CODEX ALIMENTARIUS COMMISSION





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REP16/FICS

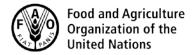
JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Thirty-ninth Session
Rome, Italy
27 June – 01 July 2016

REPORT OF THE TWENTY-SECOND SESSION OF THE
CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Melbourne, Australia
6 - 12 February 2016

NOTE: This report includes Circular Letter CL 2016/3-FICS

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CL 2016/3-FICS

TO: Codex Contact Points

Interested International Organizations

FROM: The Secretariat

Codex Alimentarius Commission

Joint FAO/WHO Food Standards Programme

FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: Distribution of the report of the Twenty-second Session of the Committee on Food

Import and Export Inspection and Certification Systems (REP16/FICS)

The report of the Twenty-second Session of the Committee on Food Import and Export Inspection and Certification Systems (CCFICS) will be considered by the 39th Session of the Codex Alimentarius Commission (Rome, Italy, 27 June - 1 July 2016).

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

Proposed Draft Standards and Related Texts at Steps 5/8 of the Procedure

- 1. Proposed Draft Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food (REP16/FICS para. 26 and Appendix II);
- 2. Proposed Draft Revision of the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) (REP16/FICS para. 45 and Appendix IV); and
- 3. Proposed Draft Revision of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) (REP16/FICS para. 50 and Appendix V).

Proposed Draft Standards at Step 5 of the Procedure

Proposed Draft Guidance For Monitoring the Performance of National Food Control Systems (REP16/FICS para. 33 and Appendix III).

Governments and international organizations wishing to comment on the above documents should do so in writing to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: codex@fao.org) before 31 May 2016.

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SUMMARY AND CONCLUSIONS

The Twenty-Second Session of the Codex Committee on Food Import and Export Inspection and Certification Systems reached the following conclusions:

<u>Matters for Adoption by the 39th Session of the Codex Alimentarius Commission and by the 71st</u> Session of the Executive Committee

The Committee agreed to forward the following texts for adoption at Step 5/8:

- Proposed Draft Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food (REP16/FICS para. 26 and Appendix II);
- Proposed Draft Revision of the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) (REP16/FICS para. 45 and Appendix IV);
- Proposed Draft Revision of the *Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food* (CAC/GL 25-1997) (REP16/FICS para. 50 and Appendix V).

The Committee agreed to forward the following texts for adoption at Step 5:

- Proposed Draft Guidance for Monitoring the Performance of National Food Control Systems (REP16/FICS para. 33 and Appendix III).

Matters Referred to other Committees

The Committee held a discussion on Food Integrity/Food Authenticity as Emerging Issues (see paras 71 and 72) which is also of interest to the Committees on Food Labelling (CCFL) and on Methods of Analysis and Sampling (CCMAS) as well as the CCEXEC71 and CAC39.

Other Matters for Information

The Committee agreed to consider at its next session:

- Discussion Paper On System Comparability/Equivalence (see para. 54);
- Discussion Paper on the Use of Electronic Certificates by Competent Authorities and Migration to Paperless Certification (see paras 58 60);
- Discussion Paper on Third Party Certification (with broad parameters) (see para. 63)
- Discussion Paper on Consideration of Emerging Issues and Future Directions for the Work of the Codex Committee on Food Import and Export Inspection and Certification Systems (see paras 65 67); and
- Discussion Paper on Food Integrity/Food Authenticity as Emerging Issues (see paras 71 and 72).

INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) held its 22nd Session in Melbourne Australia, from 6 to 12 February 2016, at the kind invitation of the Government of Australia. Mr Gregory Read, First Assistant Secretary, Exports Division, Department of Agriculture and Water Resources, Australia, chaired the Session. The Session was attended by 51 Member countries and one Member organization, and 9 international governmental and non-governmental organizations, including FAO and WHO. The list of participants, including the Secretariats, is contained in Appendix I to this report.

Division of Competence¹

2. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD1.

ADOPTION OF THE AGENDA (Agenda Item 1)2

3. The Committee agreed to discuss a proposal from the Islamic Republic of Iran regarding food integrity/authenticity (CRD8) under agenda item 11 and adopted the Provisional Agenda as its agenda for the session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION, OTHER CODEX COMMITTEES (Agenda Item 2)3

- The Committee noted the approval of new work as indicated in document CX/FICS 16/22/2. 4.
- The Committee considered the request from the 70th Session of the Executive Committee, which 5. recommended to all Committees to consider the need to develop an approach for the management of their work similar to that used by the Codex Committee on Food Hygiene. The Committee agreed, in response, that the Delegation of Australia would examine the criteria in the Codex Procedural Manual and practices in other Codex committees, and in the context of updating the Discussion paper on consideration of emerging issues and future directions for the work of the Codex committee on food import and export inspection and certification systems (CX/FICS 16/22/9) develop a prioritisation framework to be used by the Committee in future sessions.

REPORT ON ACTIVITIES OF FAO AND WHO RELEVANT TO THE WORK OF CCFICS (Agenda Item 3a)4

- 6. The Representative of FAO introduced document CX/FICS 16/22/INF/1 on behalf of FAO and WHO. The Representative announced the finalization of the FAO Guidance on risk based imported food controls and updated the Committee on the work conducted on the tool to assess national food control systems which aims to better target priorities for improvement and monitor progress. The second version of the tool was peer reviewed at technical meeting in December 2015 and will be field-tested in a number of countries throughout 2016. Finally, the Representative presented activities related to strengthening the INFOSAN network, which have resulted in a 10% increase in active members in 2015.
- The Representative confirmed that another priority for FAO and WHO is anti-microbial resistance (AMR). Steps 7. taken by FAO and WHO following the adoption of the FAO resolution on AMR and of the AMR global action by the World Health Assembly in 2015 were presented to the committee. The importance of tripartite (FAO, OIE and WHO) collaboration in the area of AMR was underlined.
- The Representative from WHO recalled that all Member States will have to develop core capacities required 8. for implementation of the International Health Regulations (IHR) by June 2016 and that food safety is one of these core capacities.
- He recalled that World Health Day 2015 had been dedicated to food safety and that WHO had released 9. estimates of the global burden of foodborne diseases for the first time in December 2015. These estimates have created momentum for better surveillance and response to food safety events.
- 10. WHO has been promoting INFOSAN networking at country levels which will be crucial to respond to food safety emergencies. Strengthening surveillance and response capacity for food borne diseases has been a priority for core capacity development under IHR implementation.
- 11. The WHO Global Action Plan to combat antimicrobial resistance (AMR) will provide guidance for development of a National Action Plan for AMR in Member States and WHO has been working with FAO, OIE and other partners to develop National Action Plans and technical capacity in Member States.

¹ CRD1

² CX/FICS 16/22/1

³ CX/FICS 16/22/2

⁴ CX/FICS 16/INF/1

REPORT ON ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS RELEVANT TO THE WORK OF CCFICS (Agenda Item 3b)

Information from the World Organisation for Animal Health (OIE) 5

12. The Committee noted the information provided by OIE on activities relevant to its work, as presented in CX/FICS 16/INF/2.

13. The Representative of the OIE also underlined the organization's support for the WHO global plan on AMR and confirmed that work on AMR was a major strategic activity of OIE.

Information from the World Customs Organisation (WCO)

14. Contrary to the provisional agenda, WCO did not participate in the meeting and no information document was distributed.

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION (INCLUDING QUESTIONNAIRES) BETWEEN COUNTRIES TO SUPPORT FOOD IMPORT AND EXPORT (Agenda Item 4)⁶

15. The Chair of the Working Group, New Zealand, presented the paper (CX/FICS 16/22/3).

Discussion

- 16. The Committee recalled that the aim of the guidelines was to reduce the burden on exporting countries in replying to a large number of overly complex and diverse questionnaires required by importing countries. In considering the draft text, the Committee sought to balance providing guidance on when such exchanges were justified and a simplified process of information exchange with the information requirements necessary to establish or maintain trade of foods or groups of foods between two countries.
- 17. The Committee decided to remove the text "(including questionnaires)" from the title of the document, recognizing that while questionnaires are commonly used, there are other ways for exchanging information between countries.
- 18. The Committee decided that the scope of the document was sufficiently broad to include information requests with regards to elements such as organics or halal.
- 19. Several developing countries raised concerns about difficulties for them as importing countries, to provide in writing a detailed description of the relevant components of their National Food Control System (NFCS), as prescribed in para 13 c) of the draft text, as their NFCS were still under development.
- 20. The Committee was reminded that of the need for the importing country's competent authority to describe and justify its import requirements follows from the basic World Trade Organization (WTO) principle stating that no country shall have rules for imports that are in excess of what is applied within the importing country. However, to add a degree of flexibility to the process of information exchange, "to the extent possible" was added to the chapeau sentences of paragraphs 13 and 14 of the draft text.
- 21. Concern was expressed that although the aim of this work was to reduce the burden on exporting countries, questionnaires are still widely used by countries. It would therefore be useful to provide a standard template for questions to allow for swifter analysis, to harmonize the information exchanged, to avoid duplication and repetition and ultimately facilitate the initiation and maintenance of trade. However the Committee agreed not to utilize such a template as it would be difficult to design a single template suitable for all scenarios.
- 22. The Committee amended footnote 1 in order to better capture the notion that information exchange between countries may also concern feed for food producing animals in cases where it could impact food safety and/or fair practice in food trade.
- 23. The Representative of FAO underlined the supportive relationship of the work carried out by FAO and WHO to the current discussion on information exchange. She explained that as part of the revitalization of FAO/WHO Regional Coordinating Committees (RCC), proposals would be presented by both parent organizations and the Codex Secretariat to member countries, during the coming cycle of RCC meetings (2016-17), on a prototype platform allowing countries to exchange the information that they deem relevant.
- 24. The Representative of FAO also mentioned the potential for countries of the FAO/WHO food control system assessment tool under development. She explained that while the information gathered and the resulting

⁵ CX/FICS 16/INF/2

⁶ CX/FICS 16/22/3; CX/FICS 16/22/3 Add 1 (Comments of Brazil, Canada, Chile, Ecuador, El Salvador, Ghana, Indonesia, Japan, Kenya,); CRD10 (Comments of Philippines, United States and Uruguay). CRD12 (Comments of Uganda); CRD13 (Comments of Thailand); CRD14 (Comments of Colombia)

analysis belong to the countries participating in the assessments, they can decide to share it with their trading partners with a view to facilitating commercial exchanges.

