CODEX ALIMENTARIUS COMMISSION







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Agenda Item 5

CX/FICS 14/21/4

August 2014

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

Twenty-first Session

Brisbane (Australia), 13-17 October 2014

DISCUSSION PAPER ON PRINCIPLES AND GUIDELINES FOR MONITORING REGULATORY PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS

(Prepared by the United States of America)

Background

- During the 19th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) held in Cairns, Australia, 17-21 October 2011, the Committee considered a proposal prepared by the United States to develop a set of principles and guidelines for establishing performance metrics to enable countries to assess the capacity of either their own National Food Control System (NFCS) or their trading partners' systems.
- 2. The Committee agreed that it was premature to start new work and established an electronic working group (eWG), chaired by the United States, to develop a questionnaire on how countries currently assess and manage the performance of their NFCS and, where possible, to give examples of indicators used. The questionnaire was circulated to Codex Members, and the results were incorporated into a revised proposal, prepared by the United States.
- 3. During the 20th Session of CCFICS held in Chiang Mai, Thailand, 18 to 22 February, 2013, the Committee considered the revised proposal prepared by the United States. The questionnaire provided an opportunity for Members to identify additional examples of indicators used when monitoring the effectiveness of their NFCS. It was also beneficial in identifying the prevalence and availability of data maintained by responding countries.
- 4. By developing principles and guidelines, individual countries would be able to consider the use of regulatory performance indicators to reach supportable conclusions regarding the ability of their NFCS to meet its objectives and to facilitate continuous improvement. During plenary discussion, some countries raised concerns that the work may be premature as work on the principles and guidelines for NFCS had just been finalized in the same session.
- 5. The Committee agreed that the an electronic working group, chaired by the United States, should (i) revise the project document taking into account discussion from the plenary and (ii) prepare an outline of the proposed *Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems* for consideration at the next session. The Chairperson also noted that regional workshops could be an efficient tool to demystify and clarify the intent of the proposal.

Discussion

6. Two regional workshops (Costa Rica in December 2013 and Belgium in February 2014) were held to discuss the proposed new work related to monitoring the performance of NFCS and to consider work that member countries and international organizations have undertaken in this area. Through the presentations and discussion, it is apparent that many countries have developed or are developing mechanisms for monitoring and evaluating their food control systems, in the absence of high-level international guidance. The varied approaches that were discussed suggest that there is a need for this new work in Codex and that there needs to be direct linkage of this work to the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013), so that the self-evaluation of a NFCS is consistent with CAC/GL 82-2013.

7. It is suggested that the performance indicators used in any self-evaluation of a NFCS should focus primarily on public health outcome indicators, or a proxy of these, to demonstrate the NFCS effectiveness in achieving food safety, food suitability and technical outcomes. More operationally aligned performance indicators are also useful to monitor trends in levels of compliance, both with respect to competent authority's continuous prioritizing of verification activities and identifying program resource gaps. These operational performance indicators may also be used with respect to the impact of these trends on the achievement or improvement of the public health outcomes.

