CODEX ALIMENTARIUS COMMISSION E



Food and Agriculture Organization of the United Nations



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REP13/FICS

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty sixth Session Rome, Italy, 1-5 July 2013

REPORT OF THE TWENTIETH SESSION OF THE CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Chiang Mai, Thailand 18-22 February 2013

NOTE: This report contains Codex Circular Letter CL 2013/4-FICS

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CL 2013/4-FICS February 2013

- To: Codex Contact Points Interested International Organizations
- From: Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme Viale delle Terme di Caracalla 00153 Rome, Italy

Subject: Distribution of the Report of the Twentieth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (REP13/FICS)

The report of the Twentieth Session of the Codex Committee on Food Import and Export Inspection and Certification Systems will be considered by the 36th Session of the Codex Alimentarius Commission (Rome, Italy, 1-5 July 2013)

MATTERS FOR ADOPTION BY THE 36TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

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

Draft and Proposed Draft Principles and Guidelines for National Food Control Systems (N06-2009), at Step 8 and 5/8 (para. 38 and Appendix II).

<u>Others</u>

Draft amendments to Guidelines for the Exchange of Information in Food Safety Emergency Situations (CAC/GL 19-1995) (para. 58 and Appendix III).

Governments and international organizations wishing to submit comment on the above texts should do so in writing, *by e-mail*, to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (e-mail: <u>codex@fao.org</u>) <u>before 31 May 2013</u>.

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SUMMARY AND CONCLUSIONS

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

Matters for the 36th Session of the Codex Alimentarius Commission

Matters for adoption / approval

The Committee agreed to forward to the 36th Session of the Codex Alimentarius Commission:

- Draft and Proposed Draft Principles and Guidelines for National Food Control Systems (N06-2009) for adoption at Steps 8 and 5/8 (see para. 38 and Appendix II); and
- Draft amendments to *Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) for adoption (see para. 58 and Appendix III).

Matters of interest

The Committee agreed to consider at its next session the amendments to the *Guidelines for the Exchange of Information between Countries on Rejections of Imported food* (CAC/GL 25-1997) to address animal feeding (see para. 60).

Matters referred to other Committees / Task Forces

Committee on Fish and Fishery Products (CCFFP)

The Committee agreed to inform the CCFFP that section "Information exchange" of the *Guidelines for Import Control System* (CAC/GL 47-2003) (paragraphs 34 and 35) provided guidance on exchange of information between importing and exporting countries (see para. 11).

INTRODUCTION

1. The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) held its 20th Session in Chiang Mai, Thailand, from 18 to 22 February 2013, at the kind invitation of the Government of Australia and the Government of Thailand. Mr Gregory Read, Executive Manager, Food Division, Australian Quarantine and Inspection Service, Australian Government Department of Agriculture, Fisheries and Forestry, chaired the Session. The Session was attended by 153 delegates from 56 Member countries and one Member organization, and nine international governmental and non-governmental organizations, including FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

2. The Vice-Governor of Chiang Mai, Mr Rittiphong Tachapunt, welcomed the delegates to Chiang Mai and wished them a fruitful and successful meeting.

3. Dr Hiroyuki Konuma, Assistant Director-General and FAO Regional Representative for Asia and the Pacific, welcomed the delegates on behalf of FAO and WHO. He stressed the importance of the work of Codex specifically on inspection and certification systems and the current work of the Committee to provide guidance to governments on the development, operation, evaluation and improvement of their national food control systems.

4. Dr Konuma highlighted recent food safety initiatives in the Asia Pacific Region and said that considerable progress on Codex matters had been achieved and that FAO had provided assistance to countries through Trust Fund projects and through FAO's regular and extra-budgetary programme activities. He reaffirmed the commitment of FAO and WHO to continue and increase their efforts in supporting food safety in member countries of the region.

5. His Excellence Dr Yukol Limlamthong, Minister of Agriculture and Cooperative of Thailand, welcomed the delegates to Thailand. In his opening remarks, the Minister said that Thailand had launched its food safety strategy in 2004 and that its implementation included inspection, certification and traceability systems at every step of the food chain. The Minister explained that the objectives of the systems had been developed in line with the principles and guidelines of CCFICS.

6. The Minister also mentioned the Association of South East Asian Nations (ASEAN), which will establish the ASEAN Economic Community in 2015 and that several activities had taken place to harmonise food standards, inspection and certification systems to facilitate the trade of safe food among ASEAN countries. In concluding, the Minister recalled that 2013 marked the 50th Anniversary of the Codex Alimentarius Commission and highlighted the importance for Codex to develop food standards, guidelines and codes of practices, which could be used by all countries.

Division of Competence¹

7. 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 CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)²

8. The Committee adopted the Provisional Agenda as its Agenda for the Session.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION, OTHER CODEX COMMITTEES AND TASK FORCES AND OTHER INTERNATIONAL ORGANIZATIONS (Agenda Item 2) 3

9. The Committee noted the decision of the 35th Session of the Codex Alimentarius Commission regarding the adoption at Step 5 and advancement to Step 6 of Sections 1-3 of the proposed draft Principles and Guidelines of National Food Control Systems (Agenda Item 4).

¹ CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)

² CX/FICS 13/20/1

³ CX/FICS 13/20/2; CRD 2 (Comments of Kenya and the Philippines); CRD 8 (Comments of India and Malaysia)

10. The Committee noted the request for advice of the 18th Session of the Committee of Fish and Fishery Products (CCFFP) regarding horizontal guidance developed by CCFICS on exchange of information between importing and exporting countries. The Committee noted that its advice would assist the CCFFP in the decision concerning the provision on determination of added water, especially on the exchange of information, in the draft Standard for Raw, Fresh and Quick Frozen Scallop Products.

Conclusion

11. The Committee agreed to inform the CCFFP that the section "Information exchange" of the *Guidelines for Import Control System* (CAC/GL 47-2003) (paragraphs 34 and 35) provided guidance on exchange of information between importing and exporting countries.

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

12. The Representative of FAO introduced FICS/20 INF/1 and CRD12 on the global FAO and WHO activities relevant to CCFICS. In particular, the Representative mentioned the FAO work on imported food control guidance, currently being finalized, which aims at bridging the gap between principles, as contained in CCFICS texts, and implementation, thus assisting official authorities in the assessment, review and improvement of risk-based imported food control programmes.

13. The new work of FAO on a food control systems assessment tool was also presented. This work complements the current work by CCFICS on principles and guidelines on national food control systems; activities have started in 2012 and should reach significant results by the end of 2013.

14. The Representative also informed the Committee of the recent FAO/WHO pre-CCAFRICA Workshop on National Food Control Systems (CRD 12), which aimed at strengthening the contribution of African countries to the CCFICS text under development.

15. The Representative further reported on current FAO work on: a multi-criteria decision making approach, which develops a systematic methodology to inform improved food safety policy making; and on the risk analysis toolkit, designed to assist countries in the practical use of the risk analysis paradigm to strengthen their food control systems.