Status of the proposed draft *Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food*

25. The Committee agreed to forward the proposed draft *Principles and Guidelines to CAC39 for adoption at* Steps 5/8 (with the omission of steps 6 and 7) (Appendix II).

PROPOSED DRAFT GUIDANCE FOR MONITORING THE PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS (Agenda Item 5)⁷

26. The Chair of the Working Group, the United States of America, introduced the paper (CX/FICS 16/22/4).

Discussion

- 27. The Committee discussed whether the proposed four principles of the performance monitoring framework sufficiently covered all aspects that should be addressed when designing a framework. The demand for quality and reliability of data used for monitoring was added to the third principle, now called "Efficiency and Reliability", and text covering practicability and affordability was also added.
- 28. Additional principles were proposed (continuous improvement, organizational commitment) however, the Committee did not add them as they were more generally related to the monitoring of an NFCS rather than to the more specific requirements of performance monitoring.
- 29. While the figure and table of the Appendices were seen as helpful, it was agreed that the document would benefit from explanatory text underscoring that the simplified framework and its listed indicators were to be seen only as illustrative examples including the addition of qualitative indictors.
- 30. Further to the requests of a number of countries for technical support to implement this guidance on monitoring performance, the Representative of FAO indicated that the FAO/WHO food control system assessment tool analyses monitoring performance capacities as part of its "continuous improvement" dimension. Implementing a national food control system assessment using the FAO/WHO tool would help countries building their capacities by identifying gaps or weaknesses in that and other areas. In addition, or alternatively, FAO could discuss with interested countries the content of specific technical assistance to support development of performance monitoring frameworks for continuous improvement, in a comprehensive, targeted or phased approach, as appropriate to the needs of the country. This would include support to identify relevant indicators.

Conclusion

31. The Committee:

- Noted that the draft Appendix B (Additional Resources) contained several web references, which would require continuous updating, that it would therefore not be prudent to leave it as a part of the final text, and that the text of the Appendix would be published as a separate information document related to the guidance.
- Noted that some delegations needed to further consult at the national level on the text of the document and that therefore they preferred to undertake another round of comments and discussions (steps 6 and 7) instead of attempting adoption at step 5/8.
- Acknowledged the request made to FAO/WHO for assistance in the form of training in order to implement the guidance for monitoring the performance of an NFCS.
- Recognized the possible need to develop additional text for inclusion in the guidance regarding how to apply the performance monitoring framework using phased or targeted approaches.

Status of the proposed draft *Guidance for Monitoring the Performance of National Food Control Systems*

32. The Committee agreed to forward the proposed draft *Guidance to CAC39 for adoption at* Step 5 (Appendix III).

⁷ CX/FICS 16/22/4; CX/FICS 16/22/4 Add. 1; (Comments of Brazil, Chile, Ecuador, El Salvador, Ghana, Indonesia, Japan, Kenya, Mexico, Thailand and NFS International) CRD9 (Comments the European Union and its Member States (EUMS), New Zealand, Papua New Guinea, Philippines and Uruguay); CRD12 (Comments of Uganda).

PROPOSED DRAFT REVISION OF THE PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS (CAC/GL 19-1995) (Agenda Item 6)⁸

33. The Chair of the WG, the European Union, introduced the paper (CX/FICS 16/22/5).

Discussion

34. The Representative of WHO, also speaking on behalf of FAO, noted that appropriate references had been made in the document to FAO/WHO's International Food Safety Authority Network (INFOSAN); FAO Emergency Prevention Systems (EMPRES Food Safety); and WHO's International Health Regulations (IHR, 2005). He expressed appreciation for statements from Member States and Member Organizations in support of INFOSAN for transparent and real time reporting of food safety events in line with requirements of IHR.

- 35. The text concerning food safety emergency plans was amended to highlight the accountability of various parties in the exchange of information in a food safety emergency, stating that the responsibilities of all parties involved in an emergency situation should be established in the plan.
- 36. The Committee noted the need to keep the text closely aligned with the *Working Principles for Risk analysis for Food Safety for Application by Governments* (CAC/GL 62-2007).
- 37. The Representative from WHO, also speaking on behalf of FAO, was of the opinion that the primary official contact point should be either the INFOSAN Emergency Contact Point and/or the National IHR Focal Point as there was already a functional system of communication in place in line with existing international agreements for implementation of the IHR. He noted further that FAO and WHO have been supporting Member States in strengthening functional INFOSAN networking systems at country and regional levels and advocating better communication between INFOSAN Emergency Contact Points and National IHR Focal Points. He recalled the FAO/WHO framework for development of National Food Safety Emergency Response plans and confirmed that both organizations would be providing technical support to develop such plans considering country specific situations.
- 38. The Representative of WHO, in addition, noted that WHO would be supporting strengthening of foodborne disease surveillance through self-assessment questionnaires and national workshops to determine a national action plan for prioritization of foodborne diseases for surveillance and reporting. He informed the Committee that WHO Regional Offices have conducted and will continue to organize simulation exercises at regional level to test the functional aspect of INFOSAN and IHR communication.
- 39. Some delegations supported the view that the INFOSAN Emergency Contact Point of a country would typically be the designated primary official contact point for food safety emergencies, and that this should be clearly stated. Other delegations argued that this was not always the case. The Committee agreed on a text stating that information regarding the primary official contact points should be provided to INFOSAN.
- 40. The need for food business operators to provide practical and timely information on tracking and tracing their foods in emergency situations and through complex networks was underlined and new text stressing the value of having records that are searchable and that can be transmitted electronically was added.
- 41. The Representative from WHO speaking on behalf of FAO and WHO noted that both alternative annexes contained essentially the same information. However the original annex went into greater detail and the more concise Alternative Annex was the preferred option to align the necessary information with INFOSAN requirements. He stated that in emergency situations there was a need for rapidly available clear and concise information. Through its network the INFOSAN Secretariat can acquire any further information needed from the INFOSAN Emergency Contact Points and alert all affected countries to respond to the food safety emergency.
- 42. The Committee decided to retain the current longer format for information exchange, despite delegations acknowledging that having such a long list of information to gather might delay competent authorities from sharing important information as it became available. To prevent any unnecessary delays arising from this longer format, text was added stating that the initial information exchange should occur as fast as possible, even if it is not complete, and that further information can be exchanged as soon as it becomes available. New text was also added indicating that the list in the Annex of suggested information to provide in food safety emergencies was not exhaustive.

⁸ CX/FICS 16/22/5; CX/FICS 16/22/5 Add 1 (Comments of Brazil, Chile, Ecuador, Ghana, Indonesia, Japan, Thailand and the International Dairy Federation); CRD3 (Comments from European Union and its Member States (EUMS), El Salvador, Kenya, Mexico, New Zealand, Philippines and Uruguay); CRD12 (Comments from Uganda); CRD 14 (Comments from Colombia).

Status of the proposed draft revision of the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995*).

43. The Committee agreed to forward the proposed draft revised *Principles and Guidelines to CAC39 for adoption at* Step 5/8 (with the omission of steps 6 and 7) (Appendix IV).

PROPOSED DRAFT REVISION OF THE GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD (CAC/GL 25-1997) (Agenda item 7)⁹

44. The Chair of the Working Group, Australia, introduced the paper (<u>CX/FICS 16/22/6</u>) and stated that the revision of the guidelines had focused on adding appropriate references to animal feed and on improving the logical flow of the text, so as to make it more user-friendly.

Discussion

- 45. Some delegations proposed adding text on suitable actions to decrease the number of rejections to the introduction of the guidelines. The Committee however noted that such measures were dealt with in 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 Food Import Control Systems* (CAC/GL 47-2003) and should therefore not be duplicated. These proposed revised guidelines describe a logical thought process to guide the parties involved in a rejection situation towards a transparent exchange of information. They deal explicitly with what information should be exchanged when foods have been rejected, not the more general aspects of rejections.
- 46. Broad discussions took place around the issue of appeals (para 13 of the proposed draft revised Guidelines). The Committee noted that the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) extensively covered the issue of appeals and Members expressed many opinions both in favour of maintaining and of excluding this section of the proposed revision. It was eventually decided to exclude para 13 from the draft revised Guidelines, as well as the section referring to appeals in Annex 1.
- 47. The Delegation of Nigeria proposed that the Committee develop a separate guideline on an appeals mechanism and the Committee agreed to include this request in agenda item 10¹⁰.

Status of the proposed draft revision of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997)

48. The Committee agreed to forward the proposed revised *Guidelines to CAC39 for adoption at* Step 5/8 (with the omission of steps 6 and 7) (Appendix V).

DISCUSSION PAPER ON SYSTEM COMPARABILITY/EQUIVALENCE (Agenda Item 8)11

49. The Delegation of New Zealand introduced the discussion paper (<u>CX/FICS 16/22/7</u>) and a project document (<u>CRD11</u>) on the possible development of guidance on the use of systems equivalence/comparability.

Discussion

- 50. The Committee noted that while systems equivalence was a complex topic, it was important to expand the suite of tools that recognized the ability of a competent authority to provide assurances regarding the safety of food. This work would represent the next stage of evolution of existing CCFICS texts on equivalence. With regards to the scope of the document, the following suggestions were made:
 - To improve the consistency of the paper, the text should clearly distinguish between equivalence for a set of measures versus equivalence on a system wide basis.
 - There should be a thorough discussion involving both developing and developed countries on: the reasons for new guidance, the gaps to be filled to identify the problems that require solutions, and the benefits of additional guidance.
 - The Committee should attain a better understanding of some of the issues of the previous CCFICS work
 that attempted to cover technical barriers to trade in the context of equivalence as this could inform the
 Committee's thinking and ensure that past difficulties were avoided.

⁹ CX/FICS 16/22/6; CX/FICS 16/22/6 Add 1 (Comments of Brazil, Chile, Ecuador, Ghana, Indonesia, Japan, Mexico, Thailand and the United States); CRD 4 (Comments from El Salvador, Kenya, Philippines, Uruguay); CRD 12 (Comments of Uganda); CRD 14 (Comments of Colombia).

