as a means to further facilitate protection of the health of consumers and ensuring fair practices in the food trade. It is intended to cover situations where it can be reasonably expected that the national food control system (NFCS) of the exporting country will, on an ongoing basis, likely reliably deliver food that meets similar overall human health, food suitability and technical outcomes as achieved within the importing country. The scope of the guidance is intended to apply to the process for importing and exporting countries to follow when a request has been made by an exporting country for the recognition of the equivalence of the whole or part of its NFCS. In this regard it is noted that a NFCS includes import and export inspection and certification systems and has the objective of both protecting public health and ensuring fair practices in trade (CAC/GL 82/2013 para 2 and para 6).

This project document has been expanded during CCFICS 24. In parallel with progressing the systems equivalence guidance to adoption, the Committee has agreed to initiate work that will ultimately produce a consolidated guidance including the new systems equivalence guidance, CAC/GL 34-1999 and CAC/GL 53-2003. The purpose of this proposal is to consolidate all equivalence guidance to provide clear, consistent and useful guidance to countries considering the use of any or all forms of equivalence. The scope of the consolidated guidance would include the process to be followed for considerations of equivalence for specifically identified measures as well as whole or parts of NFCS. It would also include guidance on how any such recognitions may be formalised in an agreement.

2. Relevance and timeliness

With the continuing globalization of the food trade and growth in associated consumer concerns, countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Better use of systems equivalence recognition where effective regulatory systems are already in place could reduce the burden on resources and unnecessary restrictions on trade caused by such processes. Specifically, it could provide for facilitated individual establishment listings, where required, and expedited border clearance processes based on confidence in the systems already in place in the exporting country to appropriately manage any risk associated with the trade to the level of protection required and achieved by the importing country.

The recognition of systems equivalence for all or part of the trade in food between countries has the potential not just to remove unnecessary restrictions on trade but also to free up resources in importing and exporting countries alike, which could be better allocated to manage more pressing areas of risk.

Consolidation of all three texts will provide guidance to countries considering the use of any or all forms of equivalence and ensure there is appropriate consistency and improved clarity as to which process to follow in different situations. This can be started while concluding the current work.

3. The main aspects to be covered

This new work will provide principles and processes for the initial consultation process to determine if more in-depth consideration of systems equivalence is appropriate; principles and processes possibly appropriate to an in-depth consideration of systems equivalence; and any additional guidance as required on the development of bilateral agreements to document the recognition of systems equivalence, including expectations for maintenance. The new work will also consider the factors that facilitate the appraisal of systems equivalence, including criteria for Equivalence, Knowledge, and Confidence, and for evaluating systems equivalence. The new work will consider the application of systems equivalence to countries at different stages of development.

The proposed new work will consolidate all guidance related to equivalence (CAC/GL 34-1999, CAC/GL 53-2003 and the current systems equivalence guidance) into a single cohesive guide that provides clear guidance as to which process may be appropriate in different situations.

4. An assessment against the Criteria for the Establishment of Work Priorities

The proposal is consistent with the criteria as follows:

General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed new work will further facilitate the trade of safe food while freeing up resources to allow better targeting of greater risk scenarios, thus meeting the general criterion of consumer protection.

Criteria Applicable to General Subjects:

a) Diversification of national legislations and apparent resultant or potential impediments to international trade:

Countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Recognition of systems equivalence, where competent regulatory systems are already in place, could reduce the burden on resources and unnecessary restrictions on trade caused by such processes.

b) Scope of work and establishment of priorities between the various sections of work:

Refer to Scope above.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):

The WTO/SPS Committee's decision (G/SPS/19) provides for some further clarification on how WTO members should make use of the "equivalence" provisions of the SPS Agreement, i.e. Article 4. This decision strongly encourages the CAC to, on an ongoing basis, further progress its guidance covering the full scope of the decision. CCFICS has developed a number of standards that provide for the use of systems equivalence but to date has only developed specific guidance more targeted to the judgement of the equivalence of specific sanitary measures (CAC/GL 53-2003). Specific guidance on a process for the potential recognition of the equivalence of whole food control systems,

or those covering specific food, is however currently lacking. Development of such guidance would further facilitate and enable better use of the existing Codex guidance: Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999). The Committee will take into account any relevant international work in this area that is identified during the course of the work.

d) Amenability of the subject of the proposal to standardisation:

The Committee believes that principles and guidelines can be developed to address the issues identified. Subsequent consolidation of all three guidances will further assist standardisation and improve clarity.

e) Consideration of the global magnitude of the problem or issue:

The Committee has assessed that there is currently a significant burden imposed on importing and exporting countries due to a lack of practical international guidance in this area. The scarcity of notified equivalence agreements to the WTO/SPS Committee in accordance with G/SPS/7/Rev.2/Add.1 is further evidence that additional guidance in this area is both timely and relevant.

5. Relevance to Codex strategic objectives

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its statutes, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019 "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities."

6. Information on the relation between the proposal and other existing Codex documents

The proposed work will take into consideration the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999) and the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997). The original references to equivalence in both CAC/GL 26-1997 and CAC/GL 34-1999 incorporate a wider context for the concept and therefore can be said to explicitly contemplate the potential for systems equivalence determinations and agreements.

However, neither document provides specific, practical guidance on how such evaluations should be made. The recently promulgated Guidelines for National Food Control Systems (CAC/GL 82-2013) also now provide a basis for a more common understanding of the generic components of NFCS among countries. The Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003) was primarily developed to provide guidance on directly comparing the outcomes of a specified measure or set of sanitary measures rather than recognizing the equivalence of the system as a whole. It also does

not provide specific, practical guidance on the recognition of those aspects of a NFCS relating to fair practices in the food trade.

The proposed guidelines when completed are intended to be read in conjunction with the Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) and the Guidelines for Food Import Control Systems (CAC/GL 47-2003). The proposed guidance would also fit nicely with, and is a natural extension and progression of the Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CAC/GL 89-2016).

The proposed consolidation of all guidance related to equivalence (CAC/GL 34-1999, CAC/GL 53-2003 and the current systems equivalence guidance) should help ensure appropriate consistency, clarity and ease of use of the concept of equivalence across a full scope of potential uses. Minor amendments to other Codex guidance documents that mention equivalence may also be considered if appropriate.

7. Identification of any requirement for and availability of expert scientific advice

Not required.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for:

Not required at this time.

9. Completion of the new work and other conditions

Subject to the Codex Alimentarius Commission approval at its 42th session in 2019, it is expected that the current work can be completed at the next CCFICS meeting, and the proposed new updated and consolidated guidance within 4 years, depending on the future schedule of CCFICS meetings, which is currently meeting every 18 months:

- Current work considered at Step 5/8 by CCFICS25; and
- Adoption of the proposed Guidelines by the Commission at CAC 43.
- Agenda paper containing the proposed design and an initial draft of the new guidance at CCFICS25
- Proposed consolidated and updating guidance at Step 3 at CCFICS26
- Proposed consolidated and updating guidance at Step 5 at CCFICS27
- Adoption of the proposed Guidelines by the Commission at CAC 46.