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CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

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

(Paper prepared by New Zealand)

INTRODUCTION

1. During discussion at its 21st session, in 2013, on emerging issues and future direction of its work, the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) agreed to consider a discussion paper, to be prepared by New Zealand, on the possible development of guidance on the use of systems equivalence/comparability (para. 63, REP15/FICS), especially as a means to further facilitate safe trade while better utilizing and risk targeting inspection resources.

2. 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. CCFICS has as a result started developing guidance to cover the increased use of questionnaires for the initiation or maintenance of trade. However, there is a lack of specific guidance on how countries can, where appropriate, upgrade relationships to attain broader systems equivalence recognition.

3. Better use of systems equivalence recognition where competent 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 premises 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 required and achieved by the importing country.

4. The increased use of systems equivalence for all or part of the trade in food commodities between countries has the potential not just to remove current 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.

5. In developing the present document, New Zealand took into careful consideration the existing *Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems* (CAC/GL 53-2003). While those *Guidelines* could cover some aspects of systems equivalence determinations, they are targeted more towards providing guidance on the conduct of specific measure-by-measure determinations, as especially evident in the section on the "objective basis of comparison".

6. The original references to equivalence in both 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 the Development of Equivalence Agreements Regarding Food Import and Export Inspection and*

Certification Systems (CAC/GL 34-1999) incorporate a wider context for the concept. In both, "equivalence" is defined as "the capability of different inspection and certification systems to meet the same objectives".

7. In relation to equivalence agreements, Section 5 of CAC/GL 26-1997 states that: "The application of equivalence principles may be in the form of agreements or letters of understanding established between governments either for inspection and/or certification of production areas, sectors or parts of sectors. Equivalence may also be established through the administration of a comprehensive agreement which would cover inspection and certification of all food commodity forms traded between two or more countries."

8. CAC/GL 26-1997 further states that: "Agreements on the recognition of equivalence of inspection and certification systems may include provisions concerning:
   - the legislative framework, control programmes and administrative procedures;
   - contact points in inspection and certification services;
   - demonstration by the exporting country of the effectiveness and adequacy of its enforcement and control programmes, including laboratories;
   - where relevant, lists of products or establishments subject to certification or approval, accredited facilities and accredited bodies;
   - mechanisms supporting continued recognition of equivalence, e.g., exchange of information on hazards and monitoring and surveillance".

9. While existing Codex texts explicitly contemplate the potential for systems equivalence determinations and agreements, there appears to be a gap in the provision of specific, practical guidance on how such evaluations should be made.

10. The present discussion paper and sample draft guidelines have been envisaged to work in conjunction with the existing *Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems* (CAC/GL 34-1999). The purpose of developing an equivalence agreement, according to CAC/GL 34-1999, is:
    "Countries may wish to enter into agreements concerning food import and export inspection and certification systems to:
    a) provide an enhanced means of assuring that exported products conform to importing country requirements;
    b) eliminate duplication of activities and use collective resources more efficiently and effectively;
    c) provide a mechanism for the cooperative exchange of expertise, assistance and information to help assure and enhance conformity with requirements".

    CAC/GL 34-1999 further states that "equivalence agreements are not generally intended as a condition for trade but rather as a means for ensuring that importing country requirements are met with minimal trade impediments. For example, such agreements may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin".

11. CAC/GL 34-1999 provide some high-level guidance as to the potential scope, purpose, prerequisite considerations, consultative process and format of equivalence agreements, but falls short of detailed guidance on how countries might practically implement such a process. This is especially so for processes aimed at a wider systems equivalence consideration.

12. The recently promulgated *Guidelines for National Food Control Systems* (CAC/GL 82-2013) provide a basis for a more common understanding of the generic components of national food control systems among countries. Those *Guidelines* explicitly recognize the need for countries to tailor their food control programmes to their own risk profiles and the existing context within their boundaries rather than to seek to duplicate several other national systems.

13. Section 5 of CAC/GL 26-1997 states: "The recognition of equivalence of inspection and certification should be facilitated where it can be objectively demonstrated that there is an appropriate system for inspection and certification of food by the exporting country in accordance with these guidelines". Given the diversity of trade, risk profiles, legislative instruments and administrative organizations among countries, the means utilized to objectively demonstrate equivalence among national food control systems arguably need to be broader than

when countries consider specific measure-by-measure comparisons. Countries should consider the potential of making greater use of their recognition, in part or in whole, of another country's system in terms of the likelihood of it generating a comparable level of assurance.

14. The existing Codex texts were developed more with a view to directly comparing the outcomes of specific measures than to recognizing the equivalence/comparability of systems overall (system recognition). Given the increasing volume and diversity of internationally traded food, import assurance programmes based on questionnaires, in-country premises listing audits and product inspection are not the most efficient or effective use of resources. It is well recognized that higher levels of assurance can be gained through more direct cooperative relationships with other competent authorities based on appropriate knowledge and shared understandings.