16. The Committee was informed of two major FAO activities in the Asia-Pacific region: (i) the Regional Food Safety Policy Consultation (December 2012), which highlighted the most common factors in advancing food safety policy agendas and areas for further consideration, e.g. need for organizing a Regional Consultation on food safety indicators; support for pilot projects to review countries' food safety approach/policy focusing on strengthening coordination mechanisms and enhancing risk analysis capacity; and (ii) a three-day Regional Training Workshop for ASEAN countries on "Food Recall and Traceability - Application in National Food Safety Control", held in Chiang Mai on 15-17 February 2013. The Workshop covered various Codex texts and FAO/WHO guidelines on food safety emergencies, traceability, recall, the relationships between these texts and their practical applications. The current status of traceability and recall and a road map for introducing these concepts were also identified. The reports of both meetings will be available shortly.

REPORT ON ACTIVITIES OF OTHER INTERNATIONAL ORGANIZATIONS RELEVANT TO THE WORK OF CCFICS (Agenda Item 3b)⁵

World Organisation for Animal Health (OIE)

17. The Representative of OIE, referring to FICS/20 INF/2, informed the Committee of relevant OIE work. In particular, the Committee noted that the OIE, within the context of the WTO, is responsible for setting standards on animal health, including zoonoses, and that since 2001, at the request of its Members, had included in its mandate the development of standards for animal production food safety. The Representative also informed the Committee of the high priority that the OIE continues to give to food safety-related issues and to the close collaboration with Codex and its subsidiary bodies.

18. The Representative provided information on the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) and the OIE PVS Pathway, a global initiative aimed at strengthening veterinary and aquatic animal health services, noting the strong support from its Members and donors.

⁴ FICS/19 INF/1 (Activities of FAO and WHO relevant to the work of CCFICS); CRD 12 (Summary Report of the FAO and WHO Pre-CCAFRICA Workshop on National Food Control Systems)

⁵ FICS/20 INF/2 (OIE Contribution to the 20th Session of CCFICS); FICS/20 INF/3 (Report by the WTO Secretariat)

19. The Representative noted the importance of the collaboration between the OIE and Codex at the national level. In this respect, she referred to a special session of the Regional Seminar for OIE National Focal Points for Animal Production Food Safety⁶, held in Tokyo in November 2012, where OIE National Focal Points of Members in the Asia-Pacific region were given an opportunity to learn about Codex work and OIE/Codex collaboration

World Trade Organization (WTO)

20. The Committee noted the information provided by WTO on activities relevant to its work, as presented in FICS/19 INF/3.

World Customs Organizations (WCO)

21. The Representative of WCO, that had recently been granted observer status with the Codex Alimentarius Commission, informed the Committee that the 60 year-old WCO with 179 Members collectively administers 98% of global trade. One of its key work areas is harmonizing procedures and facilitating trade and to this end WCO develops an *Economic Competitiveness Package*, including the promotion of the *Revised Kyoto Convention on the Simplification and Harmonization of Customs Procedures* and *Coordinated Border Management*. The WCO firmly believes that better coordination and cooperation between border agencies is a major trade facilitation tool leading to improved economic competitiveness.

22. The Representative reported that in many WCO Members, coordination of activities takes place between food safety authorities and customs and that to enhance cooperation and coordination WCO has developed a Data Model containing also data elements required by other governmental agencies in cross border trade, including food safety authorities. As a result, the WCO Data Model opens opportunities for single window solutions and to "dematerialize" certificates. WCO had started cooperation with other international organizations (e.g. International Plant Protection Convention) to ensure that certificates can be lodged electronically and expects that cooperation with Codex and CCFICS will lead to further trade facilitation.

DRAFT AND PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS (N06-2009) (Agenda Item 4) 7

23. The Delegation of Australia introduced the document on Principles and Guidelines for National Food Control Systems and recalled that the 35^{th} Session of the Commission had adopted Sections 1 – 3 at Step 5, whereas Section 4 was revised by the physical Working Group held in Grange (Ireland) in July 2012. The Delegation further noted that the present document was the result of discussions at the 18^{th} and 19^{th} CCFICS and three physical Working Groups.

24. The Chairperson outlined the process he intended to use to consider the document: invite general comments to assess the overall support to finalise the document at the current session; work through it paragraph by paragraph; and then reorder and restructure the document to improve readability. A track-changes version would be distributed to all delegates after the detailed review to facilitate its finalisation.

General discussion

25. Delegations that intervened supported the document and to work at the present session with the goal of moving it forward for adoption by the Commission at Steps 8 and 5/8.

26. Several delegations considered that the level of detail in the document was adequate. It was suggested that the readability of the document could be improved by ensuring consistent use of terminology, eliminating duplication and rearranging some paragraphs; that the risk assessment functions of national food control system should be more clearly described; that the prevention dimension of enforcement activities should be more explicit; and that the concept of "appropriate level of protection" should also be addressed.

 ⁶ http://www.rr-asia.oie.int/representation/programmes/programme_i/201210%20Animal%20Food%20Safety%20FP%20TKY.html
 ⁷ CX/FICS 13/20/3; CX/FICS 13/20/3 Add.1 (Comments of: Argentina, Canada, Costa Rica, Honduras, Iran, Mauritius, Mexico, New Zealand, Norway, United States of America, Uruguay, FAO and INC); CX/FICS 13/20/3 Add.2 (Comments of Brazil, Egypt, European Union, Peru); CRD 3 (Comments of Mali, Philippines and IACFO); CRD 7 (Comments of Ghana, India, Malaysia and Thailand); CRD 13 (Comments of Panama); CRD 14 (Comments of Jamaica); CRD 15 (Comments of Indonesia)

Specific comments

27. Additionally to issues related to translation and editorial comments to improve readability of the document and to ensure consistent use of terminology, the Committee made the following comments and amendments.

Sections 1, 2 and 3

28. The Chairperson recalled that Sections 1-3 had been extensively discussed in the previous sessions and that Section 4 "Framework for the Design and Operation of the National Food Control System" further elaborated on Section 3 "Principles of a National Food Control System". Therefore, he invited comments and suggestions that focused on fundamental issues and added value without being too detailed and prescriptive.

29. The Committee agreed on some amendments and additions, which clarified or completed the text. It was also agreed that throughout the document, where appropriate, reference should be made to the dual mandate of Codex to protect the health of consumers and ensure fair practice in the food trade

30. Some suggestions were not agreed as they had already been discussed and the present text represented the compromise found. Other proposed additions to Section 3 were not agreed as they were too prescriptive and pre-empted or repeated detailed guidance that would follow in later sections of the document.

Section 4

31. The Committee carefully reviewed the responsibilities of various stakeholders, the components and elements of each of the four stages of a national food control system and, where possible, revised the text to add flexibility. The Committee noted that, due to the structure of the section dealing with the four stages of a national food control system, some repetition was unavoidable e.g. paragraphs dealing with different aspects of education and communication in Sections 4.2 "System design" and 4.3"Implementation".

- 32. In addition, the Committee agreed to:
 - Add a new element on the relation of the competent authority with other officially recognised audit, inspection, certification and accreditation bodies in the description of the pivotal role of the competent authority in a national food control system.
 - Revise the diagram in the introductory part of Section 4 to better illustrate the cyclic process of development and continuous improvement of a national food control system.
 - Include introductory paragraphs to Section 4.1 "Policy setting" to better explain what should be achieved in this stage and how, and to articulate the need to engage various stakeholders in public policy discussion.
 - Revise the paragraphs on legislation in Section 4.1 to clarify: (i) the aspects of a national food control system to be covered by legislation, e.g. roles and responsibilities of a competent authority, obligations of food business operators, cooperative arrangements with other governmental entities; and (ii) powers and authorities of a competent authority.