¹⁰ CX/FICS 16/22/9; Discussion paper on consideration of emerging issues and future directions for the work of the Codex Committee on Food Import and Export Inspection and Certification

¹¹ <u>CX/FICS 16/22/7</u>; <u>CRD5</u> (Comments from Kenya, Philippines, Thailand); <u>CRD11</u> (Project document for new work to develop guidance on the use of systems equivalence/comparability prepared by New Zealand)

51. The Committee noted that the development of guidance in this area of system equivalence should address the dual mandate of Codex, the term equivalence should be used instead of "comparability", and this work will assist trade facilitation.

Conclusion

52. The Committee considered it necessary to further refine the scope, prerequisites and procedures of the discussion paper and project document. The Committee agreed to establish an electronic Working Group (not precluding a physical Working Group prior to the next Committee meeting), lead by New Zealand with the United States of America and Chile acting as co-chairs, working in English and Spanish and open to all Codex members and observers, to revise the discussion paper and the project document taking into account the above discussion. Chile offered to facilitate the Spanish translations.

DISCUSSION PAPER ON THE USE OF ELECTRONIC CERTIFICATES BY COMPETENT AUTHORITIES AND MIGRATION TO PAPERLESS CERTIFICATION (Agenda Item 9)¹²

53. The Delegation of the Netherlands presented the discussion paper (CX/FICS 16/22/8) recalling that the 21st CCFICS had agreed to consider a discussion paper, to be prepared by the Netherlands, on the development of guidance on the use of electronic certificates by competent authorities and migration to paperless certification.

Discussion

- 54. The Committee discussed the paper in detail and gave it wide support, noting the following (not in ranking order):
 - a) The need for paper certificates will only disappear when certificate accepting countries find electronic certification sufficiently reliable during import procedures so that the paper form becomes redundant
 - b) International guidance should help to broaden participation, promote consistency and simplify the process for countries developing electronic certification solutions
 - c) Transitioning to paperless certification requires the commitment of governments
 - d) To date there are a number of concepts of electronic certification solutions and a number of formats and forms of electronic certificates that can be exchanged. For the benefit of the Committee, these should be described in detail in any forthcoming project document
 - e) Electronic certification information provided enhanced security to that of the issued paper certificates
 - f) Experiences from countries that are already using electronic certificates should be examined and described to the benefit of countries with lesser experience
 - g) Experiences of IPPC and OIE should be taken into consideration when developing a discussion paper
 - h) Transitioning to electronic certification is much more than simply replacing the existing paper certificate by an electronic version.
 - i) Drafting international guidance for this purpose is a complex, sensitive and challenging process because it constitutes a paradigm shift requiring the courage to leave the familiar paper path
 - j) Key areas identified for possible guidance are:
 - I. The need to develop a definition of electronic certificates
 - II. The use of defined data elements
 - III. Aid to determine a suitable concept of electronic certification solution
 - IV. The need to protect authenticity and integrity of exchanged certificates
 - V. Existing international standards and recommendations
 - VI. Different circumstances of Codex members
- 55. The Representative of FAO informed the Committee of the recent discussions in the Standard and Trade Development Facility (STDF)/WTO working group on the topic of e-certification. FAO has commissioned a report to gather information and form the basis for further reflection regarding actual use, good practices, and requirements related to e-certification. FAO would be interested in participating in the eWG and share analysis and findings stemming from the report.

¹² CX/FICS 16/22/8; CRD6 (Comments from Kenya and the Philippines)

Conclusion

56. The Committee considered that further discussion was needed before sending a project document to the Commission for approval.

- 57. The Committee agreed to establish an electronic Working Group (not precluding a physical Working Group prior to the next Committee meeting), chaired by the Netherlands and co-chaired by Australia (who would also provide the Spanish translations), working in English and Spanish and open to all Codex members and observers, to revise the discussion paper and prepare a project document. This work should take into account the above discussion and in particular perform a gap analysis with current Codex texts, and a technology review on this topic as well as explore resource requirements for procedural concepts of paperless electronic certification.
- 58. The Secretariat suggested using the pilot electronic platform for eWGs (which would be set up by the Codex Secretariat for this working group) and also to specifically invite the participation of OIE, IPPC and UN/CEFACT in relation to international standards and recommendations.

DISCUSSION PAPER ON CONSIDERATION OF EMERGING ISSUES AND FUTURE DIRECTIONS FOR THE WORK OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS (Agenda Item 10)¹³

59. The Delegation of the European Union presented the discussion paper (CX/FICS 16/22/9), informing the Committee of its update and in particular the information in para 23 regarding potential future work of the CCFICS, while recognising that some of the areas proposed for consideration had already been taken up during the current meeting. The delegation recommended that the Committee should continue to keep this document up to date and in particular reflect on the work it has done so far, existing gaps, new areas where guidance is needed and mechanisms for prioritisation of work.

Discussion

- 60. The Delegation of Canada noted that third party certification could play an important role in informing risk-based planning for competent authorities and expressed interest in developing a paper on this. The Delegation of the United Kingdom offered its support to collaborate on this proposal.
- 61. The Committee noted the importance of establishing the level at which it should consider the items listed in the section entitled *Forward-looking: potential work of CCFICS* (para 23) of the discussion paper. In any analysis it would be necessary to consider how the area of work filled a gap in the current CCFICS suite of texts or provided clarity to them; whether the work was new work or revision; and the possible impact on CCFICS members.
- 62. The Codex Secretariat agreed to include the introductory and background sections of the document on the CCFICS page on the Codex website so that these can be deleted from the paper.

Conclusion

- 63. The Committee agreed that the Delegation of Canada, with support from the Delegation of the UK, would prepare a discussion paper on third party certification (with broad parameters).
- 64. The Committee welcomed the offer of the Delegation of Australia to take over work on this agenda item and thanked the European Union for their work on the paper during the previous year.
- 65. The Committee also agreed that the Delegation of Australia would:
 - Develop a framework for the preliminary assessment and identification of priority areas that the Committee may need to work on in the future, as referenced in para 3(v) of the paper
 - Identify issues from the possible areas for new work described in para 23 and then match them against
 the criteria to be developed for prioritization (see also Agenda Item 2). Issues to be considered should
 include further guidance on an appeals mechanism in the context of rejections as requested by the
 Delegation of Nigeria (proposed under Agenda item 7) and the issue of food integrity/authenticity as
 presented by the Delegation of the Islamic Republic of Iran (CRD8)
 - Consider the work of the World Customs Organization and the WTO Trade Facilitation Agreement (TFA)
 when developing guidance relating to the interaction between food control authorities and customs/border
 control agencies (para 23e).

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¹³ CX/FICS 16/22/9

OTHER BUSINESS AND FUTURE WORK (Agenda Item 11)

PROPOSED NEW CODEX WORK ON FOOD INTEGRITY/FOOD AUTHENTICITY AS EMERGING ISSUES

66. The Delegation of the Islamic Republic of Iran introduced the paper (<u>CRD 8</u>). He described how increasingly difficult it is for consumers to assess the authenticity of food today, and that with the rise of food fraud there is a need for developing methodologies and possibly Codex guidelines to help authorities address this matter.

Discussion

- 67. The Committee discussed the matter and noted that the issue of food integrity/authenticity was a very difficult problem to tackle, but which nevertheless may require more attention from Codex. Many delegations expressed their support for new work to be carried out in this area, as they had experienced various forms of food fraud, where the analytical methods for detection of the fraud by food authorities were either missing or not widely available.
- 68. Aside from the more technical aspects of the issue, the Committee also recognized the need for an analysis of CCFICS texts to see whether there were any gaps in the ways food integrity/authenticity was covered in them.

Conclusion

- 69. The Committee invited the Islamic Republic of Iran to develop a discussion paper on this topic, with assistance from the Netherlands and Canada. The paper could identify, where possible, new work in the area of food integrity and authenticity could relate to (and possibly supplement) current CCFICS texts. The Australian secretariat could provide assistance in regard to process and procedure.
- 70. The Committee agreed to seek guidance from CCFL on issues relating to labelling, CCMAS on issues regarding methods of analysis and sampling in relation to food integrity/authenticity, and from CAC to verify if this issue would be covered by the mandate of CCFICS.

DATE AND PLACE OF NEXT SESSION (Agenda Item 12)

71. The Committee noted that its 23rd Session was scheduled in approximately twelve to eighteen months subject to further discussion between the Codex and Australian Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in REP16/FICS
Proposed Draft Principles and Guidelines for the Exchange of Information Between Importing and Exporting Countries to Support the Trade in Food	5/8	Governments CAC39	Para. 25 and Appendix II
Proposed Draft Revision of the <i>Principles and</i> Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995)	5/8	Governments CAC39	Para. 43 and Appendix IV
Proposed Draft Revision of the Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997)	5/8	Governments CAC39	Para. 48 and Appendix V
Proposed Draft Guidance For Monitoring the Performance of National Food Control Systems	5	Governments CAC39 CCFICS23	Para. 32 and Appendix III
Discussion Paper On System Comparability/Equivalence	-	Electronic Working Group (New Zealand, United States of America and Chile) CCFICS23	Para. 52
Discussion Paper on the Use of Electronic Certificates by Competent Authorities and Migration to Paperless Certification	-	Electronic Working Group (Netherlands and Australia) CCFICS23	Paras 56 – 58
Discussion Paper on Third Party Certification (with broad parameters)	-	CCFICS23 (Canada and the United Kingdom)	Para. 63
Discussion Paper on Consideration of Emerging Issues and Future Directions for the Work of the Codex Committee on Food Import and Export Inspection and Certification Systems	-	CCFICS23 (Australia)	Paras 64 - 65
Discussion Paper on Food Integrity/Food Authenticity As Emerging Issues	-	CCFICS23 (Islamic Republic of Iran, the Netherlands and Canada)	Paras 69 and 70

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APPENDIX II

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN IMPORTING AND EXPORTING COUNTRIES TO SUPPORT THE TRADE IN FOOD¹

(N01-2015)

(at Step 5/8)

Section 1 - Introduction

- 1. Most trade in food occurs without countries requiring an exchange of information on their National Food Control System (NFCS)². However, under some circumstances, importing countries may require an exchange of information for the initiation or maintenance of trade in food.
- 2. These guidelines are not intended to mandate such exchange of information as a necessary prerequisite for trade occurring between countries.
- 3. The exchange of information and associated assessments may be required where the risks associated with the traded commodity are high, whether they relate to food safety or fair practices in the food trade, and the necessary assurances cannot be gained by other mechanisms.
- 4. The use of Codex guidance by importing and exporting countries alike should help facilitate any necessary assessment of the relevant component(s) of the NFCS.