15. While the use of other types of cooperative agreement may be more appropriate in many situations, upgrading relationships to full systems equivalence agreements covering one or more food commodities, on the basis of demonstrated performance, is a useful additional tool. It could be used to further reduce duplication of administrative processes and regulatory burden. The increased use of system recognition provides a process for countries entering into consultations with the aim of considering the equivalence of food control systems for specific sectors. The food control system can be considered in its entirety or as applying only to a specific section of the food supply chain. The overarching consideration is whether the system as a whole, whatever the agreed scope, is both achieving and is likely to continue to achieve the required outcomes.

16. The aim of the proposed guidance is to reduce the level of redundancy and duplication of assessment and control processes currently applied to international trade where competent control systems are already in place in the exporting country. It is designed to help importing and exporting countries develop an appropriate process to achieve the necessary confidence. The guidance should assist countries in addressing the key question of whether the design and operational performance of an identified food control system is likely to achieve the same or higher (comparable) overall human health, food suitability and technical outcomes as achieved within the importing country.

17. The following sample draft guidelines provide an example of what guidance in this area may look like so that member countries and observers can better envisage the sort of product that advancing new work in this area may achieve.

Sample Draft Guidelines for Systems Equivalence/Comparability Evaluations

1. Objective

The objective of these guidelines is to facilitate better use and risk targeting of import and export assurance resources through the recognition of systems equivalence.

The guidelines provide:

- Principles and processes applicable during an initial consultative process in determining whether a more in-depth consideration is appropriate;
- Principles and processes possibly applicable to an in-depth consideration of systems equivalence; and
- Guidance on the development of bilateral agreements documenting any recognition of systems equivalence, including expectations for maintenance.

2. Scope

These guidelines provide a process for countries entering into consultations with the aim of considering the equivalence of food control systems for specific sectors. The food control system for the sector can be considered in its entirety or as applying only to a prescribed section of the food supply chain.

Considerations may apply to food safety, suitability and technical outcomes.

These guidelines are not intended to replace CCFICS guidance on the judgment of the equivalence of more specific/targeted measures in terms of food safety outcomes[1].

3. Definitions

Comparable outcome: A determination that the overall human health, food suitability and technical outcomes of different food control systems, in part or in whole, are likely to be similar.[2]

Equivalence: The capability of different inspection and certification systems to meet the same objectives (CCFICS).

Food safety control measure: Any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level (CCFICS).

Food control system: A dynamic and documented system that may consist of components at the infrastructure, programme or measures level.[3]

Level of assurance: For the purposes of this guide means an objective measurement of the outcomes achieved with respect to overall risks to human health and food suitability characteristics, and technical descriptions.

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control (CCFICS).

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (CCFH).

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[1] Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003).
[2] The word “similar” also includes those situations whereby an assessment may indicate a superior level of performance.
[3] Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003).

Sanitary measure: Any measure applied to protect human life or health within the territory of the country (WTO SPS Agreement).

Suitable: Fitness for intended purpose of food, including conformance with any claim.

Systems equivalence: Recognition by an importing country that the design and operational performance of an identified food control system is likely to achieve the same or higher [comparable] overall human health, food suitability and technical outcomes as achieved within the importing country.

4. Principles

The consideration of any request for recognition of systems equivalence is a multi-step and iterative process. The scope, process and timelines may vary according to how readily it can be assessed and as to whether there is likely to be sufficient evidence to make a comparison of the systems.

Recognizing equivalence should increase efficacy and efficiencies for importing and exporting countries alike and reduce the need for replication of measures as well as the type and intensity of continuous verification activities.

Principles to be applied in determining and documenting systems equivalence for one or more sectors are as follows:

- Initial consultations should be entered into to determine whether or not the sector control system meets relevant prerequisites before a decision is made as to how to proceed further, including the scope of any systems equivalence consideration.

- The importing country should describe in writing, with appropriate references, the key objectives, core elements and key operational performance characteristics of its sector food control system that will form the basis for any assessment.

- The exporting country should describe in writing, providing appropriate evidence or references, how its sector food control system shares similar objectives and core elements (as appropriate) and is likely to deliver comparable outcomes.

- The decision criteria used for assessing the equivalence of the sector food control system should reflect whether or not the effect of the alternative design/core elements, as relevant to their operation in the exporting country, are capable of delivering comparable outcomes to those in operation in the importing country.

- The decision criteria used for assessing the equivalence of operational performance characteristics should reflect whether or not there is appropriate evidence that the overall performance of the sector food control system as operating within the exporting country consistently delivers comparable outcomes.

- A determination of systems equivalence should result in a documented agreement delineating the scope of the recognition, the associated benefits, expectations with respect to continuing information exchanges and any processes associated with ongoing maintenance.

5. Initial consultations on prerequisite requirements

The initial consultations should determine whether or not the sector food control system meets any prerequisite requirements before a decision is made as to how to proceed, including the scope of any systems equivalence considerations.

5.1. Consistency with relevant international standards

Having robust national food control systems as described by CCFICS and related Codex commodity codes and guidelines, particularly in respect of clear legislative frameworks, robust implementation of regulatory requirements

and appropriate monitoring of the performance of the system as a whole (including participants other than government as necessary) provides a good starting point for any comparison.

5.2. Similarity of macro-elements

Similarity of macro-design elements, application of risk-based approaches to food safety, and system performance expectations will facilitate comparison.

