

CODEX ALIMENTARIUS COMMISSION



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DISCUSSION PAPER PROPOSING TO CONSOLIDATE AND MODERNIZE GUIDANCE ON THE USE OF EQUIVALENCE

Prepared by the United States of America

1. The United States appreciates the leadership of New Zealand in developing the Proposed Draft Guidance on the Use of Systems Equivalence and the excellent contributions made by members of the physical and electronic working groups in the year since the work was approved. While the document has made significant strides over the course of the last year, the United States proposes that the Committee consider new work to align the draft Systems Equivalence text with existing Codex text on equivalence, with the goal to make guidance on all types of equivalence more useful to countries. This will provide a consistent and integrated approach to equivalence, and give countries a better road map for using equivalence.
2. This Discussion Paper provides a mechanism for the Committee, while it continues to advance work on Systems Equivalence, to also consider the need to merge and integrate the draft Systems Equivalence text with existing CCFICS text on equivalence. While this Discussion Paper presents the concept as new work, its relevance to the agenda item on Systems Equivalence is clear, and the United States believes this paper could inform the discussion on Agenda item 4 on Systems Equivalence.
3. The benefits of equivalence will be more relevant to countries if the concepts are clearly defined and its application is described in a manner that is fully inclusive of countries at all stages of development. Systems equivalence could facilitate greater reliance on a partner's national food safety system if it builds confidence in multiple components of national food safety systems, e.g. inspections, laboratory procedures, and compliance and enforcement activities. Systems equivalence can also advance cooperation and confidence building between regulatory counterparts, including sharing of best practices to inform food safety risk management activities and enhance the safety of food in trade.
4. The current draft Systems Equivalence paper includes a significant number of concepts that overlap or duplicate existing Codex Guidelines, especially the *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)* and the *Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems (CAC/GL 34-1999)*. This overlap may be confusing to countries when determining which text is applicable for each specific circumstance. Aligning or merging new and existing equivalence documents is an important first step for the Committee to accomplish its larger objective of providing guidance that better supports importing and exporting countries in their use of all types of equivalence. This includes systems equivalence, as a means to protect the health of consumers and ensure fair practices in the food trade.
5. Should the Committee continue forward with the proposed Guidance on the Use of Systems Equivalence, countries will be left with a patchwork of text that does not adequately assist countries in evaluating when systems equivalence should be used. Cross-referencing between guidance is problematic as it relies on the reader to properly interpret competing and duplicative concepts thus creating an interpretive challenge. In addition, systems equivalence often employs measures in the assessment of the system, so the concept of "top down" versus "bottom up" approach is difficult to

distinguish. The distinction between systems equivalence and measure-by-measure equivalence may rest in the scope of the assessment, rather than the specific tools being employed to make the assessment.

6. To achieve alignment with the existing CCFICS guidance, it is necessary to describe how the various guidance documents outlined below are related:

Core Guideline for establishing the national food control system

Principles and Guidelines for the National Food Control Systems ([CAC/GL 82-2013](#))

Core Guidelines for establishing controls and information exchange for foods in international trade

Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems ([CAC/GL 26-1997](#))

Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food ([CAC/GL 89-2016](#))

Guidelines for Food Import Control Systems ([CAC/GL 47-2003](#))

Core Guidelines when countries use equivalence for foods in international trade

Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems ([CAC/GL 53-2003](#))

Guidelines on the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems ([CAC/GL 34-1999](#))

NEW Proposed Guidance on the Use of Systems Equivalence

Aligning the work more closely with existing CCFICS work

7. The concept of equivalence with respect to an entire food control system (systems equivalence) was envisaged when CCFICS developed the Appendix to the *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003). Specifically, paragraph 2 of the Appendix to the document includes the following language:

”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 sanitary measure (e.g. analytical method).” (emphasis added)

8. The Committee should consider incorporating the new guidance relating to systems equivalence with the text from CAC/GL 53-2003 and its Appendix. In this manner, concepts that are common to both measure-by-measure and systems equivalence can be understood together, while concepts that are relevant to only one approach can be recognized and separately described. This approach would assist with integrating systems equivalence into the larger scope of application of equivalence. As an example of how a combined equivalence text could more clearly guide governments, the new equivalence guidance could advise governments on the elements of a national food control system (NFCS) that should be considered when undertaking systems equivalence (i.e., components identified in the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013)).
9. Combining the texts could also address the use of historic evidence as a component of knowledge, experience and confidence to support an actual equivalence determination related to the components and measures that are critical to ensuring the safety of the product. For example, relevant information on foreign systems includes data gathered through routine audits, surveillance of food-related disease and outbreaks and import inspections. This information can inform the likely success of a systems equivalence assessment.
10. The combined equivalence text should also incorporate key concepts contained in the *Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems* (CAC/GL 34-1999), describing the steps to be employed when undertaking an equivalence determination. The current draft of the proposed Guidance on the Use of Systems Equivalence duplicates many of those steps.

Questions to consider for discussion:

1. What is missing from the existing guidance? What is missing from the new work?
2. What are the differences and/or similarities in the existing guidance and new work? Is there anything you do not understand?
3. What is your expectation of equivalence with trading partners (e.g. market access, leveraging the regulatory resources of a variety of trading partners)?
4. Is there an expectation that agreements will be reciprocal?