Codex texts of particular relevance for example include:

- Principles and guidelines for national food control systems (CAC/GL 82-2013);
- Guidelines for Food Import Control Systems (CAC/GL 47-2003);
- Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995);
- Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC/GL 53-2003); and
- General Principles of Food Hygiene (CAC/RCP1-1969).
- 5. These guidelines may also be useful in clarifying the information exchange requirements of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997) specifically paragraphs 55-57 of Section 9 Assessment and verification of inspection and certification systems.

Section 2 - Objectives

- 6. Provide guidance to assist the competent authority of the importing and exporting countries to identify when the exchange of information may be necessary and what information is essential for the assessment of the relevant component(s) of the NFCS.
- 7. Provide guidance to simplify and harmonize the information and the process of the exchange between the competent authorities of the importing and exporting countries.

Section 3 - Scope

8. These guidelines address situations where information exchange may be required between the competent authority of the importing and exporting country for the assessment of relevant component(s) of an exporting country's NFCS that may cover a product or group of products prior to the initiation or maintenance of trade.

Section 4 - Exchange of information and assessment

9. Information exchange is justified when the risks posed by the specific food product or group of products to food safety or fair practices in the food trade are such that an assessment of whether the

¹ These guidelines also apply to feed for food producing animals in cases where it could impact food safety and or fair practice in food trade.

² Official inspection and certification systems may be considered a part of a national food control system given today's global market (refer to the last sentence of paragraph 2, CAC/GL 82-2013). The "relevant component(s)" of a NFCS or a country's official inspection and certification system should clearly relate to the food being exported.

relevant component(s) of the NFCS of the exporting country is appropriately managing the risks, is required and the assurance is not able to be attained by other means.

- 10. The competent authorities of the importing and exporting countries, in the process of exchanging information and the associated assessment of the relevant component(s) of a NFCS, should:
 - a) not impose an outcome, a standard or a process in excess of what is being applied within the importing country without justification;
 - b) recognize that the relevant component(s) of NFCS may be designed and structured differently while still meeting the same objectives or outcomes;
 - c) recognize the official controls, assessments and approval mechanisms already in place in the exporting country;
 - d) focus on the relevant component(s) of the NFCS in place in the exporting country as they relate to the outcomes; and
 - e) involve only the level of detailed information that is essential to gain the necessary assurances with regard to food safety and fair practices in food trade as opposed to routinely requiring detailed information on specific food business operators.³
 - f) recognize previous information exchanges and assessments for the purposes of maintaining trade and not routinely require re-assessments without justification

Section 5 - Principles

- 11. The following principles should apply to the exchange of information and/or the associated assessment process:
 - a) Be between the relevant competent authorities of the exporting and importing countries.
 - b) Be appropriately transparent, structured, focused, interactive and timely.
 - c) Be in English or a language mutually agreed between the importing and exporting countries.
 - d) In addition to other means, allow for and promote electronic transmission, including the ability to appropriately reference information already supplied or that may be readily available online.
 - e) Recognize existing experience, knowledge and confidence ⁴ already gained or possible to extrapolate from assessments by other countries or international organizations.
 - f) Not require the submission of commercially sensitive information for specific food business operators unless essential to assess the public health objective, in which cases, it should be protected from inappropriate use or disclosure to other parties.

Section 6 - Process

- 12. Where the necessity of exchanges of information and assessments has been established, in accordance with paragraph 9 above, the competent authorities of the importing and exporting countries should seek to observe the following processes.
- 13. The importing country should, to the extent possible:
 - a) Clearly outline the information required, why it is required, and the process and methodology to be followed, including timelines.
 - b) On request, make itself available to discuss what information may already be available from previous exchanges, publications or existing knowledge, confidence or experience and what further information may be necessary from the exporting country to fill information gaps.
 - c) Provide in writing a clear description, with appropriate references, containing the objectives, core elements and key operational performance characteristics of the relevant component(s) of its own

³ For the purposes of this document, food business operators include producers, processors, wholesalers, distributers, importers, exporters and retailers.

⁴ Experience, knowledge and confidence in an exporting country's food inspection and certification system by an importing country includes the history of food trade between two countries and the history of compliance of foods with the importing country's requirements, particularly the food products involved. Further examples that may inform the importing country's experience, knowledge and confidence are listed in paragraph 10 points (a) to (n) in the annex to CAC/GL 53-2003.

- NFCS, to assist the exporting country to understand and respond to the importing country's information requests.
- d) As far as practical, and especially where consistent with the relevant Codex guidance, allow exporting countries to describe the relevant component(s) of the NFCS that is in place in their country and how it meets the objectives and outcomes required by the importing country.
- e) Focus its information exchange request and assessment on whether the relevant component(s) of the exporting country's NFCS achieve(s) the objectives and outcomes as required and achieved by the importing country's system.
- f) Engage with the exporting country where additional information or clarity is needed so as to ensure any assessment process can be concluded in a timely manner.
- g) Focus any requests for information, for the purpose of updating assessments relating to existing trade, on only those importing country requirements or the relevant component(s) of the exporting country's NFCS which have changed.
- 14. The exporting country should, to the extent possible:
 - a) Describe the relevant component(s) of its NFCS that meet(s) the objectives and outcomes required by the importing country.
 - b) Describe the relevant component(s) of its NFCS consistently with existing Codex guidance.
 - c) Engage with the importing country where additional information or clarity is needed to ensure any assessment process can be concluded in a timely manner.
 - d) Ensure the importing country is notified of any relevant changes to the relevant component(s) of its NFCS.

Section 7 - Information exchange content

15. To facilitate the possible provision of information to multiple importing countries, exporting countries may develop standardised responses to describe the relevant components of their NFCS in so far as they relate to food safety and/or fair practices in the food trade.

Possible standard responses include:

- a) Legislative or administrative framework;
- b) Competent authority capability, resourcing and organizational design;
- c) Roles and responsibilities of all relevant parties;
- d) How the independence and credibility of the competent authority responsible for certification is maintained;
- e) Relevant administrative policies and procedures;
- f) Official controls and standards;
- g) Verification programmes;
- h) Enforcement and compliance programmes;
- i) Laboratory capacity and capability;
- j) Emergency preparedness and response and recall systems;
- k) Training and competency assessment requirements;
- Monitoring and system review;
- m) Criteria for registering and approving specific food business operators, including where such lists may be available.
- 16. Importing countries should exercise flexibility with respect to the format of information received from exporting countries; focus on whether the content of the submissions provides necessary assurances, and only request additional information in response to gaps or risks not addressed.

Appendix III

PROPOSED DRAFT GUIDANCE FOR MONITORING THE PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS

(N02-2015)

(at Step 5)

SECTION 1 INTRODUCTION

- An effective national food control system (NFCS) is essential for ensuring the safety and suitability of food for consumers and ensuring fair practices. An effective NFCS may employ different approaches, core elements, and components, as appropriate to the national circumstances, and as described in the Codex *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013).
- 2. The policy setting, design, implementation and other technical components of the NFCS should operate effectively over the course of time, and have the capacity and capability to undergo continuous improvement. As scientific and technical advances occur, it is important that the NFCS demonstrates its ability to adapt.
- 3. The monitoring and system review function of the NFCS calls on the competent authority¹ to regularly assess the effectiveness and appropriateness of the NFCS in achieving its objectives of protecting the health of consumers and ensuring fair practices in the food trade.² The evidence generated through monitoring and system review informs the policy setting, system design, and implementation functions of the NFCS.
- 4. This document presents a performance monitoring framework to support the monitoring and system review function of the NFCS as described in section 4.4 of CAC/GL 82-2013. The guidance is not intended to be used as a basis for comparing systems or imposing barriers to trade.
- 5. Many strategies for performance monitoring exist, but there is no guidance specific to performance monitoring for an NFCS. This document seeks to fill this gap.
- 6. Other assessment tools, like the FAO/WHO food control system assessment tool, can be used in conjunction with performance monitoring to provide a comprehensive view of the NFCS.

SECTION 2 PURPOSE OF GUIDANCE

- 7. This document describes a logical framework of planning, monitoring, and system review steps for performance monitoring of an NFCS and establishes a common understanding of performance monitoring principles, terminology, and best practices.
- 8. The guidance is intended to support self-assessment of countries NFCS.
- 9. This guidance focuses on planning steps within the performance monitoring framework that establish a foundation for assessing the effectiveness of the NFCS and for facilitating continuous improvement as appropriate.
- 10. A competent authority can use this framework to implement monitoring and system review, or incorporate this approach to make existing processes more robust.

SECTION 3 DEFINITIONS³

Activity: Actions taken or work performed through which inputs are mobilized to produce specific outputs.

Assessment: A process of determining the presence or absence of a certain condition or component, or the degree to which a condition is fulfilled.

Effectiveness: The extent to which NFCS objectives or related outcomes were achieved, or, are expected to be achieved, taking into account their relative importance.

Indicator: Quantitative variable or qualitative factor that provides a simple and reliable means to measure achievement, to reflect the changes connected to activities, or to help assess the performance of a program or system.

 $^{^{\}rm 1}$ Throughout the document "competent authority" refers to one or more competent authorities.

² Throughout this document, the term "Objectives" refers to the NFCS Objectives *Principles and Guidelines for National Food Control Systems* (CAC/GL 82-2013).

³ Most definitions were adapted from OECD. 2002. "Glossary of Key Terms in Evaluation and Results-Based Management." Paris: OECD/DAC.

Inputs: The financial, human, technical and material resources used for activities.