33. Text was added in Sections 4.1 and 4.2 on: (i) the responsibility of food business operators to have in place procedures for the prompt removal of unsafe food from the market and of the competent authority to notify consumers; and (ii) on the role of traceability/product tracing in food safety emergencies.

34. In Section 4.2 the Committee added definitions for "control programme" and "compliance and enforcement" in footnotes for clarity. In the Section it was also clarified that compliance and enforcement activities might be undertaken by third parties under the supervision and control of the competent authority.

35. In Section 4.3 the Committee added: the obligation for the competent authority to have in place a process for engaging with various stakeholders; and examples of international organizations with which the competent authority should communicate and collaborate in emergency situations involving food.

Finalisation

36. After completing the detailed review, the Committee considered the document in its entirety and made a number of editorial amendments, including deletion and reordering of paragraphs, to improve readability and logical flow of the document.

Conclusions

37. The Committee concluded the review and noted the extensive work and compromise that had enabled the finalisation of the document, which could now be moved to the Commission for adoption.

Status of the draft and proposed draft Principles and Guidelines for National Food Control Systems (N06-2009)

38. The Committee agreed to forward the draft and proposed Principles and Guidelines to the 36th Session of the Commission for adoption at Step 8 and 5/8 (see Appendix II).

DISCUSSION PAPER ON BURDEN OF MULTIPLE QUESTIONNAIRES DIRECTED AT EXPORTING COUNTRIES (Agenda Item 5a)⁸

39. The Delegation of Costa Rica introduced the report of the electronic Working Group, established by the 19th CCFICS, which included: (i) a discussion paper which described the problems faced by exporting countries due to multiple questionnaires and identified possible solutions; and (ii) a project document proposing new work on the development of a harmonised questionnaire.

40. The Delegation further explained that, following informal discussions with other delegations, they considered that the development of principles and guidelines on the elaboration and management of questionnaires would be more suitable to address the problems identified in the discussion paper than just developing a questionnaire. They further explained that the proposed new work did not intend to mandate the use of questionnaires but to provide orientation for their use and would focus on those situations where a questionnaire might be useful, e.g. to assess a food import and export inspection and certification system, or parts thereof, prior to new trade between countries.

41. The Delegation said that the proposed new work should provide a competent authority with a systematic approach to the use of questionnaires for assessing a food import and export inspection and certification system. A generic model questionnaire could be developed after completing this work.

42. Some delegations noted that the focus of the work should be on the national food control system. A number of delegations supported the revised scope of the proposal, which was narrower than the original proposal and were of the view that general guidance on the development of questionnaires to assess the ability of an exporting country to export safe food would be beneficial.

43. Other delegations, while noting that the proposal was important, especially for exporting countries, considered it premature to take a decision at the present session as the scope and focus of the new work had substantially changed and they did not have the opportunity to study the revised proposal.

44. The Committee in principle supported the revised approach to address the issue of the burden of multiple questionnaires. However, the Committee considered it necessary to clarify in the project document: that the new work aimed at providing guidance on which information might be useful to assess the exporting country's national food control system or parts thereof; that the scope of the work was on the exchange of information between competent authorities of importing and exporting countries; and that the focus of the work would initially be limited to specific areas of trade or specific products or groups of products entering the market for the first time. It was also suggested to indicate when the use of questionnaires was advisable.

Conclusion

45. The Committee generally supported this new work. However, it considered it necessary to further refine the scope of the new work before sending it to the Commission for approval. Therefore, in order to advance this proposal rapidly, the Committee agreed to establish an electronic Working Group, chaired by Costa Rica, working in English and Spanish and open to all Codex members and observers to: (i) revise the project document taking into account the revised proposal presented at the current session and the above discussion; and (ii) prepare an outline of the proposed document for consideration at its next session.

DISCUSSION PAPER ON MONITORING REGULATORY PERFORMANCE OF NATIONAL FOOD CONTROL SYSTEMS (Agenda Item 5b)⁹

46. The Delegation of the United States of America recalled that the 19th CCFICS had established an electronic Working Group to: (i) develop a questionnaire on how countries currently assess and manage the performance of their national food control system and give examples of indicators used; and (ii) prepare a more detailed discussion paper and project document on monitoring regulatory performance of national food control system¹⁰.

⁸ CX/FICS 13/20/4; CRD 4 (Comments of Kenya and Philippines); CRD 9 (Comments of European Union, India and Thailand); CRD 13 (Comments of Panama)

⁹ CX/FICS 13/20/5; CRD 5 (Comments of Kenya and Philippines); CRD 10 (Comments of India); CRD 13 (Comments of Panama)

¹⁰ REP12/FICS para. 62

47. Based on the replies to the questionnaire, the United States of America had developed a proposal for new work on Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems using the list of performance indicators proposed in the questionnaire as a starting point. The document could be an Annex to the new Principles and Guidelines for National Food Control Systems (Agenda Item 4) and would initially be limited to the monitoring of national food control systems.

48. Several delegations considered that the proposed new work was premature as work on the Principles and Guidelines for National Food Control Systems had just been finalised and countries needed to have more experience with the use of this document. It was also noted that, since only a limited number of countries (16) had replied to the questionnaire, it was necessary to collect more information and examples on how countries assess and manage the performance of their national food control systems.

49. Other delegations said that it was timely and beneficial for Codex to develop this guidance, which would help to apply the Principles and Guidelines for National Food Control Systems. However, the scope should be narrowed to the evaluation within a country for the purposes of continuous national improvements as, in their views, the use of metrics for comparison of countries systems and for equivalence was a somewhat different matter. It was noted that future work could profit from input of FAO work in this area.

50. Other delegations supported this work as many countries are developing measures, while others had difficulties to objectively assess and continuously review and improve their national food control systems. They were of the opinion that the work was a natural continuation of the just completed work on national food control systems; that the proposed timeline of three sessions to develop the document was sufficient to allow all members to actively participate and contribute to this work; and that workshops could be organised to promote understanding.

51. The Representative of FAO informed the Committee on the status of development of the FAO food control system assessment tool and the timeframe for its completion (see Agenda item 3a). She explained that the approach taken for its development included a peer review of other tools and collaboration with different categories of stakeholders, including OIE, WHO and UNIDO, interested members, other international organizations having similar experience in tools development (such as IPPC and IICA) and academia.

52. The Chairperson noted that regional workshops could be an efficient tool to demystify and clarify the intent of the proposal as had been beneficial when developing the principles on traceability/product tracing.

Conclusion

53. The Committee considered it necessary to further refine the scope of the new work before sending it to the Commission for approval. Following the above considerations and in order to make progress on this proposal, the Committee agreed to establish an electronic Working Group, chaired by the United States of America, working in English and Spanish and open to all Codex members and observers to: (i) revise the project document taking into account the above discussion; and (ii) prepare an outline of the proposed Principles and Guidelines for Monitoring Regulatory Performance of National Food Control Systems for consideration at its next session.

