



**Food and Agriculture
Organization of
the United Nations**



**World Health
Organization**

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Agenda Item 5 (b)

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

**Nineteenth Session
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**PROPOSALS FOR NEW WORK
(Replies to CL 2011/5-FICS)**

(Proposals from Costa Rica, United States of America and International Dairy Federation)

Costa Rica

Costa Rica is grateful for the opportunity to submit the following proposal for future work by CCFICS.

Title: Documentary information directed at exporting countries and food establishments.

Objective: Standardise and harmonise questionnaires requested by the authorities of commercial partner countries; to assess food exporting countries and establishments in order to authorise, renew or update the exports from a country and/or establishment.

Background: At present the authorities responsible for food safety in exporting countries receive a large number of various questionnaires from governments wanting to assess aspects, such as, inspection systems, animal health, official laboratories, relevant authorities, etc., together with specific information about the exporting establishments. In some cases, they request additional information from the correspondent without indicating a final date for the review of documents by the authorities, resulting in extremely slow processes that form obstacles to trade between countries.

Proposal: Create a standard document that contains the most relevant information for the competent authority and exporting establishments, which is able to effectively demonstrate and guarantee the health situation in the exporting country and the safety of the products.

With regard to the comment in the circular letter CL 2011/5-FICS, "*Members are also reminded that any proposals should conform to the Criteria for the Establishment of Work Priorities, as set out in the Codex Alimentarius Commission's Procedural Manual, as well as be within the Committee's Terms of Reference*", if this proposal for future work is approved, Costa Rica consents to conform to the provisions in the criteria for the establishment of work priorities, as set out in the Codex Alimentarius Commission's Procedural Manual, as well as with the Committee's Terms of Reference.

United States of America

The United States is pleased to submit for consideration by CCFICS a request for proposed new work on regulatory performance measures.

The United States is proposing new work on “Monitoring Regulatory Performance of National Food Control Systems”. This proposal relates to the development of performance metrics to assess the capability of a national food control system. Whether it be in the context of a country assessing its own system, in the context of systems recognition or other approaches to assessing and recognizing a food control system, or in the context of one country simply wishing to assess the performance of another food control system, the need for metrics to objectively carry out these assessments is important. Attached as an Annex is a Discussion Paper regarding this new work that includes a Project Document.

We appreciate the opportunity to provide this response regarding new work that could be undertaken by CCFICS.

DISCUSSION PAPER ON PROPOSED NEW WORK RELATING TO MONITORING REGULATORY PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS (Paper prepared by the United States of America)

1. The concept of equivalence of food safety systems was incorporated into the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to facilitate trade while ensuring that the appropriate level of health protection was maintained. In practice, most countries have found that, with the exception of certain situations, particularly those associated with a single measure or small group of measures, demonstrating that an exporting country’s level of protection meets that of an importing country has been technically difficult.
2. However, the original reason for the establishing the provision for equivalence in the SPS Agreement remains.
3. Countries have invested in, and developed comprehensive national food control systems as described by CCFICS¹, that include robust legislative framework, consistent implementation of regulatory requirements and system wide performance monitoring.
4. Competent Authorities are seeking to use system wide performance monitoring to leverage investment in their food control systems and demonstrate comparable food safety outcomes, thus facilitating trade.
5. A regulatory performance baseline is needed in order to compare likely food safety, food suitability and technical outcomes resulting from the national food control systems. Full documentation of the food control system and demonstration of consistent and satisfactory level of compliance with regulatory requirements over time by the industry within the exporting country, indicates that the exporting country is able to demonstrate system wide regulatory performance.
6. To assist a competent authority in evaluating its own performance, or to evaluate the performance of another food control system, the establishment of indicators of regulatory performance will be beneficial.
7. Regulatory performance indicators should be objective and quantified, to the extent possible, and should only be applied to the aspects of food control systems that are regulated and/or assured by the Competent Authority (CA) and/or an officially recognized body. Regulatory performance measures can include public health outcome measures and operational measures.
8. Regulatory performance indicators should demonstrate the effectiveness of the food control system in achieving food safety, food suitability and technical outcomes and could include the following:

¹ Proposed draft principles and guidelines for national food control systems (CCFICS) which is currently under development.