Outcome: Intended effects or results that contribute to achieving the NFCS Objectives. Outcomes may be categorized at different levels, such as ultimate, high-level, intermediate, preliminary, or initial.

Outputs: The products and services which result from activities; may also include changes resulting from activities which are relevant to the achievement of outcomes.

Performance monitoring: A continuous or ongoing process of collecting and analyzing data to compare how well the stated objectives and outcomes of the NFCS are achieved.

SECTION 4 PRINCIPLES OF THE PERFORMANCE MONITORING FRAMEWORK

- 11. In a comprehensive approach, a competent authority would monitor its performance across all components of the NFCS. However, depending on the priorities and capabilities of the competent authority, it may be more practical and affordable to apply the performance monitoring framework in a phased or targeted approach. A targeted approach is application of performance monitoring to specific programs or components of the NFCS. A phased approach is a gradual expansion of the performance monitoring framework as capacity within a country grows.
- 12. Regardless of whether it is used in a comprehensive, phased, or targeted approach, the performance monitoring framework is characterized by the following principles:

Principle 1 Relevancy

13. It is customized to the unique needs and structure of the NFCS, and uses information collected from within and outside the system to identify gaps, optimize operations, and promote continuous improvement.

Principle 2 Transparency

14. It is open to consultation and review by relevant national stakeholders during multiple stages of the process, while respecting legal requirements to protect confidential information as appropriate.

Principle 3 Efficiency and Reliability

15. It should operate within its current capacity to remain practicable and affordable. It builds on existing data collection and program management and utilizes appropriate external data sources to assess the performance of its NFCS. Attention should be given to the quality and reliability of the data.

Principle 4 Responsiveness

16. It is adaptive to changes to the NFCS and the environment in which it operates and accommodates revisions to both the outcomes sought, associated activities, and the indicators applied.

SECTION 5 PERFORMANCE MONITORING FRAMEWORK FOR AN NFCS

- 17. Countries should have established an NFCS or components of an NFCS prior to using this framework.
- 18. The performance monitoring framework presents a cyclical process (refer fig 1) that includes three broad tasks: planning, monitoring, and system review. Performance monitoring is an on-going process, where each step feeds into the next step in the cycle and will be revisited over time.
 - Through the planning steps, the competent authority identifies specific and related outcomes through which the NFCS contributes to its objectives and identifies indicators that can measure progress toward the outcomes. The planning steps establish a foundation for monitoring and system review.
 - Through the monitoring steps, the competent authority collects data and generates the information necessary.
 - Through the system review steps, the competent authority uses information generated through the
 monitoring steps to assess the effectiveness and appropriateness of the NFCS. This can confirm
 that the relevant component(s) are operating as intended, and facilitate continuous improvement as
 necessary.

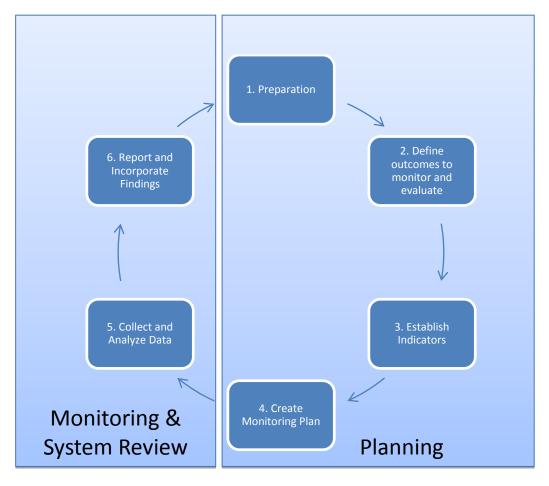


Figure 1: Performance Monitoring Framework

SECTION 5.1 PLANNING STEPS

- 19. The planning steps are arranged in logical order, in which a preceding step supports or enables the next step. For example, it is necessary to identify the intended outcomes (step 2) before identifying indicators to measure progress toward those outcomes (step 3).
- 20. Upon completion of these steps, the competent authority will have clearly defined the specific outcomes that the NFCS is designed to achieve and developed a plan for monitoring progress towards achieving these outcomes.

Step 1: Preparation

- 21. Effective performance monitoring requires organisational commitment, established processes, and sufficient resources and technical capacity. The first step of the performance monitoring framework is to conduct a assessment to determine the competent authority's current capacity for monitoring and system review. The following paragraphs may assist the competent authority in assessing their readiness to design and implement a performance monitoring framework.
- 22. Organizational commitment is essential for ensuring that monitoring and system review are prioritized and resourced as an integral component of the NFCS. The following questions can help the competent authority to assess the level of organizational commitment to monitoring and system review:
 - What are the legislative or policy objectives of the NFCS and how does the competent authority support those objectives?
 - How does the competent authority intend to support performance monitoring at various levels of the NFCS?
 - How does the competent authority intend to use performance monitoring data (e.g. to assess the
 effectiveness of the NFCS and take preventive or corrective action or improve the system as
 appropriate)?

- 23. Established processes for data collection and program management can be used for monitoring and system review. The following questions can help the competent authority to assess established processes that support monitoring and system review:
 - What types of data are currently being collected?
 - How is the data used (i.e. what types of information is being generated and for what purpose)?
 - What are the existing processes for data collection and analysis?
 - What are the existing processes for ensuring data quality?
 - What are the existing processes for reporting data on results or progress toward goals or objectives?
 - How is data currently being used to assess the effectiveness of different programs or components?
- 24. Monitoring and system review requires sufficient financial and human resources with relevant expertise to support the collection and use of data. The following questions can help the competent authority to assess existing resources and technical capacity:
 - What resources (financial, human, technical and material) are available to support monitoring and system review? How can existing resources be leveraged if necessary?
 - Does the competent authority have access to individuals with expertise in strategic planning, performance management, program management, analysis, and data management?
- 25. If the competent authority lacks sufficient capacity or resources to monitor performance of the entire NFCS, the competent authority may implement monitoring and system review in a phased or targeted approach, beginning with a limited number of priority components. The competent authority may use CAC/GL 82-2013 in conjunction with national goals to identify priority components for a phased or targeted approach.
- 26. If the competent authority decides to implement monitoring and system review in a phased or targeted approach, the competent authority should consider steps to address these challenges to enable comprehensive performance monitoring at a later date.
 - If there is insufficient human resource capacity, the competent authority should develop a plan to develop capacity where necessary, setting the shortest possible deadlines for completion.
 - If there are insufficient financial resources available, the competent authority should seek out additional funding from national or international sources, setting the shortest possible deadlines for completion.
- 27. On a regular basis, the competent authority should revisit the above assessment. As capacity for monitoring and system review improves, or becomes available, the competent authority may consider a more comprehensive approach.

Step 2: Define Outcomes to Monitor and Evaluate

- 28. Monitoring and system review should go beyond measuring the outputs of activities and focus on measuring intended effects or outcomes. Outcomes capture what has to be achieved for success, as opposed to what processes or steps need to be completed. By defining and monitoring outcomes, a competent authority can make more informed decisions and better target its programs and resources to achieve the objectives it is seeking.
- 29. In addition to capturing what is to be achieved, outcomes should follow SMART criteria.
 - Specific: What exactly is going to be achieved?
 - Measurable: Can the outcome be measured through qualitative or quantitative indicators?
 - Attainable: Is the outcome in line with the competent authority's competencies and authorities?
 - Relevant: Will achieving an outcome contribute to achieving the NFCS Objectives?
 - Time-bound: Can a timescale be defined for achieving the outcome?
- 30. The competent authority should engage relevant stakeholders in a participatory process for the identification and general understanding of the outcomes to be achieved.
- 31. The starting point for defining outcomes will depend on the competent authority's approach to monitoring and system review. In a comprehensive approach, a competent authority may start by

- defining an NFCS Objective or a national goal as the highest-level outcome to be achieved. If the competent authority decides to implement monitoring and system review in a phased or targeted approach, it should identify the highest-level outcome that is applicable to their approach.
- 32. After defining the starting point, the competent authority should ask "How will this be achieved?" to identify the next level of outcomes that contribute to achieving the highest-level outcome. There may be several intermediate or lower-level outcomes that contribute to achieving the highest-level outcome. The competent authority can ensure that all of the relevant outcomes have been identified by asking "What else is necessary?" to achieve the highest-level outcome.
- 33. This process of asking "How will this be achieved?" and "What else is necessary?" should be repeated for each intermediate and lower-level outcome until no further outcomes can be identified. For outcomes at the lowest-levels, the answer to "How will this be achieved?" will usually be outputs or activities.
- 34. Through this process, the competent authority will develop an outcome framework that visually reflects the causal or logical processes that contribute to achieving the highest-level outcome. When read from the top down, an outcome framework explains how each outcome will be achieved by first achieving the outcomes at the next lowest level. When read from the bottom up, it explains why each outcome is important because it contributes to achieving an outcome at the next highest level. See Appendix A for an example of a simplified outcome framework.
- 35. There are other approaches that may be used for identifying and visually displaying outcomes and their causal relationships, including logic models, program theories, or theory of changes.
- 36. Some outcomes may be beyond the full control of the competent authority in that they rely on other government entities or stakeholders to be fully accomplished. Such outcomes can still be monitored if they can be significantly impacted through the competent authority's activities.
- 37. After identifying outcomes, the competent authority should map current activities that contribute to achieving the outcomes, assess gaps, and identify additional activities that could further contribute. Once current and potential activities have been identified, a competent authority can prioritize and schedule activities.

Step 3: Establish Indicators

- 38. Indicators are means for measuring achievement, reflecting changes, or assessing performance. Indicators should be established for each individual outcome.
- 39. Indicators may also be established for inputs and outputs to allow the competent authority to monitor how specific activities are contributing to specific outcomes. Various tools may be used to manage inputs and outputs, such as budgets, staffing plans, and activity plans.
- 40. Where there is limited capacity for monitoring and system review, the competent authority may choose to start with a limited number of indicators and increase the number of indicators as capacity expands.
- 41. As part of a phased or targeted approach, the competent authority may initially establish indicators for which there are existing processes for data collection and analysis or addressing priority components of the NFCS.
- 42. As the global knowledge base on indicators for NFCSs develops, the competent authority should consider these indicators as appropriate.
- 43. The process for selecting indicators should build on the review of established data collection processes conducted during the assessment phase.
- 44. The competent authority should convene a group of technical, substantive, and policy experts to brainstorm potential indicators for each of the outcomes identified in Step 2. Some examples of indicators are included in Appendix B.
- 45. Indicators may be qualitative or quantitative and should fulfil the following criteria:
 - unambiguous, easy to interpret, monitor and transparent.
 - closely linked to the outcomes (including timing) and meaningful from an organisational perspective.
 - amenable to independent validation and or verification.
 - Obtainable given available resources.