DISCUSSION PAPER ON THE NEED FOR FURTHER GUIDANCE ON FOOD SAFETY EMERGENCIES AND ON THE ANALYSIS OF PROPOSED CHANGE TO CCFICS TEXTS ON EMERGENCIES AND REJECTIONS TO ADDRESS FEED (Agenda Item 5c)¹¹

54. The Delegation of the United States of America introduced the discussion paper, which included recommendations on three issues related to the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) and the *Guidelines for the Exchange of Information between Countries on Rejections of Imported food* (CAC/GL 25-1997): (i) merging the two guidelines; (ii) proposals to include feed in CAC/GL 19-1995 and CAC/GL 25-1997; and (iii) a revision of CAC/GL 19-1995.

(i) Merging CAC/GL 19-1995 and CAC/GL 25-1997

55. The Committee agreed with the recommendation not to merge the two guidelines as this could create confusion between routine rejections against importing country standards and food safety emergency situations.

¹¹ CX/FICS 13/20/6; CRD 6 (Comments of Kenya and IDF); CRD 11 (Comments of European Union and Thailand)

(ii) Proposals to include feed in CAC/GL 19-1995 and CAC/GL 25-1997

56. The Committee recalled that the 19th CCFICS had discussed proposals from an electronic Working Group on future work on animal feeding to include feed in the two guidelines and had agreed that more reflection was needed on how these texts should consider feed in relation to food safety.

(a) CAC/GL 19-1995

57. The Committee agreed most of the proposed amendments, as presented in CX/FICS 13/20/6 Appendix 1, and made the following changes:

- To refer only to "feed" and to include the following footnote at the first occurrence of the term: "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)."
- To move the amendments concerning: the obligation to indicate the specific nature of the feed-related problem and its impact on food safety (from paragraph 9 to 7a); and the obligation to identify the feed related to the food safety emergency (from paragraph 12 to 9).

Conclusion

58. The Committee agreed to forward the draft amendments to the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) to the 36th Session of the Commission for adoption (*see* Appendix III).

(b) CAC/GL 25-1997

59. The Committee discussed the proposed amendments and agreed to include the same footnote to the term "feed" as in CAC/GL 19-1995 and to replace throughout the text "food control authority" with "competent authority".

Conclusion

60. The Committee was of the opinion that the other amendments proposed needed further reflection and, therefore, agreed that the United States of America would, in consultation with interested members, prepare a revised proposal for consideration at the next session.

(iii) Revision of CAC/GL 19-1995

61. The Committee recalled that at the 19th CCFICS had agreed that the United States of America prepare a discussion paper to address the need for further Codex guidance on: (i) the roles and responsibilities of the various parties/stakeholders involved in food safety emergency situations; (ii) the processes involved in responding to food safety emergency situations; and, (iii) communications associated with food safety emergency situations, taking into account Codex texts on emergencies and rejections (i.e. CAC/GL 19-1995 and CAC/GL 25-1997) and FAO/WHO guidance and mechanisms (e.g. INFOSAN, EMPRES) on food safety emergency situations.

62. The Committee considered the proposal for new work on the revision of CAC/GL 19-1995, as presented in CX/FICS 13/20/6, Appendix 2.

63. The Committee generally supported the proposal and made the following comments: the organizations mentioned in the document should be informed; the work should not address risk analysis, and risk management in particular, which were not within the CCFICS mandate; and the work should take into account new developments in information technology.

64. The Representative of FAO briefly introduced the FAO/WHO International Food Safety Authorities Network (INFOSAN), as well as the FAO Emergency Prevention System for Food Safety (EMPRES Food Safety), and indicated the willingness of FAO and WHO to contribute to this work.

Conclusion

65. Following the above considerations, the Committee agreed to establish an electronic Working Group, chaired by the United States of America, working in English only and open to all Codex members and observers to: (i) revise the project document; and (ii) prepare an outline of the proposed revision of the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995) for consideration at its next session.

DATE AND PLACE OF NEXT SESSION (Agenda Item 6)

66. The Committee noted that its 21st Session was scheduled in approximately eighteen months subject to further discussion between the Codex and Australian Secretariats.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document Reference (REP13/FICS)
Draft and Proposed draft Principles and Guidelines for National Food Control Systems (N06-2009) (Sections 1-3 at Step 6 and Section 4 at Step 3)	8 and 5/8	36 th CAC	Para. 38 and Appendix II
Draft amendments to <i>Guidelines for the</i> <i>Exchange of Information in Food Safety</i> <i>Emergency Situations</i> (CAC/GL 19-1995)	adoption	36 th CAC	Para. 58 and Appendix III
Discussion paper on principles and guidelines for the elaboration and management of questionnaires directed at exporting countries	-	eWG (Costa Rica) 21 st CCFICS	Para. 45
Discussion paper on principles and guidelines for monitoring regulatory performance of national food control systems	-	eWG (United States of America) 21 st CCFICS	Para. 53
Discussion paper on the revision of the <i>Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations</i> (CAC/GL 19-1995)	-	eWG (United States of America) 21 st CCFICS	Para. 65
Draft amendments to <i>Guidelines</i> for the <i>Exchange of Information between Countries on Rejections of Imported food</i> (CAC/GL 25-1997)	-	United States of America 21 st CCFICS	Para. 60

Appendix I

LIST OF PARTICIPANTS LISTE DES PARTICIPANTS LISTA DE PARTICIPANTES

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Appendix II

DRAFT AND PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS

(N06-2009)

(At Step 8 and 5/8 of the Procedure)

SECTION 1 INTRODUCTION

1. This document is intended to provide practical guidance to assist the national government, and their competent authority¹ in the design, development, operation, evaluation and improvement of the national food control system. It highlights the key principles and core elements of an efficient and effective food control system. It is not intended that the guidance results in "one system" being appropriate to all circumstances. Rather, various approaches may be used, as appropriate to the national circumstances, to achieve an effective national food control system.

2. While the focus of the Principles and Guidelines for National Food Control Systems is on the production, packing, storage, transport, handling and sale of foods within national borders, the document is consistent with and should be read in conjunction with relevant Codex texts. Codex texts of particular relevance include the *Principles for Food Import and Export Inspection and Certification* (CAC/GL 20-1995), the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification* (CAC/GL 26-1997), the *Guidelines for Food Import Control Systems* (CAC/GL 47-2003) and the *Guidelines for the Exchange of Information between countries on rejections of imported foods* (CAC/GL 25-1997). Reference to these texts relating to food import and export control is important since, while the national food control system is ultimately responsible for the safety of food offered within its border, in today's global market, much food is sourced from outside the country; hence, properly designed import and export control systems, as part of the overall national food control system, are essential.

3. In addition, the relevant chapters of the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code and Aquatic Animal Health Code are valuable resources for member governments and organizations. Documents and guidance material developed by FAO and WHO may also be useful resources².

4. A competent authority may apply these principles and guidelines, where appropriate, according to their particular situations.

5. When developing a national food control system national governments and their competent authority should ensure that the objectives of the system are addressed as outlined in the principles below and should allow for flexibility and modification as required to ensure the objectives can be achieved.