- Evidence that industry is taking primary responsibility for food safety and suitability,
- Evidence of effective and efficient regulatory oversight of the regulated industry
- Measures of the efficiency and effectiveness of verification systems at a premise and national level,
- Robust scientific validation of food control systems at premises e.g. HACCP
- Measures of the accuracy and consistency of export assurance and certification systems
- Level of compliance of exported food and related products, including results from importing country's control programs.
- Timeliness and effectiveness of CA responses to industry non-compliance as revealed by both domestic and foreign audits
- Ability to set public health goals and monitor progress towards achievement²

9. While public health outcome measures are important for overall assessment of a national food control system, other operational measures, both activity and outcome based, may be useful in assessing the exporting country's oversight by measuring day-to-day progress to ensuring safety and suitability of foods, prioritize inspection activities and identify program resource gaps.

10. Operational performance measures demonstrate that inspection activities are being carried out according to established policy. Examples of activity-based performance indicators include:

- Ensuring competencies of inspectors and verifiers e.g. training requirements and frequency of competency assessments
- Monitoring of individual inspector performance at the premises level
- Approval/recognition of food control plans in registered food premises
- Verification of compliance with food control plans and other (specified) regulatory requirements, with documented response by the CA to non-compliance
- Performance-based verification
- Response by the CA to audit of regulatory systems in registered premises
- Accuracy and consistency of export assurance and certification systems
- Trend analysis of results of port-of-entry inspection and follow up as necessary
- Documented response to foreign audit reports
- Monitoring the capability and proficiency of reference laboratories

² Noting that public health goals take different forms and timelines in different countries and control of risks due to specific product/hazard pathways are often prioritized differently e.g. reducing risks from *Campylobacter* in broiler chicken or *E. coli* O157:H7 in beef

11. Public health outcome performance measures help to track how well food facilities are meeting established policies. Examples of outcome-based performance indicators include:

- Establishment of premises and/or national limits for specified hazards in food
 - Percent positive rates from pathogen verification test results within normal variation
- Demonstration of continuous improvement in levels of specified hazards or indicators in particular foods
 - Non-compliance rates are within normal variation and are not repetitive within individual food facilities

12. Evaluation of regulatory performance will be facilitated through the use of databases or other systems (e.g., for routine microbiological, chemical or other hazard testing of products, results of product inspection, and targeting, evaluation or assessments of verification activities). The evaluation of regulatory performance should be designed to assess the performance of the entire system, or sub- component. (e.g., performance of premises, of the competent authority at a regional or national level) , as well as food safety and food suitability abnormalities.

13. 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. 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

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 ability to development regulatory performance indicators and appropriate measures to evaluate its own performance or 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.

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 leverage of food safety capabilities of those involved in ensuring food safety, including the national competent authority having jurisdiction over the producing country's food safety system. Competent authorities of exporting countries must be able to communicate the effectiveness of their existing systems to provide equivalent food safety outcomes which will facilitate trade. Development of regulatory performance indicators and appropriate measures will facilitate the ability to recognize the capability of food control systems.

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 system (systems recognition). 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.

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 with respect to leveraging their documentation of the food import control programs. By providing a means to facilitate the confidence on the food safety controls and approval of food for export, international food trade will also be facilitated.

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.

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 has a relationship with this work as the basic components outlined in this document must be monitored and evaluated to ensure the effectiveness of the food control system

This new work on the use of performance metrics in assessing the capabilities of food safety control systems is linked between this work to identify the elements and characteristics of a food safety control systems and the recognition of these systems as equivalent.

Identification of any requirement for and availability of expert scientific advice

None anticipated.

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 19th (2011) Session of CCFICS agrees to undertake this new work, an initial draft of the document will be prepared for consideration by CCFICS at its 20th Session (likely to be scheduled for 2013). The document would be anticipated to be ready for Step 5 approval following the 21st Session of the Committee (2014) and ready for Step 8 adoption following the 22nd Session of the Committee (2015 or 2016). 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: 2011
Approval by the Commission as New Work: 2012
Adoption by the Commission at Step 5: 2014
Adoption by the Commission at Step 8: 2016

International Dairy Federation (IDF)**PROPOSAL FOR NEW WORK ON CODEX GUIDELINES FOR MANAGING FOOD SAFETY EMERGENCY SITUATIONS IN RELATION TO INTERNATIONAL TRADE**