- 46. Among the many potential indicators that meet these criteria, the competent authority should consider the following information to choose the most direct indicators for which it is technically and financially capable of collecting and analysing data.
 - Frequency of data collection
 - · Financial cost of data collection
 - · Challenges for data collection or limitations to interpreting the data
- 47. Measurement influences behaviour, so it is important to choose indicators that will incentivize the actions that will lead to achieving the intended outcomes.

Step 4: Create Monitoring Plan

- 48. To ensure that indicators are successfully integrated into the monitoring and system review function of a competent authority, a performance monitoring plan (PMP) should be created to provide detailed information on how performance data will be collected and analysed. For each indicator, the PMP should include:
 - Explanation or definition of indicator
 - · Source of data
 - · Frequency of data collection
 - · Methods for data collection
 - · Methods for ensuring data quality
 - · Methods for data analysis
 - Roles and responsibilities for data collection
 - Roles and responsibilities for data analysis
 - · Roles and responsibilities for ensuring data quality
 - Baseline data
 - Targets
- 49. The competent authority should collect baseline data for each indicator. Baselines establish the current situation and are used as a starting point against which future performance will be measured. Additionally the collection of baseline data under a pilot program can serve to identify indicators that may not work.
- 50. After baseline data has been collected and as appropriate, the competent authority should establish targets for indicators. A target is a specified result that is to be realized within a specific timeframe. For some indicators, the target might simply be to "increase", "maintain", or "decrease" from the baseline.
- 51. When establishing targets, the competent authority should consider the baseline levels, the desired level of improvement, and the resource levels needed to meet the target.
- 52. For indicators with long-term targets, it may be helpful to identify sub-targets or milestones.

SECTION 5.2 MONITORING & SYSTEM REVIEW STEPS

53. Completing the steps above provides a foundation for making the monitoring and system review steps of the NFCS operational. These system review steps include: data collection, data analysis, reporting findings, and incorporating findings.

Step 5: Collect and Analyse Data

54. The PMP describes roles and responsibilities for data collection and analysis. Often, raw data will need to be managed in order to calculate indicators. Depending on the nature of the indicators, data analysis may include comparing results to baselines and targets and assessing trends over time.

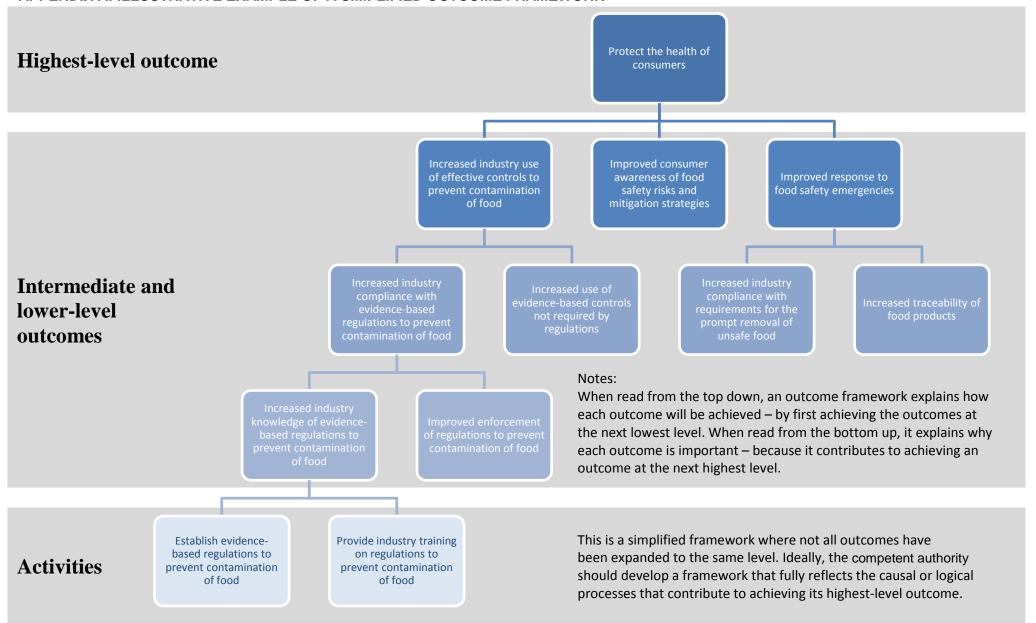
Step 6: Report and incorporate findings

55. There are multiple uses for the information produced through monitoring and system review. Performance data should be presented in a clear and understandable format that is targeted to specific audiences and may be presented in various formats as appropriate (e.g. written summaries, executive summaries, oral presentations, visual presentations, dashboards).

- 56. Monitoring and system review is only useful if the findings are used to inform and influence the policy setting design and implementation of the NFCS. Simply reporting the data is not enough. The competent authority should institute approaches that will ensure the full integration of performance data. Some examples include:
 - Conducting formal, regularly scheduled performance review meetings to assess continued appropriateness of activities and relevance of selected outcomes and associated indicators
 - Integrating performance data into resource prioritization and budgeting decisions
 - · Identifying and sharing best practices and lessons learned
 - Identifying gaps or problems that could be addressed with capacity building
 - · Assessing other opportunities within the competent authority to use performance data
- 57. When the findings from performance monitoring and systems review reflect unfavourable results, problem-solving methods, such as root cause analysis, may be used to identify corrective actions.
- 58. As the use of performance data results in changes to policies, system design, or program implementation, the competent authority should revisit the planning steps.
 - With any refinement or shift in national strategies or goals for the NFCS, the competent authority should review the outcome framework. Irrelevant outcomes should be discarded and new outcomes should be incorporated as necessary.
 - On a regular basis, the competent authority should also review the indicators used to monitor outcomes to ensure that they are meaningful and appropriate. Indicators that are not meaningful should be discarded and more appropriate indicators should be incorporated as necessary.
 - The PMP should be updated on a regular basis to reflect institutional changes, technological advancements, or evolving methods for data analysis.
- 59. Findings from monitoring and system review and subsequent changes to the NFCS should be communicated effectively and efficiently to ensure the clear exchange of information and engagement between all relevant stakeholders in the NFCS.

REP16/FICS Appendix III 30

APPENDIX A: ILLUSTRATIVE EXAMPLE OF A SIMPLIFIED OUTCOME FRAMEWORK



REP16/FICS Appendix III 31

APPENDIX B: ILLUSTRATIVE EXAMPLES OF INDICATORS FOR SELECTED OUTCOMES

The following table provides illustrative examples of indicators for selected outcomes from Appendix A. When applying the performance monitoring framework, each country will establish indicators specific to their desired outcomes.

Examples of Outcomes	Examples of Indicators
Protect the health of consumers	 incidence of foodborne illness (# of cases per 100,000 population) (e.g., Salmonella) average dietary exposure to chemical contaminants mg/kgbw per day) (e.g., organophosphate pesticides)
Increased industry use of effective controls to prevent contamination of food	 percent of samples that test positive for microbial contaminants (e.g., Salmonella spp.) percent of samples that test positive for chemical contaminants (e.g., organophosphate pesticide residues)
Increased industry compliance with evidence-based regulations to prevent contamination of food	 percent of farms using specified controls to prevent salmonella percent of inspections for which food producers were found to be compliant with pesticide regulations percent of inspections for which there is noncompliance by industry
Increased industry knowledge of evidence-based regulations to prevent contamination of food	 percent of food producers that are aware of current evidence-based regulations
Improved response to food safety emergencies	 percent of recalled products that were recovered and destroyed or disposed of properly average response time between the recognition of a food safety concern and initiation of recall
Increased traceability of food products	 existence of a food traceability tool/mechanisms (yes/no) percent of domestic food producers with traceability practices percent of imported foods that are tracked or registered using identifiers (e.g., barcodes, RFID)

Appendix IV

PROPOSED DRAFT REVISION ON THE PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS (CAC/GL 19-1995)

(N03-2015)

(at Step 5/8)

SECTION 1 - PREAMBLE

- 1. When a food safety emergency arises, in order to minimize potential adverse public health effects, it is essential to communicate the nature and extent of the emergency to all relevant parties, including action taken by the exporting country, as expeditiously as possible to ensure prompt action can be taken to manage the food safety emergency in importing countries. This must be done in a manner that avoids unwarranted action against unaffected batches of the food, or other foods from the country involved in the food safety emergency, or other countries. The global nature of food trade requires that the communication occur as rapidly as possible among all relevant competent authorities of affected countries.
- 2. The Guidelines are consistent, and should be read in conjunction, with relevant Codex texts, such as the Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013) and the Guidelines for Food Import Control Systems (CAC/GL 47-2003). In addition, documents and guidance material developed by FAO and WHO are valuable resources¹, in particular the FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies² and the FAO/WHO framework for developing national food safety emergency response plans³.
- 3. The International Food Safety Authorities Network⁴ (INFOSAN) is a mechanism for information exchange to ensure food safety authorities are aware of events that may have international implications.

SECTION 2 - SCOPE

- 4. These Guidelines provide guidance for responding to food safety emergencies. They apply to situations where the competent authority becomes aware of a food safety emergency, and action must be undertaken to communicate the risks associated with the emergency. Due to trade globalization and increased import/export operations, it is possible that the management of a food safety emergency is the responsibility of more than one competent authority, and timely and coordinated collaboration among all relevant stakeholders, including food business operators and consumers, is required to ensure an effective response. The guidance also applies to feed⁵ whenever the use of the feed may result in unsafe food.
- 5. The Guidelines apply to a food safety emergency where the food safety hazard and food product has been specifically identified. They may also apply to situations where the food safety hazard has not been identified, but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects.
- 6. The Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The Guidelines may also apply to such emergencies where feed for food producing animals is implicated⁶.
- 7. The Guidelines do not apply to import rejections caused by failure to comply with importing country requirements. These situations are covered in the Guidelines for the Exchange of Information between Countries on Rejections of Imported Food (CAC/GL 25-1997).

