CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 8 **CRD 5**

February 2016

ORIGINAL LANGUAGE ONLY

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty-second Session

Melbourne, Australia, 6-12 February 2016

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

(Comments from Kenya, Philippines, Thailand)

KENYA

Kenya appreciates the work prepared by New Zealand in the progress made in preparing this discussion paper for committee members to discuss and comment on.

Kenya therefore supports the continuation of the work on the possible development of guidance on the use of systems equivalence/comparability.

PHILIPPINES

We would like to thank New Zealand in preparing the discussion paper. We will support discussion/activities for the further development of the guidance.

THAILAND

Thailand would like to express our appreciations for efforts of New Zealand for the preparation of Discussion Paper on the Possible Development of Guidance on the Use of Systems Equivalence/Comparability.

General comments

Our comments for the document are as follows:

The existing Codex Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003), can be used as guidance for the development of agreements for recognition of the systems equivalence for food import and export. So, it is not needed to elaborate a new document for the evaluation of equivalence of the food control system.

Nevertheless, if it is considered that CAC/GL 53-2003 provides incomprehensive or insufficient recommendations, it is proposed that new guidance to provide further recommendations and details on how to apply CAC/GL 53-2003 in practice should be elaborated.

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.