SECTION 2 OBJECTIVE OF A NATIONAL FOOD CONTROL SYSTEM

6. The objective of a national food control system is to protect the health of consumers and ensure fair practices in the food trade.

SECTION 3 PRINCIPLES OF A NATIONAL FOOD CONTROL SYSTEM

7. A national food control system should be based on the following principles:

PRINCIPLE 1 PROTECTION OF CONSUMERS

8. National food control systems should be designed, implemented and maintained with the primary goal to protect consumers. In the event of a conflict with other interests, precedence should be given to protecting the health of consumers.

PRINCIPLE 2 THE WHOLE FOOD CHAIN APPROACH

9. The national food control system should cover the entire food chain from primary production to consumption.

¹ Throughout the document "competent authority" refers to one or more competent authorities as appropriate

² http://www.fao.orf/food/food-safety-quality/publications-tools/food-safety-publications/en/

PRINCIPLE 3 TRANSPARENCY

10. All aspects of a national food control system should be transparent and open to scrutiny by all stakeholders, while respecting legal requirements to protect confidential information as appropriate. Transparency considerations apply to all participants in the food chain and this can be achieved through clear documentation and communication.

PRINCIPLE 4 ROLES AND RESPONSIBILITIES

11. All participants in a national food control system should have specific roles and responsibilities clearly defined.

12. Food business operators³ have the primary role and responsibility for managing the food safety of their products and for complying with requirements relating to those aspects of food under their control.

13. The national government (and in some cases a competent authority) has the role and responsibility to establish and maintain up to date legal requirements. The competent authority has the responsibility to ensure the effective operation of the national food control system.

14. Consumers also have a role in managing food safety risks under their control and where relevant should be provided with information on how to achieve this.

15. Academics and scientific institutions have a role in contributing to a national food control system, as they are a source of expertise to support the risk based and scientific foundation of such a system.

PRINCIPLE 5 CONSISTENCY AND IMPARTIALITY

16. All aspects of a national food control system should be applied consistently and impartially. The competent authority and all participants acting in official functions should be free of improper or undue influence or conflict of interest.

PRINCIPLE 6 RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING

17. A competent authority should make decisions within a national food control system based on scientific information, evidence and/or risk analysis principles⁴ as appropriate.

PRINCIPLE 7 COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

18. The competent authorities within a national food control system should operate in a cooperative and coordinated manner, within clearly assigned roles and responsibilities, for the most effective use of resources in order to minimise duplication and/or gaps and to facilitate information exchange.

PRINCIPLE 8 PREVENTIVE MEASURES

19. To prevent and when necessary to respond to food safety incidents a national food control system should encompass the core elements of prevention, intervention and response.

PRINCIPLE 9 SELF ASSESSMENT AND REVIEW PROCEDURES

20. The national food control system should possess the capacity and capability to undergo continuous improvement and include mechanisms to evaluate whether the system is able to achieve its objective.

PRINCIPLE 10 RECOGNITION OF OTHER SYSTEMS (INCLUDING EQUIVALENCE)

21. Competent authorities should recognise that food control systems or their components although designed and structured differently may be capable of meeting the same objective. This recognition can apply at the national and international level. The concept of recognition of systems, including equivalence⁵, should be provided for in the national food control system.

³ For the purpose of this document food business operator includes producers, processors, wholesalers, distributors, importers, exporters and retailers

⁴ In accordance with members obligations under the World Trade Organisation Agreements, risk analysis frameworks adopted by national governments in the context of a national food control system should be consistent with the Codex *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) and relevant risk analysis policies developed by the World Organisation for Animal Health (OIE).

⁵ Guidelines for the development of equivalence agreements regarding food import and export inspection and certification systems (CAC/GL 34-1999) and Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CAC/GL 53-2003).

PRINCIPLE 11 LEGAL FOUNDATION

22. The government within each country should have in place fundamental legal structures to enable the establishment of food laws and competent authorities, so that they can develop, establish, implement, maintain and enforce a national food control system.

PRINCIPLE 12 HARMONISATION

23. When designing and applying a food control system, the competent authority should consider Codex standards, recommendations and guidelines whenever appropriate as elements of their national food control system to protect the health of consumers and ensure fair practices in the food trade. Standards, recommendations or guidelines from other international inter-governmental organisations whose membership is open to all countries may also be useful.

PRINCIPLE 13 RESOURCES

24. A national food control system should have sufficient resources to enable it to meet the system's objectives.

SECTION 4 FRAMEWORK FOR THE DESIGN AND OPERATION OF THE NATIONAL FOOD CONTROL SYSTEM

25. The national food control system of a country will be based on that country's particular governmental or constitutional arrangements and institutions, (e.g. presence or absence of sub national governments), national goals and objectives.

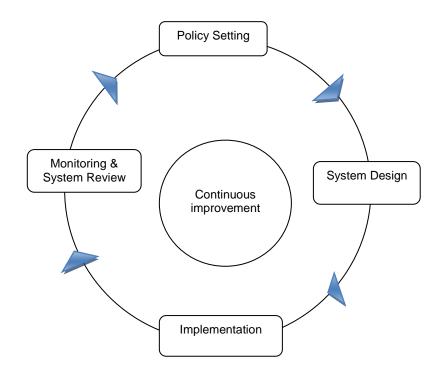
26. The competent authority has a pivotal role in the national food control system, in that the competent authority:

- Provides leadership and coordination for the national food control system;
- Designs, develops, operates, evaluates and improves the national food control system;
- Establishes, implements and enforces science and risk based regulatory requirements that encourage and promote positive food safety outcomes;
- Establishes, implements and enforces regulatory requirements supporting fair practices in the food trade;
- Establishes and maintains arrangements with supporting organizations such as officially recognised inspection, audit, certification and accreditation bodies, where appropriate;
- Advances and fosters knowledge, science, research and education regarding food safety;
- Engages with stakeholders to ensure transparency and to obtain their views; and
- Where appropriate, establishes and maintains arrangements with other countries e.g. cooperation programs, equivalence agreements etc.

27. Where there is more than one competent authority their roles and responsibilities should be clearly defined and their activities coordinated to the greatest extent possible to minimise gaps and overlaps.

28. The design and implementation of a national food control system should follow a logical and transparent process. This should include the consistent application of a systematic framework for the identification, evaluation and, as necessary, control of food safety risks associated with existing, new or reemerging hazards.

29. In developing a national food control system the competent authority, in consultation with stakeholders, should adopt the following framework, which will reflect the principles of a national food control system and are described in Section 3 this document.



Framework for the development of a national food control system

SECTION 4.1 POLICY SETTING

30. Policy setting is the process by which the goals and objectives for the national food control system are established by governments, along with the commitment to a course of action to achieve those goals and objectives. It should also include the identification and clear articulation of expected outcomes. Policy decisions guide subsequent actions, including the establishment of legislation and regulations.

31. Public policy decisions should take into account a broad range of factors and require a careful assessment of options. Governments should consider, among other things, stakeholder interests, how the food control system will relate to international and national standards, assessment of risks and/or benefits, effectiveness and efficiency of various controls and methods of oversight, existing and planned government structures, coordination among authorities along the food chain, technical and scientific information, the roles of government and food business operators, and best practices/models.