SECTION 3 – DEFINITIONS

Food Safety Emergency: 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.

Food Safety Emergency Response: A process of assessing the risk, making risk management decisions, and communicating risks in the face of time constraints, and possible incomplete data and knowledge.

⁵ The term feed refers to both feed (feeding stuffs) and feed ingredients, as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

¹ http://www.fao.org/food/food-safety-quality/publications-tools/food-safety-publications/en/

² http://www.fao.org/docrep/014/ba0092e/ba0092e00.pdf and http://www.who.int/foodsafety/publications/infosan/en/

³ http://www.fao.org/docrep/013/i1686e/i1686e00.pdf and http://www.who.int/foodsafety/publications/infosan/en/

⁴ http://www.who.int/foodsafety/areas_work/infosan/en/

⁶ Provisions for emergency situations affecting animal feed are included in the *Code of Practice for Good Animal Feeding* (CAC/RCP 54-2004): Section 4.3.1 "Special conditions applicable to emergency situations".

SECTION 4 – PRINCIPLES

- 8. Many food safety emergencies have international implications and may be reportable to WHO under the International Health Regulations (2005)⁷ (IHR) and INFOSAN. The exchange of information should follow the risk analysis principles recognized by the Codex Alimentarius⁸ in the case of a food safety emergency or a situation where a food safety hazard has not been identified, but relevant scientific information suggests a link between consumption of a food and the appearance of serious health effects. Due to time constraints, it is recognised that risk management measures may have to be taken on the basis of limited information and before the completion of a full risk assessment.
- 9. Key principles include:
 - a) A primary official contact point should be designated by each country involved in a food safety emergency to facilitate exchanges of information. Preparedness and response to food safety emergencies may require coordination between competent authorities responsible for different parts of the food chain and public health, depending on the nature and extent of the emergency.
 - b) Information on the nature and extent of the food safety emergency, including a risk assessment when completed, should, where possible, be clearly and completely described by the relevant competent authorities. If the basis for the food safety emergency is related to the use of feed, the specific nature of the feed related problem and its impact on food safety should be indicated.
 - c) In circumstances where the specific food safety hazard has not been precisely identified, any clear and substantial association between the consumption of a food and the appearance of serious public health effects should be provided by the competent authority.
 - d) The exchange of information on food safety emergencies should be between official contact points designated by the competent authority in accordance with section 6.2. A channel providing the most rapid and effective information flow should be used. All relevant information should be exchanged in a mutually agreed language or a language used by Codex.
 - e) A country detecting a food safety emergency should inform countries likely to be affected without delay utilizing existing mechanisms and international agreements (e.g. INFOSAN or IHR (2005), as appropriate). If the country detecting the emergency is not the exporting country, the exporting country must be notified as a matter of priority.
 - f) All relevant information should be shared by the competent authority detecting a food safety emergency to enable all countries likely to be affected to take informed risk assessment, risk management and/or risk communication decisions.
 - g) The competent authority should also provide clear, relevant, factual and timely information to relevant stakeholders.
 - h) Information flow should be transparent and continue during all phases of the food safety emergency to enable continuous evaluation and refinement of the emergency response.
 - i) Food should not be placed in international trade for the purpose of disposing of unsafe or unsuitable food as described in 3.2 of the Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CAC/RCP 20-1979).

SECTION 5 – STAKEHOLDERS AND THEIR RESPECTIVE ROLES

5.1 Competent authorities

- 10. The competent authority is responsible for managing and communicating food safety emergencies in accordance with the principles outlined in paragraph 9.
- 11. Upon identification of a food safety emergency, the competent authority identifying the emergency should promptly communicate with official contact point(s) (e.g. the INFOSAN Emergency Contact Point) of the country and the appropriate competent authority of other countries likely to be affected. The competent authority responsible for coordinating the response should update countries receiving the affected food of action taken, as appropriate. The accuracy and veracity of the scientific and other information regarding a food safety emergency should be verified to assist the risk assessment, risk management and risk communication process. Any misinformation should be promptly corrected by competent authorities.
- 12. The competent authority should provide industry, consumers and other stakeholders with information on the status of the food safety emergency. A communication plan, including multiple methods of providing such information on the relevant details, should be prepared and used. The information should, as relevant,

⁷ http://www.who.int/ihr/about/en/

⁸ Working Principles for Risk analysis for Food Safety for Application by Governments (CAC/GL 62-2007).

include health effects on the most sensitive groups (children, elderly people and people with reduced immune system) and how the affected food/foods can be identified and handled in order to reduce further spreading of risk.

5.2 International Food Safety Authorities Network (INFOSAN)

13. The INFOSAN Emergency Contact Point is responsible for reporting urgent food safety events of potential international significance to the INFOSAN Secretariat. INFOSAN is the FAO/WHO network for the dissemination of important information about food safety issues globally. INFOSAN maintains a network of official contact points from national government authorities involved in food safety. This includes one Emergency Contact Point from the authority responsible for national food safety emergency response, and additional focal points from other national agencies involved in food safety (in accordance with section 6.2). During food safety incidents, INFOSAN liaises with relevant national authorities to collect, validate and if required, share factual information at the international level. INFOSAN should be considered a key information resource for support during emergencies. Many food safety emergencies have serious international implications and may also be reportable to WHO under the International Health Regulations (2005).

5.3 Food business operators

- 14. Food business operators have the primary responsibility for ensuring food safety and are thus responsible for contributing to the management of food safety emergencies related to their products. They are also responsible for having in place traceability systems capable of effective tracing of food lots and for providing timely and relevant information to the competent authorities and other relevant stakeholders, including customers and/or consumers, on matters of relevance for managing food safety emergencies⁹. They are also responsible for providing training or instruction to staff and for internal communication. These provisions also apply to feed business operators if the food safety emergency is associated with feed.
- 15. A food business operator should be able to readily provide information about what food it has, where it came from and to whom it has been supplied. The keeping of records that can be transmitted digitally and are searchable should be encouraged so as to facilitate the tracing of product through more complex distribution networks in a timely fashion.

5.4 Consumers

16. Consumers can safeguard their personal health by remaining informed of and following instructions from competent authorities related to food safety emergencies.

SECTION 6 - PROCESSES FOR FOOD SAFETY EMERGENCY RESPONSE

17. The relevant sections of the FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies provide additional guidance.

6.1 Food Safety Emergency Plan

18. The competent authority should develop a national food safety emergency plan indicating procedures to be followed in the case of a food safety emergency, including specific provisions relating to communication. The plan should also establish the responsibilities of all parties involved in the emergency situation with a view to managing the coordination arrangements among them. Useful guidance on establishing a food safety emergency plan can be found in the FAO/WHO framework for developing national food safety emergency response plans¹⁰.

6.2 Designated official contact points for information exchange

19. Each country should designate a primary official contact point for food safety emergency situations, which can act as the national focal point for information exchange in such situations. Although the primary official contact point is the first contact, it is understood that, in a given food safety emergency, the competent authority may wish to designate a specific contact point for that emergency. Updated information on the primary official contact point should be provided to INFOSAN.

6.3 Level of food distribution

20. The competent authority should take account of whether the food or (as appropriate) feed involved has or is likely to have been distributed at the wholesale, retail or consumer level. They should also consider the quantity of food distributed, whether it may be in transit to a trading partner, and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food

⁹ Principles of Traceability/Product Training as a tool within a food inspection and certification system (CAC/GL 60-2006)

¹⁰ http://www.fao.org/docrep/013/i1686e/i1686e00.pdf

distribution. Useful guidance for this is available in the FAO/WHO guide for developing and improving national food recall systems¹¹.

21. In some cases, the affected food may not yet have entered an importing country, and risk management and communication measures of the importing country's competent authority will focus on the importers and border controls. However, in other cases, the food will have entered and been distributed within a country or transhipped to other countries, and risk management and communication measures by both the exporting and importing country competent authorities will need to be amended accordingly.

6.4 Information management

- 22. Given the global nature of food trade, the impact of a food safety emergency may be widespread. The competent authority of the country where the food safety emergency is identified should, to the best of its ability and in cooperation with other competent authorities, determine all potential recipient countries of the implicated food and all countries from which the potentially contaminated food or (when appropriate) feed or its ingredients was imported. All relevant information in relation to the food safety emergency should be provided to the competent authorities of the countries identified in this way.
- 23. Communication should be made by the most expedient means, as early as possible, and with verification of receipt by primary official contact points. Communications by telephone (of particular importance outside office hours at the receiving end) or electronic means should be considered in order to achieve early communication and to ensure that the competent authorities receive the message as quickly as possible.
- 24. In cases where the food safety hazard is associated with a specific food or foods, these foods should be identified in as much detail as available to facilitate the identification and location of the affected foods. In other cases, where a food safety hazard affects many different categories of foods and potentially involves a determined geographical area, all affected foods should be identified. If the food safety hazard is associated with feed, the feed should be clearly identified.
- 25. It is recognized that the initial information provided may often be incomplete, and it is therefore the responsibility of the country identifying the food safety emergency to ensure that the initial communication is supplemented by further notification(s), as and when more detailed information becomes available.
- 26. The Competent authority should also provide clear, relevant, updated, factual and timely communication on the status of the food safety emergency to all relevant stakeholders, using the media it considers appropriate.

6.5 Information to be exchanged

27. A standard format for the relevant information to be exchanged is recommended for use by both the importing and exporting countries. The competent authority will determine the nature and extent of information to be exchanged with respect to its national laws regarding protection of private information. A model standard format for information exchange in food safety emergencies is provided in the Annex.

6.6 Information flow

28. The information flow at the initial stages of the process will likely include presumptions and a level of precaution with regards to the measures implemented. This information should be refined as further detail on the nature of the food safety emergency becomes available. Communications between designated official contact points should be transparent and continue through all phases of the food safety emergency, from initial notification of the food safety problem including, whenever possible, details of any relevant risk assessments that have been used, through to notification of the resolution of the problem. This will enable countries to review their risk assessment, risk management and risk communication strategies as the situation changes.