1. In general, food safety emergency situations originate from the finding of a toxic chemical in food products at unexpectedly high levels, or from an outbreak of a microbiological hazard linked to the consumption of a specific food product.
2. The recent discovery of the presence of large amounts of melamine in milk-based products, the food and feed crisis concerning radioactivity, and the latest outbreak of *Escherichia coli* O104:H4, both resulting in severe adverse health effects and huge economical impact in several countries, are striking examples of food safety emergency situations.
3. Actually, when a food safety emergency situation arises, it is essential to take the appropriate measures to minimize potential adverse public health effects while minimizing also the economical impact.
4. The evaluation of potential health effects must be science based and done in a manner that avoids unwarranted actions against unaffected foods.
5. Amongst the most difficult elements of crisis management in food safety emergency situation is the communication about safety aspects. The handling of such situations generally require a very fast understanding of the potential health risks associated with the consumption of the incriminated products. Reaching a consensus between stakeholders about safety is essential for defining clear action levels (e.g. what levels of the chemical contaminant trigger product recall, or withdrawal) and for ensuring aligned communication.
6. Texts developed by CCFICS include provisions relating to certain aspects of food control systems, certificates and emergency response. Besides, CCFICS has defined a "Food Safety Emergency" as "*a situation whether accidental or intentional, that is identified, by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action*" (CAC/GL 19-1995, Rev. 1 2004)
7. Texts developed by other Codex subsidiary bodies (e.g., Codex Committee on Food Hygiene) provide information on certain control measures (e.g. measures relating to control of microbial pathogens, prevention of chemical/microbiological/physical contamination, food recalls), but no specific guidance to governments and feed/food manufacturers on how to evaluate potential health effects in a science based manner is available.
8. In view of the importance and necessity of a Codex guidance to governments and feed-food manufacturers on the procedure to follow in food emergency situations, and in particular on how to evaluate potential health effects in a science-based manner, IDF would like to propose the elaboration of Codex guidelines for managing food safety emergency situations in relation to international trade either through establishment of a supplementary Codex guidelines, or through a revision of existing *Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995)*, developed by CCFICS.
9. The following Codex documents will have to be taken into consideration for the proposed future work:
 - Principles and Methods for the Risk Assessment of Chemicals in Food, EHC 240 (used by JECFA and JMPR)
 - Guidance for Risk Management Options on How to Deal with the Results from New Risk Assessment Methodologies, currently under development by CCCF
 - Principles and Guidelines for the Conduct of Microbiological Risk Assessment [CAC/GL-30 (1999)]
 - Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) [CAC/GL 63-2007]

- Working Principles for Risk Analysis for Food Safety for Application by Governments [CAC/GL 62-2007]
- Code of Practice on Good Animal Feeding [CAC/RCP 54-2004]

PROJECT DOCUMENT

Codex Guidelines for Managing Food Safety Emergency Situations in relation to International Trade

This project document has been developed according to the Codex Alimentarius Commission Procedural Manual 20th Edition, 2011 Section II, Procedures for the Elaboration of Codex Standards and related texts, part 2. Critical review, proposals to undertake new work or to revise a standard (page 28).

Purpose and Scope of the Standard

The purpose of the proposed new work is to establish guidelines for governments and feed-food manufacturers on the procedure to follow in food emergency situations and in particular on how to manage potential health effects in a science-based manner. This guidance could be included in the Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995) by broadening the scope of the guidelines or through developing a standalone document.

It is proposed that **the scope** of the Codex guidelines addresses all emergency situations resulting from any biological, chemical or physical risk (to consumers) in food or feed (whether domestically produced or from imported product).

Relevance and timeliness

With the globalization of the food market, there is a need to promote consistencies in risk management practices worldwide in emergency situations, as illustrated by the recent Melamine crisis.

This should be done as much as possible in a scientific manner, depending on the availability of data (toxicological, exposure, etc), to prevent unjustified barriers to trade while protecting the health of consumer.

Main aspects to be covered

It is proposed to provide guidance to define the respective role and responsibilities of Governments and stakeholders with a view to a harmonize approach to how competent authorities react based on their risk assessment, information available etc.