32. The competent authority should actively engage stakeholders, including food business operators and consumers, in the setting of policy.

33. National goals and priorities will ensure consumer protection by taking into account amongst other things, food production and consumption patterns, risk profile and consumer concerns in relation to food safety and fair practices in the food trade and also the preparedness and capability of the country.

34. When establishing a national food control system countries should identify the main objectives to be addressed through the system for the short, medium and long term. The main objectives should be aligned with and assist in implementing the principles outlined in Section 3. Consideration should be given to the development of a national food control strategy, which will aid clarification of the objectives to be addressed set priorities and support system design.

35. Once public policy goals and desired outcomes for the national food control system are established, they should be clearly articulated and described in order to effectively guide subsequent actions.

36. A national food control system should possess three main characteristics which, among other things, can be used in self-assessment or other evaluation to determine if the system is fully functional and effective:

i) Characteristic 1 Situational awareness means that a national food control system avails itself of accurate and current information on the entire food chain.

- ii) **Characteristic 2** Pro-activity means that a national food control system is capable of identifying existing or emerging hazards before they materialise as risks in the food production and/or processing chain and at the early stages rather than in the end product. Early warning and/or rapid alert systems, traceability and contingency planning for managing and preparing for potential food safety incidents should be an inherent part of a pro-active control system.
- iii) <u>Characteristic 3 Continuous Improvement</u> means that a national food control system should possess the capability to learn through a process of review and reform utilising mechanisms that check and evaluate whether the system is able to achieve its objectives.

37. Legislation⁶ should clearly reflect the intended policy objective and be commensurate with the risks they are intended to mitigate. Legislation should, where appropriate take into account relevant scientific information and focus on prevention and outcomes and thereby allowing flexibility and innovation.

- 38. In order to reflect national policies and strategies legislation should, amongst other things:
 - Frame the structure of the national food control system and its goals and objectives;
 - Provide clarity on the roles and responsibilities of participants in the national food control system, i.e. the central government, the competent authority (or of each competent authority where there is more than one), third party⁷ providers (where these are used), food business operators and other stakeholders as appropriate;
 - Set out the overarching objectives of the national food control system and any specific or lower order objectives that relate to participants or sectors;
 - Clearly define obligations for food business operators and other participants in the food chain to establish and monitor controls; and
 - Clearly define obligations on food businesses to place only safe food on the market and apply fair practices in trade.

39. The legislation should provide the competent authority with the range of powers and mechanisms sufficient to manage and operate the national food control system. These authorities may include and are not limited to the following:

- Establish standards or other management options to prevent and control food borne hazards such as disease-causing organisms, contaminants, veterinary drug and pesticide residues;
- Establish, monitor and enforce national standards;
- Recognise other competent authorities' standards at the appropriate stage(s) in the food chain;
- The establishment of cooperative arrangements with other government entities;
- Establish approaches to ensure the safety and safe use of inputs to the food chain, such as food additives, pesticides, veterinary drugs;
- · Recognise and/or harmonize with Codex standards;
- Perform audits, verification, inspections and investigations, gather evidence, collect and analyze samples and otherwise verify compliance with standards and requirements;
- Consider official recognition of inspection, audit, certification and accreditation bodies;
- Enforce legislation and take proportionate, dissuasive and effective action in case of non-compliance with requirements including, as appropriate, investigations and application of sanctions and penalties;
- Ensure that risks associated with non-compliant foods are evaluated and the appropriate action taken; e.g. disposal, treated appropriately or redirected.
- Ensure the integrity, impartiality and independence of officially recognized inspection, audit, certification and accreditation;
- Enable traceability/product tracing; and
- Ensure that unsafe food is prevented from entering the market or is withdrawn and dealt with appropriately.

⁶ Legislation as defined in *Guidelines for Food Import Control Systems* (CAC/GL 47-2003)

Guidelines for Food Import Control Systems (CAC/GL 47-2003) paragraph 8

40. Legislation may also include provisions, as appropriate, for the registration of establishments, establishment approval, licensing or registration of traders, equipment design approval, penalties in the event of non-compliance and charging of fees or levies.

41. The competent authority should, engage with stakeholders including the food business operators and consumers, in the development of new legislation, and when making regulatory changes. The competent authority should also disseminate the legislation.

SECTION 4.2 SYSTEM DESIGN

42. When designing a national food control system countries should ensure the main objectives as defined in the policy are addressed as well as how to incorporate the principles in Section 3.

- 43. The design of a food control system should take into account the following elements:
 - Existing or necessary regulatory and legislative framework (laws, regulations, guidance);
 - How the national food control system relates to international and national standards including food import and export system requirements;
 - The recognition of other food control systems, including equivalence⁸;
 - The level and method of oversight including control programs from primary production through manufacturing to transportation and distribution;
 - How issues and risks are managed;
 - Enforcement and compliance programs;
 - Coordination and communication between authorities with control responsibilities in different parts of the food chain and with the public health authorities;
 - Clearly defined roles and responsibilities;
 - Access to adequate laboratory capacity and capability;
 - Staff competence and training;
 - The resources needed to meet the objectives of the national food control system, their allocation and how the system is to be funded;
 - Surveillance, investigation, emergency preparedness and response to food borne and food related incidents;
 - Assessment and evaluation;
 - Stakeholder engagement;
 - International communication and harmonization; and
 - Periodic review and continuous improvement.

44. Consideration should be given to the development and implementation of a standardised approach to risk management incorporating the *Working principles for risk analysis for food safety for application by governments* (CAC/GL 62-2007).

45. An appropriate system design should consider a range of factors including (but not limited to) product risk, current scientific information, industry based controls and system review findings. It should also provide for flexibility in the application of control measures to reflect variations in these factors.

46. Development of an effective method of data collection across the food chain is important for situational awareness, performance measurement and continuous review and system improvement. For instance, surveillance and monitoring programs can be used to target priority risks.

47. The competent authority should utilise findings from laboratories to monitor trends in the food chain and assist in compliance and enforcement. Laboratory access and capacity should be commensurate with the need to address priority food risks.

48. The national food control system should be fully documented and publicly available, to ensure its transparency and consistent application of control measures, including a description of its scope and operation, and a clear description of the roles and responsibilities of all parties.

⁸ Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CAC/GL 53-2003)

49. National food control systems should be designed to ensure administrative procedures are in place for documentation of control programs and their findings.

50. Control programs⁹ should be based on risk and designed to take into account a number of factors¹⁰ including but not limited to:

- Food safety hazards associated with different products and the risk to human health posed by the food or food related products;
- Risk of unfair practices in the food trade associated with different products, such as potential fraud or deception of consumers;
- Information that may be available from a range of sources including government, academia, scientific institutions and industry data;
- Statistical data on production, trade and consumption;
- · Results of previous controls including analytical results;
- The effectiveness and reliability of controls including those of food business operators;
- Knowledge of operators at various stages of the food chain typical and atypical use of products, raw materials and by-products; structure of production and supply chains; production technologies, processes and practices; relevant product tracing information; and
- Epidemiological data on food borne disease.

51. In the absence of risk analysis data control programs should be based on technical and scientific data developed from current knowledge and practice.