5.3. Existing knowledge, confidence and experience

The importing country's existing knowledge and experience of and confidence in the exporting country's sector control system will inform any consultative process.[4]

It may also be useful to take into account situations where other countries enforcing a similar or higher level of protection have recognized systems equivalence.

6. System description by the importing country

Following a decision to progress with consideration of systems equivalence, the importing country should describe in writing with appropriate references the key objectives, core elements and key operational performance characteristics of its sector food control system that will form the basis for any assessment.

6.1. Key programme objectives

Key programme objectives should be identified. These should be readily referable in legislative and policy documents, including reference to commitments to risk-based approaches to hygiene, and referenced accordingly.

6.2. System design

The importing country should describe the core components of its system using a system description template. The narrative associated with each component element should describe the purpose and requirements of the component as well as the "programme elements" that the country considers necessary to satisfy the basic requirements. Key operational performance characteristics should be described.

Descriptions should be as objective and outcome-focused as possible so as to provide a systematic template record for the exporting country to similarly describe how its system is comparable.

Components that should be described may include:

- Regulatory foundations;
- National/federal plans;
- Hygienic processing system elements;
- Competency standards and training;
- Approval and verification;
- System audit and monitoring;
- Compliance and enforcement;
- Industry and community relations;
- Programme resources;
- International communication and harmonization;
- Laboratory support; and
- Quality management system.

[4] In some cases, the relationship between parties may have already contributed to tacit or informal acceptance of overarching food sector controls.

6.3. Evidence of outcomes

Evidence as to how the importing country's system meets its stated objectives and outcomes should be referenced and separately available as relevant (e.g. web links). This information should illustrate compliance with operational requirements and key performance characteristics.

Linkages to sources of information on monitoring of products for biological, chemical and physical hazards over time should be provided, together with evidence of both regulatory and industry responses to unacceptable trends in levels of hazards.

A good description of any key operational performance characteristics that must be met should be provided, referencing as appropriate evidence as to how the importing country is achieving the required characteristics. Where possible, these should be described in terms of food safety, food suitability and technical outcomes to be met, and include description of any statistical process control parameters. Similarly, the required regulatory performance of the competent authority and/or officially recognized bodies should be described in objectively measureable terms directly relating back to the above parameters.

Reference to any sector public health goals and associated public health statistics on food-borne illness can provide further evidence of achieving sector control objectives.

7. System description by the exporting country

The exporting country should utilize the system description template provided by the importing country to comparably describe the components and operational characteristics of its system and to discuss how the components of its system achieves the objectives and comparable outcomes as specified by the importing country. Evidence should be provided or cross-referenced (e.g. web links). A fuller explanation of how comparable outcomes are achieved should be provided where the most substantial differences in any components or operational performance characteristics occur, such as by use of risk profiles.

Risk profiling/risk assessment may need to be undertaken (and specific controls agreed upon) if there is evidence that significantly different risks may arise from products from the exporting country compared with the importing country.

8. Decision on systems equivalence

8.1. Decision criteria for system design

The decision criteria used for assessing the design equivalence of the sector food control system by the importing country should reflect whether or not the effect of the alternative design/core elements, as relevant to their operation in the exporting country, are capable of delivering comparable outcomes to those in operation in the importing country.

8.2. Decision criteria for operational performance characteristics

The decision criteria used for assessing the equivalence of operational performance characteristics should reflect whether or not there is appropriate evidence that the overall performance of the sector control system operating within the exporting country consistently delivers comparable outcomes.

Decision criteria may take a number of factors into consideration, including the existence and appropriateness of the design components mentioned in Section 6.2 above, together with the adequacy of associated operational performance characteristics.

8.3. Decision on systems equivalence

The decision will take into account:

- Level, type and transparency of operational documentation (regulatory standards, systems and records)

- Level of compliance by the regulated industry with good hygienic practice requirements, operational performance characteristics and any regulated hazard targets;
- Responses by the competent authority to non-compliance by industry;
- Robustness and credibility of export assurance systems;
- Adequacy of monitoring systems, data analysis and responses;
- Results of audits carried out by the importing country [or other importing countries];
- Results of port of entry inspections;
- Willingness to take safeguard actions; and
- Policies, such as risk-based, continuous improvement,

9. Systems equivalence agreement

When the importing country makes a determination of systems equivalence, the scope and conditions of that determination should be documented in an agreement between the importing and the exporting country. Where necessary, specific legal requirements can be specified and maintained.

Such an agreement should outline the intentions of the countries with respect to ongoing cooperation, information exchange, certification, border checks, processes applied when issues arise, future reviews and thresholds under which some degree of reassessment may be required.

Such an agreement should also outline the principles that will be applied to allow for normal evolutionary changes to be made to the food control system, including the ability for trials to be conducted without the need for prior consultations or reassessments.

Any systems equivalence agreement should describe in broad terms the level of change that may be accommodated in hygiene control systems in the exporting country without recourse to consultation with the importing country as a prerequisite. This includes field trials in support of innovative change in hygiene systems. Such changes should not materially change the level of control that was the basis for the systems equivalence determination.