- 8. The final analysis could reflect a synergism between the different types of performance indicators, as reflected in the following progression which illustrates the linkages between the resources and activities of the NFCS and the corresponding outputs and public health outcomes:
 - Objectives: the outcome to be achieved over a period of time, determined by the implementation of activities
 - Inputs: resources available to the NFCS
 - Activities: regulatory or business processes and services that the NFCS performs
 - Outputs: the tangible and immediate results of the organization's activities
 - Outcomes: consequences of outputs in the public sector. These may include intermediate or long-term changes in behaviors or events that lead to improvements to public health and welfare
- 9. While countries may continuously strive to improve the quality of the information collected, an initial step toward objective self-evaluation would be to establish baseline performance measures. Under that framework, further guidance could be developed to assist this process including characteristics of relevancy, transparency, and applicability.
 - Relevant indicators focus on results that matter. Where outcomes are measured, there are clear and strong relationships to activities and outputs. Where outputs are measured, there are clear and strong relationships to higher-level goals and public health outcomes.
 - *Transparent* indicators provide clear evidence based on performance data or observable events. The methods for analyzing and summarizing performance data should also be clear.
 - Applicable measures are practical and affordable. Data sources should be reliable and credible, and the process for data collection and analysis efficient.
- When conducting self-evaluation of their NFCS, countries should consider how to maximize the collection, presentation and analysis of outcomes to ensure that results are reflective of the system's effectiveness.
- 11. Standardization of reporting mechanisms and methods of analysis should include both quantitative and qualitative aspects, as it is difficult to develop a unified model which is based exclusively on quantitative results. Challenges associated with quantitative analysis include prioritization of individual performance indicators, development of combined indices, and standardization for methods of comparison. It is therefore suggested that efforts to use quantitative information are targeted to support self-evaluation of the core competencies of the NFCS. These core competencies would be based on the CAC/GL 82-2013, for which cross-references between each related section and corresponding proposed performance indicators can be established.
- 12. In consideration of internationally available tools used to evaluate the performance of veterinary services or food safety systems that are in use and under development, CCFICS should consider the need develop guidance that may help countries to identify and define measurable outcomes to evaluate the performance of their NFCS for self-improvement. Any such guidance should contain the necessary elements of flexibility taking into account that NFCS in different countries vary depending on the national circumstances and may be at different stages of development.

Recommendation

13. As a complement to the Codex Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), it is proposed that CCFICS undertake the development of Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems, with emphasis on a means to ensure effective implementation and continuous improvement within the NFCS. A project document for the new work is provided in the Annex, as well as an outline for the principles and guidelines that will be developed.

PROJECT DOCUMENT

Principles and Guidelines for Monitoring the Regulatory Performance of National Food Control Systems

1. Purpose and scope of the proposed standard

The purpose and scope of the work is to develop a framework and a set of principles and guidelines to assist the competent authority(ies) of a National Food Control System (NFCS) to develop other appropriate tools (e.g. measurement mechanisms, indicators, analysis and evaluations) which can be used to help design, evaluate, and adjust its own system.

2. Relevance and Timeliness

This proposal relates to the Codex document *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013). This proposed new work provides a link between the identification of the elements and characteristics of NFCS, as described in (CAC/GL 82-2013)2013, and the self-evaluation of the system to ensure it is functioning as designed and is continuously improved and is effectively achieving its objectives. This will help countries to ensure that finite resources invested in food safety are producing desired results and assist with stakeholder communication.

3. The main aspects to be covered

The work would develop a set of principles and guidelines that would underpin the ability of competent authorities(ies) to monitor effective implementation and support continuous improvement of their NFCS by the use of adequate tools.

Development of agreed key definitions relating to the terminology of self-assessment and monitoring of a NFCS will also assist in consistency of understanding and interpretation.

Additionally the new work would, in guideline form, delineate those components of a NFCS that should be considered and evaluated to identify any specific areas in need of improvement. These components should reflect the Principles upon which a NFCS should be based, as listed in the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013 section 3).

The guidance would take into account and be sufficiently flexible to provide for different countries having systems at different stages of development, depending on their national circumstances.

Whether the principles and guidance are developed as a stand-alone document or as an annex to an existing Codex text is an open question with a decision to be made at a later date.

4. Assessment against the Criteria for the Establishment of Work Priorities

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

This work will provide useful guidance to countries to self-evaluate the capability of their NFCS thus contributing to consumer protection. The guidance will also assist with continuous improvement. The needs of developing countries will be taken into account by recognising that NFCSs in different countries may be at different stages of development.

<u>Criteria applicable to general subjects apply and, specifically the following criterion Diversification</u> of national legislations and apparent resultant or potential impediments to international trade

While the purpose and scope of the new work focuses on the self-evaluation and improvement of national control systems within a country, it can also provide competent authorities with additional tools to use in documenting their food import and export control systems and thus, provide means to build confidence in their food safety controls.

5. Relevance to Codex strategic objectives

The proposed work directly relates to Codex Strategic Goal 1: Promoting sound regulatory frameworks. The proposed work provides the basis for countries to undertake systematic self-evaluation of the functioning of their NFCS to determine whether desired public health outcomes are being met and to identify mechanisms to strengthen their overall food safety regulatory system.