52. Control programs should be applied at the point or points in the production or supply chain where hazards can be most effectively or efficiently controlled taking into account the available resources and capability. Control programs amongst other things may cover, as appropriate:

- Establishments, installations, equipment, personnel and material;
- Products, from raw material to the final products, including intermediate products;
- Preventative controls including Good Agricultural Practice GAP, Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) principles;
- Means of distribution; and
- Human resources, infrastructure and confidentiality.

53. Control programs should be designed to include the following elements but not limited to:

- Inspection, verification and audit including on-site visits;
- Market surveillance;
- Sampling and analysis;
- · Examination of written and other records;
- · Documentation of observations and of findings; and
- Examination of the results of any verification systems operated by the establishment.

54. Where quality assurance systems are used by food business operators, the national food control system should take them into account where such systems relate to protecting consumer health and ensuring fair practices in the food trade. The competent authority should encourage, as appropriate, the use of Good Laboratory Practices (GLP)¹¹ GAP, GMP, GHP and HACCP approach in accordance with *General Principles of Food Hygiene* (CAC/RCP 1-1969).

⁹ Control program is the collective actions and activities in place to manage specific food safety hazards and assure the quality and safety of food and fair practices in the food trade.

¹⁰ Effective use of these factors provides for system characteristics 1 and 2 as described in paragraph 36.

¹¹ Guidance on laboratory competency is available in the *Guidelines* for the assessment of the competence of testing laboratories involved in the import and export of food (CAC/GL 27-1997) and International harmonised protocol for the proficiency testing of (chemical) analytic laboratories (CAC/GL 28-1997) may be useful.

55. The system design should provide for the capability to evaluate the effectiveness of the national food control system. Verifying the effectiveness of the national food control system should be targeted at the most appropriate stages of the food chain, based on risk analysis conducted in accordance with internationally accepted methodology¹².

56. A national food control system should be subject to regular review of results obtained so that it can be continuously improved to reflect changes in product risk, the production environment (including technology), increased scientific knowledge, and level of confidence in industry, to ensure the objective of the national food control system is met in an efficient and effective manner.

57. Compliance and enforcement¹³ programs should be designed to provide the ability for the competent authority to take corrective action to ensure the situation is remedied where the food business operators are not meeting their obligations or a product or process is found not to be in conformity. Programs should be designed to:

- Be proportionate to the degree of public health risk or potential fraud or deception of consumers;
- Encourage acceptance of responsibility and compliance by all participants; and
- Provide for a full range of responses from provision of information or education material, imposing of corrective actions, setting of sanctions.
- Take into account repeated non-conformity by food business operators.

58. The competent authority and any officially recognised bodies undertaking compliance and enforcement activities on behalf of the competent authority should be resourced sufficiently and transparently to enable the national food control programs to achieve its objectives without compromising the programs integrity and independence. Third party providers may be approved and/or authorised to implement the national food control system and the competent authority must have capacity to supervise and control third party providers.

59. The design and implementation of a national food control system should be on a scale appropriate to the resources available, while allowing for appropriate expansion. Resources should be prioritized to maximise protection of public health. Resource allocations made in the context of a national food control system may, dependent on the above be attributed to:

- Training and basic infrastructure;
- Suitably qualified personnel of relevant disciplinary backgrounds
- Reliable transportation systems and equipment to perform inspection, audit and verification services and transmission of samples to laboratories; and
- Information, communication and technology (ICT) systems;

60. The design of a national food control system should incorporate timely access to adequate information relating to the surveillance, investigation and response to food borne illness and food related incidents. Such information can identify the risks or issues that need to be addressed and also whether or not the controls or measures in place are effective.

61. In order to respond to food safety emergencies, consideration should be given to the establishment of a national food safety emergency plan with establishment of a coordination arrangement with links to public health authorities, law enforcement agencies, food recall systems, risk assessment specialists, food business operators, and others. Traceability/product tracing systems¹⁴ provides for the timely identification of the sources for emergencies and allowing effective recall of affected products.

62. The national food control system should have procedures covering the prompt removal of unsafe food¹⁵. Setting up these procedures is the primary responsibility of food business operators and they should ensure that products that are deemed to be unsafe should be recalled, appropriately dealt with to ensure consumer protection. The competent authority should ensure appropriate consumer notification is carried out when distribution has occurred.

¹² Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)

¹³ Compliance and enforcement refers to the range of controls, procedures or other interventions undertaken by a competent authority or a third party on its behalf when monitoring or verifying food business operator compliance with official requirements including but not limited to, instigating any corrective measures to achieve compliance.

¹⁴ Principles for Traceability/product tracing as a tool within a food inspection and certification system (CAC/GL 60-2006)
¹⁵ Principles for traceability/product tracing as a tool within a food inspection and certification system (CAC/GL 60-2006)
and OIE Terrestrial Animal Health Code, Chapter 4.1.General principles on identification and traceability of live animals

63. Recall systems and other market withdrawal systems should be a coordinated effort between the competent authority and food business operators and be effective and enforceable. If the competent authority requires or requests a recall, operators should have an affirmative duty to give effect to established procedures to recover recalled products and to destroy or dispose of them properly. National laws should include penalties or sanctions for companies that fail to comply with recall requests.

64. In order to promote consumer confidence in food safety and ensure fair practices in the food trade, the competent authority should be clear and transparent in their communications relating to all aspects of the national food control system for which they are responsible, including the development, implementation and enforcement of the requirements.

65. Communication among public health (food safety), agriculture and other relevant authorities, consumers and consumer organizations, and food business operators should be an ongoing function of a competent authority with responsibility for a national food control system.

66. Consideration should be given to the development of communication programs to provide outreach and education programs and information exchange on food safety risks and mitigation steps which may be taken to reduce these risks, amongst regulators, food business operators, consumers and academia.

67. When developing an educational program the relevant authorities should clearly identify the target audience, the priority content and the strategies to be implemented. The educational materials developed should use language suitable for the intended audience. Basic elements of food safety educational activities should be widely disseminated, preferably using mass communication.

68. Where appropriate, the competent authority should utilize the *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995), the International Health Regulations (IHR), OIE disease notification requirements, IPPC regulations and the International Food Safety Authorities Network (INFOSAN), for national and international emergency notification and response.

SECTION 4.3 IMPLEMENTATION

69. Following the design or modification of the national food control system the competent authority should prepare an implementation plan including the sequence for different elements of design suitable with their preparedness and capability. This will require engagement and analysis by a variety of experts, disciplines and all stakeholders. The competent authority's plan may include;

- Priorities and time frames for implementation;
- Deliverables;
- Responsibilities for implementation;
- Allocation of resources for personnel and infrastructure;
- · Training and operation manuals; and
- Stakeholder engagement.

70. Guidance and instructions relating to the national food control system, control programs and compliance and enforcement, including legal requirements should be developed for competent authority staff and food business operators to ensure;

- That all participants are fully aware of the objectives of the system and what is expected from them;
- Uniform application of legislation; and
- That they have the necessary resources (human, material and financial resources) available to carry out their tasks.