Content of the decision, including elements to consider regarding systems equivalence, criteria for evaluating systems equivalence and experience, knowledge and confidence in the foreign food safety system

11. Elements to consider when evaluating for food control system equivalence are included in Section 5 of the Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) and may be broadly characterized as follows:
 - System infrastructure¹
 - Program design, implementation, and monitoring²
 - Specific requirements³.
12. A key issue the guidelines should address in a comprehensive manner is how to conceptually link “objectives,” “outcomes” and “decision criteria”. A detailed equivalence evaluation requires identification of the objectives that support the overall goals of protection of public health and elimination of unnecessary trade barriers. Countries set objectives that support desired outcomes. Criteria employed in decision-making should focus on meeting objectives directly linked to desired outcomes, while also being concrete enough for meaningful quantitative or qualitative evaluation. Thus, the guidelines should

¹ including the legal and regulatory framework (e.g., food laws, regulations and enforcement) and administrative architecture (e.g. organization of national and regional authorities, food control management, laboratory capacity, and enforcement systems and mechanisms)

² including documentation of inspection and certification systems, monitoring, performance, decision criteria and action, provisions for program evaluation and audit; education and training of program personnel

³ including requirements applicable to individual facilities, water resources, equipment, processes, procedures, methods for laboratory sampling and analysis

make clear that equivalence is based on identified objectives, outcomes and decision criteria that are logically related.

13. The combined equivalence text should identify factors that facilitate appraisal of the exporting country's food control system based on the importing country's knowledge and confidence of that system, including:
 - Prior history of food trade between the importing and exporting countries, including the level of compliance achieved by the products of the exporting country with the importing country's requirements.
 - The level and extent of cooperation between the competent authorities of the importing and exporting countries.
 - Operational similarities between the food control systems of the importing and exporting countries.
14. The combined equivalence text should guide countries on how the requirements of the exporting country's food control system achieve or exceed the objectives of the importing country's system. Factors to consider include:
 - Results of audits/inspections/field examinations by the importing country, exporting country, or recognized third party organization
 - Knowledge of the exporting country's application of risk analysis principles within its food control system
 - Contingency plans for containing and mitigating the effects of food safety emergencies
 - Foodborne disease surveillance data associated with food products produced in the exporting country
 - The extent to which preventive and processing controls are applied by producers in the exporting country
 - Specific export control programs
15. Further, the combined equivalence text should outline how experience with, knowledge of, and confidence in, an exporting country food safety system can assist in identifying the proper scope of equivalence to be employed by:
 - Establishing priorities for determining the scope of the systems equivalence determination
 - Establishing outcome-based criteria for determining whether an exporting country's food regulatory control system achieves the regulatory objectives and same level of public health protection established by the importing country
 - Identifying the attributes of control that a measure must exhibit to produce the outcomes associated with a specific regulatory objective
 - Identifying the number of sanitary measures requiring in-depth examination
 - Identifying the amount and type of scientific evidence required to determine equivalence
16. While many of these concepts are included in both CAC/GL 53-2003 and, to a more limited extent, in the new *Proposed Guidance on the Use of Systems Equivalence*, combining the new and existing guidance could assist governments in applying the concepts when undertaking systems equivalence determinations. The Proposed Guidance for the Use of Systems Equivalence paper does not adequately address these questions.

Questions to consider for discussion:

1. Are the principles that a country has the right to set its own (science-based) level of protection considered?
2. Are you applying equivalence, either to individual sanitary measures, group of measures, the entire food control system or specific component(s) of thereof?
 - a. If so, are there specific areas where you experience problems [challenges]?
 - b. If not, why not? Is it difficult to scope (e.g. individual measures, group of measures, food control system or component(s) of the system) or a lack of understanding of how to apply the process?
3. How do you make an equivalence decision [judgement] (e.g. qualitative or quantitative)?
4. Should equivalence for a set of measures be treated in the same manner as equivalence for the entire food safety system? Should processes be different? Why? Why not?

Maintenance of equivalence arrangements/agreements and other resource considerations

17. The combined equivalence text should adequately describe the considerations concerning the resources necessary for the maintenance of equivalence. Countries should identify what type of equivalence is best suited for the type of trade that it is intended to support, balancing the need with its available resources, enforcement and technical capabilities.
18. The combined equivalence text should provide guidance on the importance of maintenance of equivalence, through regular consultations and periodic reassessments to verify the continued effectiveness and performance of the systems or measures determined equivalent. If conditions change, such that a participant in equivalence determines the arrangement with a foreign competent authority is no longer effective as an import control tool or where an importing country no longer has confidence that the equivalence arrangement meets the intended objectives, the guidance should specify that the status of the equivalence should be reassessed and, if necessary, rescinded.

Recommendation for New Work

19. The Committee is invited to respond to the questions raised in this Discussion Paper, with the goal to address any gaps or overlaps between existing and the new text related to equivalence.
20. In summary, the proposed new work will:
 - i. Merge existing Codex Guidelines (CAC/GL 53-2003 and CAC/GL 34-1999) and the new draft Guidance on the Use of Systems Equivalence to create a single unified and updated Guidance on the use of equivalence.
 - ii. Provide principles and the process for initial consultation to determine if systems equivalence is appropriate.
 - iii. Provide additional guidance, as required, on the development of bilateral agreements to document recognition of systems equivalence, including maintenance of Equivalence Agreements/Arrangements.
 - iv. Consider the factors that facilitate assessments of systems equivalence, including identifying objectives, outcomes and decision criteria.
 - v. Consider the application of systems equivalence to countries at different stages of development.