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

This proposal relates to the Codex document *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013)). The basic components of a NFCS outlined in CAC/GL 82-2013 are

reflected in this proposal and should be monitored and evaluated to ensure the effectiveness and continuous improvement of the NFCS. When monitoring food safety systems, all Codex texts (the Codex Alimentarius) which includes guidance on control programs will be considered relevant.

In the course of the development of the new work, analysis will include other existing CCFICS text that may be applicable.

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

None anticipated.

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

None anticipated.

Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the timeframe for developing a standard should normally not exceed five years

It is proposed that the work will extend over three (3) sessions of CCFICS. If this 21st (2014) Session of CCFICS agrees to undertake this new work, and approved by the Commission, an initial draft of the document will be prepared for consideration by CCFICS at its 22nd Session (likely to be scheduled for 2016). The document would be anticipated to be ready for Step 5 approval following the 23rd Session of the Committee (2017) and ready for Step 8 adoption following the 24th Session of the Committee (2018). It would be anticipated that adoption by the Codex Alimentarius Commission would occur at the Commission's 2019 Session. Electronic and/or physical working groups are likely to be needed, as well as Regional workshops.

In summary:

Agreement to undertake work: 2014

Approval by the Commission as New Work: 2015

Adoption by the Commission at Step 5: 2018

Adoption by the Commission at Step 8: 2019

Draft Outline

Principles and Guidelines for Monitoring

Regulatory Performance of National Food Control Systems

I. Introduction (purpose and scope)

The purpose and scope of the work is to develop a set of principles and guidelines to assist a competent authority(ies) to develop and use regulatory performance indicators and other appropriate measurement mechanisms to help design, evaluate, and make necessary adjustments to its own national food control system (NFCS), based on performance.

II. Objective

The objective is to ensure effective policy setting, design, implementation and continuous improvement of a NFCS. Effective monitoring and system review should be developed in line with elements outlined in section 4.4 of CAC/GL 82 -2013.

III. Terminology (definitions)

Need to establish a common understanding of terminology related to self-assessment and monitoring of the NFCS.

IV. Principles

Proposed Principles for Monitoring the Effectiveness of National Food Control Systems

- Self-evaluation of the NFCS should encompass different aspects of a given NFCS and as far as possible provide a full evaluation of system performance.
- Self-evaluations should evaluate specific components of the national food control system including: policy setting; system design; and implementation (as outlined in Section 4 CAC/GL 82-2013CAC/GL 82-2013)
- Results of the self-evaluations should reflect three main characteristics to determine if the system is fully functional and effective, including:
 - Situational awareness;
 - o Pro-activity; and
 - Continuous improvement.
- Criteria for evaluation should be established, clearly defined and documented, and may also include cost benefits and efficiency.
- Indicators should be simple, clearly defined, easy to interpret, and measurable.
- Self-evaluations, should encompass all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade.
- The evaluation of control programs should cover issues such as:
 - Effectiveness of control procedures (including history of nonconformance);
 - Suitability in achieving objectives;
 - Whether the program has covered relevant stages in the production chain, taking into account risk factors; and
 - Consideration of emerging trends.

V. Guidance for Monitoring the Effectiveness of the NFCS

Ensure that the guidance incorporates the principles from CAC/GL 82-2013 when assessing the effectiveness of a NFCS.

Include guidance to assist countries with the selection of regulatory performance indicators that can be used to measure the performance of the NFCS in relation to:

- · policy setting,
- · system design, and
- implementation

Include guidance to assist countries in identifying clear indicators that incorporate characteristics of relevancy, transparency, and applicability.

Include guidance to assist countries to improve the quality of the information collected, including establishing a baseline performance or conditions, upon which to build, timeframes and milestones for the given period to be measured.

Include guidance on "putting it all together", including how the NFCS can utilize or leverage the outcome of the self-evaluation to demonstrate the effectiveness of the system to protect the health of the consumer and to ensure fair practices in food trade.