CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twentieth Session

Chiang Mai (Thailand), 18 – 22 February 2013

DISCUSSION PAPER ON MONITORING REGULATORY PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS

(Prepared by the United States of America)

Background

1. 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. Two types of regulatory performance indicators (RPI) were proposed: public health outcome measures to demonstrate the NFCS effectiveness in achieving food safety, food suitability and technical outcomes; and operational performance measures, which demonstrate the exporting country's oversight by measuring day-to-day progress in ensuring safety and suitability of foods, prioritizing inspection activities and identifying program resource gaps.

3. While the Committee agreed that it was premature to start new work, it 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.

Information Collected and Analysis of Comments Submitted

4. The questionnaire was divided into two portions: I) Public Health Outcome Measures (PHOM); and, II) Operational Performance Measures (OPM). Each of these sections were further divided into: A) examples of indicators/measures outlined in the discussion paper presented at CCFICS19; and, B) additional indicators/measures which countries identify as being important and not included in section A.

5. For each indicator/measure, countries were asked to indicate whether it is quantifiable, how it is utilized, the types of foods covered, and the current status of the data collection activities. This last point also included a description of each country's ability to share the information collected; e.g., some data may be difficult to share due to electronic security concerns.

6. The United States received responses from 16 countries, 11 of which elected to provide completed versions of the survey. Several countries continued to express the opinion that the discussion related to performance metrics is premature, and could be pursued once CCFICS has completed the proposed draft *Principles and Guidelines for National Food Control Systems*.

7. Some Members expressed concern that responses could only be provided for certain sectors of food production or areas of regulatory oversight for which they had an active role, so the responses may not present a complete overview of the information available on a country level.

8. The results indicate that there is concurrence between Members regarding the types of regulatory performance indicators which may be useful, with at least three-quarters of the countries responding to the survey using the proposed performance indicators. While the questionnaire offered Members the opportunity to report performance measures which had not been previously identified, very few were provided. A summary of the responses received is presented in Table 1, as well as references to the appropriate paragraphs in the current draft of the NFCS paper.

9. It should be noted that privacy issues may impact the ability to share information, as only 30% of countries that maintain information for a given performance measure identified this as "readily available."

This may be a result of electronic security concerns or legislative requirements that require establishment of agreements to enable the exchange of information.

Discussion

10. The questionnaire has been beneficial in identifying the prevalence and availability of data maintained by many countries. By developing principles and guidelines, all countries can consider the use of both public health and operational performance measures to reach supportable conclusions regarding the ability of its inspection system to meet intended goals.

11. Where possible, the analysis of a NFCS should be consistent with the guiding principles outlined in the proposed draft *Principles and Guidelines for National Food Control Systems,* which include policy setting, system design, implementation, and monitoring and system review. Likewise, the analysis of the system should ultimately reflect the characteristics of situational awareness, pro-activity, and continuous improvement outlined in this document.

12. Rather than treat the two types of proposed measures independently, the final analysis could reflect a synergism between the public health and operational performance measures, as reflected in the following progression:

- Inputs: resources needed to carry out organization's mission
- Activities: regulatory or business processes and services that produce outputs and outcomes
- Outputs: the tangible and immediate results of the organization's activities
- Outcomes: consequences of outputs in the public sector. These may include intermediate outcomes, or changes in behavior or events that lead to ultimate outcomes; i.e., improvements to public health and welfare

13. While countries continuously strive to improve the quality of the information collected, an initial step would be to establish a baseline performance or conditions, upon which to build. Once the metrics or indicators are established, it is then important to establish timeframes and milestones for the given period to be measured. 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.

14. The use of performance metrics is applicable to a country's domestic system, and also provides a mechanism to assess the performance of its trading partners, so individual countries should consider how to maximize the collection and presentation of outcomes for their intended purposes. For example, the information maintained by countries with little or no export activity may consider the focus on OPMs as applicable to their specific needs. On the other hand, assessments occurring between trading countries will likely be more robust. In this case, the resulting level of confidence provided through the information exchange can ultimately affect activities such as equivalence or comparability reviews, onsite audits, and other typically resource-intense activities. In this sense it will be beneficial for countries to continue to work together to standardize the methods through which the outcomes are reported and analyzed.

