

CODEX ALIMENTARIUS COMMISSION



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Agenda Item 6

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

Twenty-third Session

DISCUSSION PAPER ON THE POSSIBLE DEVELOPMENT OF GUIDANCE ON THE USE OF SYSTEMS EQUIVALENCE

Comments of United States

United States

The United States appreciates the leadership of New Zealand in developing this paper and the excellent contributions made by members of the electronic working group. While the document has made significant strides over the course of the last year, we would like to propose revisions with the goal to make the document more useful to countries.

The U.S. revisions in the following areas:

1. Application of the work to countries at different stages of development
2. Content of the decision, including elements to consider when we advance to systems equivalence, criteria for Experience, Knowledge and Confidence, and criteria for evaluating systems equivalence
3. Maintenance of systems equivalence arrangements/agreements and other resource considerations
4. Aligning the work more closely with existing CCFICS work, especially the Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003).

1. Application of the work to countries at different stages of development

The benefits of systems equivalence will be more relevant to countries if its application is described in a manner that is fully inclusive of countries at all stages of development. System 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.

While equivalence of specific sanitary measures or targeted components of a NFCS directed to specific products can be assessed, systems equivalence may be useful for assessments of countries that are similarly situated. Countries considering systems equivalence should utilize assessment criteria that can be readily and objectively compared, and developed consistent with the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013).

Countries should also build in methods for maintenance of agreements that anticipate NFCSs will change over time. Regular consultation and periodic reassessments can promote continuous improvement and alignment of two national food control systems once they are recognized as equivalent.

2. Content of the decision, including elements to consider when we advance to systems equivalence, criteria for Experience, Knowledge and Confidence, and criteria for evaluating systems equivalence

Elements to consider when evaluating for food control system equivalence are expressed in Section 5 of the Codex *Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003) are broadly characterized as:

- System infrastructure, including the legislative framework (e.g. food and enforcement law) and administrative architecture (e.g. organization of national and regional authorities, food control management, laboratory capacity, and enforcement systems and mechanisms);

- Program design, implementation, and monitoring, 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, and/or
- Specific requirements, including requirements applicable to individual facilities, water resources, equipment, processes, procedures, methods for laboratory sampling and analysis.

The new work should consider factors that facilitate appraisal of the experience, knowledge, and confidence the importing country has with the exporting country's food control system, including:

- Prior history of food trade between the importing and exporting countries, including the level of compliance achieved by the exporting countries' products with the importing country's requirements.
- The level and extent of cooperation between the competent authorities of the importing and exporting countries.
- Operational similarity between the food control systems of the importing and exporting countries.

The new work should guide countries on how the exporting country's food control system requirements that exceed the core requirements of the importing country is considered in the equivalence determination of the 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,
- Bilateral or multilateral recognition agreements that the importing and exporting countries may have with other countries,
- Contingency plans for containing and mitigating the effects of food safety emergencies,
- Foodborne disease surveillance data associated with food products of the exporting country,
- The extent to which preventive and processing controls are applied by producers in the exporting country,
- Specific export control systems maintained by the exporting country.

Further, the new work should outline how experience, knowledge, and confidence can assist in identifying the proper scope of equivalence by:

- Establishing priorities for determining the scope of a systems equivalence determination,
- Establishing outcome-based criteria for determining whether an exporting country's food regulatory control system achieves the regulatory objectives and level of protection established by the importing country.
- Identifying the attributes of control a measure must exhibit in order to produce the outcomes associated with a regulatory objective.
- Identifying the number of sanitary measures requiring in-depth examination,
- Identifying the amount and type of scientific evidence required to determine equivalence.

3. Maintenance of systems equivalence arrangements/agreements and other resource considerations

The new work should outline considerations regarding resources and maintenance of systems equivalence. Countries should identify what type of equivalence is best suited for the trade that it is intended to support, balancing the need with its resources and capabilities.

The new work should provide guidance on the importance of maintenance of equivalence, through regular consultations and periodic reassessments to verify continued effectiveness and performance. If conditions change such that a participant in systems 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 system equivalence arrangement meets its intended objectives, the guidance should specify that the status of the system equivalence should be reassessed and if necessary revoked.

4. Aligning the work more closely with existing CCFICS work, especially the Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003)

The undertaking of equivalence with respect to a food control system (systems equivalence) was envisaged when CCFICS undertook the development of the Appendix to the Codex *Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003). In particular, paragraph 2 of the Appendix to the document states the following:

”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)

It is appropriate therefore, to consider the currently proposed work relating to systems equivalence in relationship to the broad context of equivalence generally. The United States suggests to the Committee that the project document consider developing guidance relating to systems equivalence as part of CAC/GL 53-2003 or its Appendix, rather than as a separate document. This would better integrate systems equivalence into overall scope of application of equivalence.

The new work could advise governments on the elements of a national food control system (NFCS) that should be taken into account when undertaking systems equivalence, calling attention in particular to the components identified in the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013). The new work could also address the use of historic evidence as a component of knowledge, experience and confidence to support the actual equivalence determination related to the components/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 exercise.