In this regard, this guidance should reference existing Codex standards such as MLs for contaminants, particularly useful where a country does not have the capacity to assess risks themselves, and identify gaps to be addressed by other Codex Committees such as CCFH and CCCF.

It is further proposed that the guidelines evaluate how Inter-Governmental Organizations, e.g. FAO/WHO/OIE, could assist in the coordination of crisis situations, where several countries are concerned.

Assessment against the Criteria for establishment of work priorities

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The new work will address the need for providing guidance on the roles and responsibilities of competent authorities, manufactures, importers, distributors etc in controlling the situation.

While many Codex members have well developed national food control systems that include the ability to assess risks, identify food safety incidents which are supported by robust recall systems or food safety action plans, many developing countries do not. Development of specific guidance that defines roles and responsibilities based on risk assessments will provide greater harmonisation of national and international approaches to food safety incidents including better use of existing international guidelines (EMPRES Food Safety) and networks (INFOSAN).

Amongst the most difficult elements of crisis management in food safety emergency situation is the communication about safety aspects. The handling of such situations generally require a very fast understanding of the potential health risks associated with the consumption of the incriminated products. Reaching a consensus between stakeholders about safety is essential for defining clear action levels (e.g. what levels of the contaminant trigger product recall, or withdrawal) and for ensuring aligned communication.

Codex guidance to governments and feed-food manufacturers on the procedure to follow in food emergency situations and in particular on how to evaluate potential health effects in a science-based manner will deliver increased consumer protection and fair practices in the food trade during food safety incident management.

Diversification of national legislations and apparent resultant or potential impediments to international trade.

National and international responses to food safety incidents in general are not harmonized while there is international guidance EMPRES Food Safety, INFOSAN, etc the response is not always proportionate to the risk. It is proposed that the guidance will contribute to strengthening the involvement/role of intergovernmental organizations, e.g. FAO/WHO, in the coordination of food safety emergency situations, where several countries are concerned.

Relevance to the Codex strategic objectives

Goal 1: Promoting sound regulatory frameworks

The result of this work will assist in promoting sound regulatory frameworks in international trade by using scientific knowledge to underpin responses to food safety incidents. This work will provide harmonized regulations for developed and developing countries, leading to enhanced consumer protection and fair trade.

Goal 2: Promoting widest and consistent application of scientific principles and risk analysis

This work will further strengthen the linkages between risk-management options based upon scientific evaluation in the management of food safety incidents.

Goal 4: Promoting cooperation between Codex and relevant international organizations

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of relevant international organisations as well as developed and developing countries to conduct the work.

Information on the relation between the proposal and other existing Codex documents

- The Codex Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995), developed by CCFICS, **focus on communication not on risk management.**

- The 'FAO/WHO framework for developing national food safety emergency response plans (<http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>) issued 2010, **sets up general principles for national food safety emergency plan, but does not provide the required level of details for risk management** .
- Proposed draft Principles and Guidelines for National Food Control Systems (N06-2009) CX/FICS 11/19/3, currently under development by CCFICS **do not specifically address management of food safety emergency situations** but clearly recognise that 'the design and operation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the evaluation and, as necessary, control of food safety risks associated with existing, new or re-emerging hazards. This food safety risk management framework should be based upon internationally agreed standards and guidelines and incorporate the following steps:
 - o preliminary risk activities, including identification and characterisation of the risk and ranking or prioritisation of the risk for risk management consideration;
 - o identification, analysis and selection of possible risk management options;
 - o implementation of the selected risk management option(s); and
 - o monitoring of the outcome or effectiveness of the implemented option(s) and review or revision as appropriate³.'

Identification of any requirement for and availability of expert scientific advice

None identified at present

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

None identified at present

Proposed time-line for completion of the 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 not normally exceed five years

Guidelines to be developed as a standalone document (revision of CAC/GL 19-1995 or establishment of a supplementary Codex guideline).

Subject to approval by the Commission, the proposed Guidelines for Managing Food Safety Emergency Situations in relation to International Trade will be considered by the 20th Session of the CCFICS (2013) with a view to its finalization in 2015 or 2016.

³ Extract from CCFICS proposed draft Principles and Guidelines for National Food Control Systems CX/FICS 11/19/3 paragraph 24