6.8 Early warning systems

29. Consideration should be given to setting up early warning systems. The FAO Emergency Prevention System for Food Safety¹² (EMPRES Food Safety) may provide assistance in setting up such systems.

¹¹ http://www.fao.org/docrep/017/i3006e/i3006e.pdf and www.who.int/foodsafety/publications/recall/en/

¹² http://www.fao.org/food/food-safety-quality/empres-food-safety/en/

ANNEX

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCIES

The following constitutes the information that should be exchanged between competent authorities of both exporting and importing countries involved in a food safety emergency. Initial information exchange should occur as fast as possible, even if it is not complete. Further information can be exchanged as soon as it becomes available.

1. Nature of the food safety emergency

The nature of the food safety hazard causing the food safety emergency should be described, and may include the following as appropriate:

- biological/microbiological contamination (specify organism or toxin of concern);
- chemical contamination (e.g. pesticides, drugs, industrial chemicals, environmental contaminants);
- physical contamination (e.g. foreign bodies);
- radionuclide contamination (specify radionuclide(s) of concern);
- undeclared allergen (the allergen should be explicitly named);
- other identified hazards (e.g. inherent chemicals in foods or produced through processing, processing/packaging faults);
- unknown agent (specify serious adverse health effects associated with consumption of specified foods).

In each of the above cases, the specific food safety hazard and its level or prevalence based on available information and, as appropriate, the sampling and methods of analysis used, and any assumptions made should be notified.

The nature and extent of any adverse health effects associated with a food safety emergency should be described, e.g. incubation period, severity, other epidemiological data.

2. Identification of foods or, as appropriate, feeds concerned

The foods or feeds concerned should be described completely. The following information should be provided if available, as appropriate to the product:

- description and quantity of product(s), including brand, the name(s) of the product listed on the label, grade, preservation method (e.g. chilled or frozen) and shelf life;
- type and size of package(s);
- lot identification, including lot code, dates of production and processing, and identification of premises where last packed or processed;
- other identification marks/stamps (e.g. bar codes, UPC codes);
- name and address of producer, manufacturer, packer, seller, exporter or importer, as appropriate;
- pictorial image;
- export certificate(s) reference number(s), official name and mark.

An indication of the countries to which the product has been exported should also be provided, as soon as it is known, to enable countries to quickly identify whether they are likely to be affected, and to help locate the affected foods.

3. Affected or potentially affected population group(s)

Food safety emergencies may predominantly affect certain segments of a population, e.g. children, pregnant women, immune-compromised persons or the elderly. In such instances, this information should be communicated.

4. Shipping and related information

Information on the following should be provided if available:

- exporter name and contact information;
- importer name and contact information;
- container and shipping details, including port of origin and destination;

- applicable harmonized system (HS or tariff) codes used to ship the implicated product;
- consignee(s) and shipper(s) and contact information.

5. Action taken by exporting or importing country

Information on action taken where available, such as:

- measures taken to identify and prevent the sale and export of the food;
- measures taken to recall food from markets including whether these recalls are voluntary or mandatory;
- measures taken to prevent further problems;
- measures taken to reduce the risk by appropriate physical treatment;
- methods of diagnosis and treatment of affected persons;
- measures taken regarding final disposition (e.g. destruction of the food);
- laboratory analyses.
- any additional information that may be useful to assess the risk of this event

6. Details of the designated primary official contact point and of the relevant competent authority

Full contact details, including the name of the competent authority, address, telephone, email address and facsimile numbers of persons or offices that can supply further information that may be sought by affected or potentially affected countries to assist in the management of the food safety emergency. A website address should be used where available to provide up-to-date information.

Appendix V

PROPOSED DRAFT REVISION ON GUIDELINES FOR THE EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD¹(CAC/GL 25-1997)

(N04-2015)

(at Step 5/8) SECTION 1 - INTRODUCTION

- 1. The following guidelines provide the basis for structured information exchange on rejections of imported food where the reason for the rejection is related to food safety and fair practices in food trade.
- 2. These guidelines apply where food has been refused entry to a country due to a failure to comply with importing country requirements. Where a food safety emergency situation ² has been identified, the *Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) should be used.
- 3. The use of these guidelines is intended to improve transparency where food is rejected and to build on:
 - the Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1995), in particular the transparency provisions contained in paragraph 15 of the Principles
 - the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003), in particular the decisions and information exchange provisions contained in paragraphs 27-29 and 34 of the guidelines respectively.

SECTION 2 – GENERAL CONSIDERATIONS

- 4. Rejections may occur where the competent authority of the importing country has identified that the consignment does not comply with importing country requirements, which may include:
 - evidence the consignment presents a food safety risk
 - evidence that the consignment has been compromised during handling, storage or transport
 - evidence of misrepresentation or consumer fraud.
- 5. When the competent authority rejects a consignment of food presented for importation due to non-compliance with importing country requirements, information should be exchanged to advise relevant parties of the rejection, to enable relevant parties to attain any necessary clarifications, and where appropriate implement corrective and preventative measures.
- 6. Where appropriate, information should be provided to the competent authority of the exporting country (or embassy if the competent authority is not known) and the importer and/or exporter of the rejected consignment.
- 7. Where appropriate, the competent authority of the exporting country should have reasonable access to the evidence found by the importing country, so as to be able to investigate the cause of the non-compliance and implement and manage any corrective actions as required.
- 8. If requested, the competent authority in the exporting country should provide the competent authority in the importing country with information on the outcome of the necessary investigations and corrective actions taken.
- 9. Based on the information provided, in accordance with the importing country's legislation, the importer and/or exporter, in consultation with the competent authority of the importing and exporting countries as appropriate, may determine what action to take³.
- 10. Where there is evidence of repeated failures of a correctable nature that are not associated with food safety (e.g. labelling errors, mislaying of documents) or there have been systematic failures, the competent authority in the importing country may also make appropriate notification to the competent authority in the exporting country, either periodically or upon request.
- 11. Bilateral discussions should take place as necessary between the competent authorities of the importing and exporting countries regarding information of rejected food.

¹ For the purposes of these guidelines, food shall be taken to include feed for food producing animals where the reason for the rejection is related to food safety.

² A food safety emergency is defined in CAC/GL 19-1995 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 attention.

³ As described in paragraphs 27-29 of the Guidelines for Food Import Control Systems (CAC/GL 47-2003)

- 12. As far as possible, importing countries should minimise restrictions on the disclosure to exporting countries of information on rejected foods.
- 13. To enable FAO and WHO to assist exporting countries in their efforts to meet the requirements of importing countries, information on rejections of imported food should be made available to FAO and WHO if their assistance is requested by an exporting country.

SECTION 3 – DETAILED INFORMATION

- 14. Information exchange should be:
 - transmitted electronically to all relevant parties wherever possible
 - transparent, structured and timely to ensure rapid resolution and so alternative actions may be taken wherever possible
 - made in the language of the importing country, English or a third language, as mutually agreed.
- 15. The reason(s) why a consignment of food has been rejected should be clearly stated and reference should be made to the regulations or standards which have been contravened. A clear description of the criteria for rejection should be provided to ensure transparency. Details on the type of information to exchange are provided in Annex 1.
- 16. Where a consignment is rejected on the basis of analysis performed in the importing country, the competent authority of the importing country should make available, upon request, details of the sampling and analytical methods employed, the results obtained and the details of the testing laboratory.
- 17. Where the level of a contaminant has been found to be above the maximum permitted level, the contaminant should be specified, together with the level found and the maximum permitted level. In the case of biological contamination or contamination by biological toxins, where no maximum level has been fixed, the identity of the organism or toxin should be given as specifically as possible, and as appropriate, the level of contamination found.
- 18. Contraventions of regulations on food additive or compositional standards should be specified.
- 19. Some countries accept certain foods (e.g. fresh meat) only from specifically approved establishments in the exporting country. If such foods are refused entry because of evidence that they come from such an establishment is lacking or incomplete, this should be stated.

ANNEX I

STANDARD FORMAT FOR EXCHANGE OF INFORMATION BETWEEN COUNTRIES ON REJECTIONS OF IMPORTED FOOD

The following information should be provided by countries in relation to rejections of imported food, as available and appropriate to the circumstances.

Identification of the food concerned

The foods concerned should be described as completely as possible. If available, the following information should be provided:

- Description and quantity of product
- Harmonized System (HS) code of the product
- Type and size of package
- Lot identification (number, production date, etc.)
- Container number, bill of lading or similar transportation details
- Other identification stamps, marks or numbers
- Certificate number (if applicable) and a copy of the certificate if applicable
- Name and address of manufacturer, producer, seller and/or exporter, establishment number

Importation details

Information on the following should be provided:

- Exporter name and contact information
- Importer name and contact information
- Container and shipping details, including port of origin and destination
- Date presented for entry

Details of rejection, decision

Information about the decision to refuse importation should be provided including:

- Whole/part of (specify) consignment rejected
- Name and address of competent authority making decision to reject
- Date of decision
- Name and address of competent authority which can provide more information on reason for rejection

Reason(s) for rejection

The reasons for rejection must be specified and supporting evidence provided as appropriate. The reason for rejection may include:

- Biological/microbiological contamination
- Chemical contamination (heavy metals, etc.)
- Pesticide or veterinary drug residues
- Radionuclide contamination
- Incorrect or misleading labelling
- Compositional defect
- Non-conformity with food additive requirements
- Organoleptic quality unacceptable
- Noncompliance of temperature requirements
- Technical or physical defects (e.g. packaging damage)
- Incomplete or incorrect certification

- Does not come from an approved country, region or establishment
- Food adulteration
- Other reasons

Action taken

Information on action taken should be provided, such as:

- Food destroyed
- Food held pending reconditioning/rectification of deficiencies in documentation
- Import granted for use other than human consumption
- Re-export granted under certain conditions, e.g. to specified informed countries
- Importer notified
- Embassy/food control authorities of exporting country notified
- Authorities in other likely destination countries notified
- Other