15. Standardization of reporting mechanisms and methods of analysis will most likely include both quantitative and qualitative aspects, as there is a certain degree of difficulty in developing a unified model which is based exclusively on quantitative results. Challenges which face quantitative analysis include prioritization of individual performance measures, development of combined indexes, and standardization for methods of comparison. Likewise, because the survey results indicate that these performance metrics are not always "readily available" for sharing with outside countries, the ability to conduct direct analysis is further inhibited. It is therefore suggested that quantitative information be used to support summary analyses or other reports, which take into account core competencies of the food control system. These core competencies would be based on the proposed draft *Principles and Guidelines for National Food Control Systems,* for which cross-references between each related section and the proposed performance metrics can be established.

16. If CCFICS moves forward with this new work, the Committee should review existing tools which are used to evaluate the performance of veterinary services or food safety systems, including country specific as well as internationally available tools. The U.S. Food and Drug Administration's International Comparability Assessment Tool (ICAT) is an example of a country specific tool that is used to assist with comparing foreign food safety systems with FDA's laws and regulations. Two examples with international applicability include the World Organization for Animal Health's (OIE) global initiative to evaluate the performance of veterinary services through the OIE PVS tool, and the Institute for Inter-American Cooperation in Agriculture's (IICA) Performance, Vision and Strategy (DVE) tool, which was developed in conjunction with the Pan American Health Organization (PAHO) to assist national food safety authorities in: determining their level of performance, creating a shared vision with the private sector on setting priorities, and planning a strategy for meeting their responsibilities to the consumer.

Recommendation

17. As a complement to proposed Codex guidance on *National Food Control Systems*, it is proposed that CCFICS undertake the development of *Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems,* using the list of performance measures proposed through the questionnaire as a starting point. A project document for the new work is provided in the Annex.

PROJECT DOCUMENT

Principles and Guidelines for Monitoring 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 set of principles and guidelines to enable a governmental national competent food safety authority's to develop regulatory performance indicators and appropriate measures which can be used to help design, evaluate, and adjust its own system based on performance. These indicators can also be utilized to evaluate the performance of another country's food control system, specifically to ensure the effectiveness of the national systems to achieve similar food safety outcomes.

2. Relevance and Timeliness

Countries are increasingly sourcing their food from foreign markets with the accompanying need to ensure its safety. At the same time, scarce resources necessitate the need to leverage food safety capabilities of those involved in ensuring food safety in the exporting country. Competent authorities of exporting countries must be able to communicate the effectiveness of their existing systems that ensure equivalent food safety outcomes which will facilitate trade. Additionally, competent authorities of importing countries may wish to evaluate food control systems of their trading partner countries. Development of regulatory performance indicators and appropriate performance measures will facilitate the ability to recognize the capability of food control systems.

3. The main aspects to be covered

The work would develop a set of principles that would underpin the ability of a national competent authority to establish regulatory performance indicators and measure the performance of the food control system.

Additionally the new work would, in guideline form, delineate those components of a food safety control system that would need to be considered and evaluated to permit recognition of the food safety system. These components would include: regulatory foundation (laws, regulations, and infrastructure); inspection programs; compliance and enforcement programs; laboratory support programs; program assessment and evaluation; training programs; food-borne illness surveillance/investigation/response; program resources; and, communication, education and information exchange programs.

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 assess capable national food control systems which will facilitate equivalence determination or recognition of such systems. Documentation of regulatory performance will enable countries to help ensure the safety of imported food and should facilitate fair practices in the trade of such food.

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

This work will provide national food safety competent authorities additional tools to use in documenting food import control programs. By providing a means to facilitate confidence in the food safety controls and approval of food for export, international food trade will also be facilitated.

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 systems recognition of other national food safety control systems, strengthening their overall food safety regulatory system.

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

The proposed draft *Principles and Guidelines for National Food Control Systems,* currently under development by CCFICS are related to this work as the basic components outlined in this document must be monitored and evaluated to ensure the effectiveness of the national food control system.

This new work on the use of performance metrics is the link between identification of the elements and characteristics of a food safety control systems, and recognition of systems as equivalent.

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 planned for

None anticipated.

9. 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 20th (2013) Session of CCFICS agrees to undertake this new work, an initial draft of the document will be prepared for consideration by CCFICS at its 21st Session (likely to be scheduled for 2014). The document would be anticipated to be ready for Step 5 approval following the 22nd Session of the Committee (2016) and ready for Step 8 adoption following the 22nd Session of the Committee. It would be anticipated that adoption by the Codex Alimentarius Commission would occur at the Commission's 2016 Session. Electronic and/or physical working groups are likely to be needed.

In summary:

Agreement to undertake work: 2013

Approval by the Commission as New Work: 2013

Adoption by the Commission at Step 5: 2015

Adoption by the Commission at Step 8: 2016

Table 1: Summary of Responses

	N[1]	Performance Measure	# of Countries[2]	% of Submitting Countries[3]	% Quantifiable[4]	% Readily Available[5]	PGFNFCS Reference[6]
PHOM	1	Results from industry or government testing concerning the presence biological, chemical, or physical hazards in food.	11	100%	100%	57%	43, 44, 47, 50, 84
PHOM	2	Results from industry or government testing concerning non-hazardous indicators used to assess process control of the safe production of food (e.g., generic E. coli, TPC, APC, assessment of sanitary dressing procedures, etc.).	8	73%	100%	75%	43, 44, 47, 84, 89
PHOM	3	Level of compliance of exported food, including results from importing country's control programs. This may include results of audits or port-of-entry testing conducted by the receiving country.	10	91%	94%	44%	43, 47, 63, 66, 79, 86
PHOM	4	Foodborne illness and outbreak information.	10	91%	92%	50%	43, 73, 86
PHOM	5	Information related to the number of product recalls, including the severity of the recall and amounts of affected product.	9	82%	93%	50%	36, 43, 47, 59, 60, 86
PHOM	6	Results of programs designed with the purpose of reducing the prevalence of zoonotic diseases or other hazards in live animals and plants.	10	91%	100%	71%	9, 43, 84
OPM	1	Demonstration of legislation that requires that industry is taking primary responsibility for food safety and suitability through the use of validated food control systems. For example, this may include an indication of the extent to which a specific food is required to be produced under a system of preventative controls including GAP, GMP, GHP and HACCP.	11	100%	75%	70%	12, 49, 51
OPM	2	Demonstration of a transparent regulatory process which considers input from relevant stakeholders.	8	73%	45%	73%	10, 28, 62

[1] Measure number, as per the original questionnaire
[2] Number of submissions indicating that information for each performance measure is either maintained or intended
[3] Percentage of submissions indicating that information for each performance measure is either maintained or intended
[4] Percentage of databases for this performance measure which where identified as “quantifiable”
[5] Percentage of databases for this performance measure which where identified as “readily available” for sharing
[6] Relevant portions of CCFICS’ *PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS* (currently in draft form), provided for information and planning purposes

	N[1]	Performance Measure	# of Countries[2]	% of Submitting Countries[3]	% Quantifiable[4]	% Readily Available[5]	PGFNFCS Reference[6]
OPM	3	Demonstration that food safety personnel (e.g., inspectors, laboratory analysts, risk assessors) have the training, equipment, and skills required to perform their duties (e.g., training to curriculum).	11	100%	78%	57%	40, 57, 68, 72, 73
OPM	4	Quality Management Systems: CA has a system in place to establish standards and to monitor the activities of food safety personnel (e.g., consistency, accuracy) inspectors, laboratory analysts, etc.	10	91%	87%	33%	75, 76, 77, 80, 81, 89
OPM	5	Measures to ensure that resources are used consistent with agency mission, and protected from waste, fraud, and mismanagement.	10	91%	100%	30%	40, 57,80
OPM	6	Approval/recognition of food control plans in registered food premises.	8	73%	91%	73%	37,50
OPM	7	Evidence that laws and regulations are followed: verification of compliance with food control plans and other (specified) regulatory requirements, with documented response by the CA to non-compliance.	10	91%	87%	40%	70, 80,81
OPM	8	Demonstration of a performance-based verification system where reliable and timely information is obtained, maintained, analyzed, reported and used for decision making.	8	73%	73%	64%	17, 43, 47, 80, 81, 86
OPM	9	Timeliness and effectiveness of CA responses to industry non-compliance as revealed by both internal and external audits or inspections.	10	91%	69%	38%	75, 81, 87
OPM	10	Measures of the accuracy and consistency of export assurance and certification systems (e.g., % of certificates that require amendments or re-issuances because of inaccuracies).	8	73%	100%	50%	40, 81, 89
OPM	11	Trend analysis of results of port-of-entry inspection and follow up as necessary.	10	91%	100%	50%	79, 81, 86
OPM	12	Demonstration of the effectiveness of tracking systems and the ability to address adulterated food which has entered the distribution chain.	9	82%	85%	38%	59, 60, 61, 73
OPM	13	Monitoring the capability and proficiency of laboratories.	11	100%	93%	50%	47, 76, 77
OPM	14	Evidence of communication among public health (food safety), agriculture, and other relevant authorities, consumers and consumer organizations, and food business operators.	10	91%	82%	59%	10, 26, 62, 63, 64, 85