71. Programs and training manuals should be developed and maintained to ensure consistent application of requirements. This material should include as appropriate and not limited to:

- An organizational chart of the official control system;
- Roles of each level in the hierarchy (including other relevant jurisdictions; i.e. State, Provincial);
- Job functions and qualifications as appropriate;
- Operating procedures including methods of audit, verification, inspection and control, sampling plans, and testing;
- · Relevant legislation and requirements;
- · Processes and procedures relating to compliance and enforcement;

- Arrangements for coordination with relevant competent authorities and stakeholders;
- · Relevant information about food contamination and food control;
- Procedures for dealing with food safety emergencies and conducting food recalls and investigations;
- Relevant information on staff training; and
- Formal review process of the national food control system.

72. National food control systems should be supported by training programs designed to ensure that all appointed officers (e.g. inspectors or verifiers), analysts, and other individuals carrying out technical and/or professional duties receive the training required to adequately perform their work assignments and to maintain their professional competence and ensure consistent application of requirements.

73. The competent authority should ensure that sufficient guidance, training and awareness programs targeted at all relevant stakeholders are in place to facilitate effective notification of suspect cases of food related illnesses or health hazards detected in the food chain. Administrative procedures or contingency plans (as appropriate) should provide guidance on initiating coordination mechanisms when involvement of several competent authorities is required to resolve the incident. Rapid alert systems and response should be designed and implemented for this purpose.

74. Food business operators should also be encouraged to develop or access training and education programs relevant to their activities and responsibilities. Such programs can include formal education and/or academic studies, industry training organisation courses or individual business staff training

75. Where a competent authority intends to use third party¹⁶ providers to implement controls, before being authorised the third party provider should be assessed against objective criteria to ensure their competency. The ongoing performance of officially authorised bodies should be regularly assessed by the competent authority. The competent authority should initiate procedures to correct deficiencies and, as appropriate, enable withdrawal of official authorisation.

76. Competent authorities should utilize laboratories that are authorised or accredited under officially recognized programs to ensure that adequate quality controls are in place to provide for the reliability of test results. Internationally recognized and validated analytical methods should be used wherever available and Good Laboratory Practices should be adhered to.

77. Competent authorities should ensure that authorised or accredited laboratories¹⁷ participate in regular proficiency testing. Such testing may be organised nationally or internationally and reference laboratory may have a role in organising proficiency testing programs.

78. Where appropriate, the competent authority should provide access to educational information on food safety risks and mitigation steps, which may be taken to reduce these risks.

79. As appropriate, the competent authority should:

- Communicate food safety issues and concerns with (relevant competent authorities) trading partners;
- Participate in bilateral exchange with (relevant competent authorities) trading partners and international organisations related to food safety regulations and their enforcement;
- Communicate and collaborate with international organisations, such as FAO and WHO through International Food Safety Authorities Network (INFOSAN), WHO in accordance with the International Health Regulations (2005) and OIE as appropriate, in cases where food(s) implicated in incidents or outbreaks of food borne illness may be circulating in international trade and.
- Have in place a process for engagement with stakeholders including food business operators, consumers and other interested parties.

80. The competent authority should implement a range of food control activities, including inspections, audits, verification and surveillance to ensure that food business operators meet their responsibilities and are in compliance with requirements. Detailed procedures should be developed to articulate the key tasks and responsibilities of verification of compliance and the consequences of non-compliance, including repeated non-compliance.

¹⁶ Guidelines for Food Import Control Systems (CAC/GL 47-2003) paragraph 8

¹⁷ Guidance on laboratory competency is available in the *Guidelines for the assessment of the competence of testing laboratories involved in the import and export of food* (CAC/GL 27-1997) and the *International harmonised protocol for the proficiency testing of (chemical) analytic laboratories* (CAC/GL 28-1997) may be useful.

81. Where a product or process is found not to be in conformity, the competent authority should take action to ensure that the operator remedies the situation. The resulting measures should take into account any repeated non-conformity of the same product or process to ensure that any action is proportionate: to the degree of public health risk, potential fraud or deception of consumers. As an example to illustrate this point the specific measures that may be applied in continuous cases of non-conformity may include:

- Increased intensity of audits and/ or inspection and/or monitoring of products and/or processes; identified as being not in conformity and/or the undertakings concerned; and
- In the most serious or persistent cases, de-registration of the producer and/or processor or closure of the relevant establishment.

SECTION 4.4 MONITORING AND SYSTEM REVIEW

82. The effectiveness and appropriateness of the national food control system should be regularly assessed against the objective of the system, effectiveness of control programs, as well as against legislative and other regulatory requirements. Criteria for assessment should be established, clearly defined and documented, and may also include cost benefits and efficiency.

83. Control programs should be subject to ongoing monitoring to ensure that its objectives are being achieved at all stages of the food chain, including production, manufacture, importation, processing, storage, transportation, distribution and trade. The assessment of control programs should cover issues such as:

- Effectiveness of control procedures;
- Suitability in achieving objectives;
- Whether the program has covered relevant stages in the production chain, taking into account risk factors; and
- Consideration of emerging trends.

84. A national food control system should be regularly reviewed to contribute to the systems improvement, in response to for example, control program data, non-compliances, food safety incidents, scientific research, and history of conformance, external and self-reviews of the system and changes to product risk or the production environment. Such reviews may take place at the level of system or program design or implementation as appropriate.

85. The review of food-related non-compliances and/or incidents is an opportunity to learn which can be used as a feedback loop for the planning process by the competent authority. A competent authority should use these opportunities to engage in continuous improvement by assessing an incident from first signal through response and incorporating lessons learned in the design and planning phase.

86. Competent authorities should ensure that the response system in regards to food safety and related events is effective, with clear communication between competent authorities, food business operators and consumers. These systems should be periodically tested to ensure that the communication and response systems work effectively.

87. Competent authorities and/or national governments should periodically review their surveillance systems with respect to their capacity to recognize emergencies rapidly. Elements of review include:

- Links between the symptomatic food borne illness surveillance system and the food monitoring system;
- Data on the symptoms and effects of chronic exposure to food borne contamination;
- · Systems to allow rapid detection of contamination incidents to ensure prompt public alerts; and
- Links with the veterinary public health sector.

88. Particular attention should be paid to early warning mechanisms, coordination between competent authorities, communication to stakeholders and the use and effectiveness of contingency planning. Corrective action should be taken as appropriate.

89. A competent authority should utilize information gained from the surveillance of food borne illness as a risk management tool in the operation of their food control systems. Food recalls and adjustments to food production and processing operations, including emergency responses, may be based on information obtained from food borne disease information and food monitoring systems. Food borne illness and outbreak information should be used to inform the risk analysis activities of competent authorities.

90. The results of the evaluations¹⁸, including the results of self-assessment and audits should also be taken into account in further improvement of the system, and corrective actions should be taken into account as appropriate.

91. Any review and continuous improvement of the national food control system should be communicated effectively and efficiently to ensure that clear exchange of information and engagement between all stakeholders in the national food control system occurs. Following any review, all related documentation, procedures and guidance should be reviewed and updated if necessary to reflect any changes.

92. Competent authorities should consider the results of monitoring and review processes and take preventive or corrective action or improve the system as appropriate.

¹⁸ For example, the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) provides for independent evaluation of the performance of veterinary services. The OIE PVS tool could be used to evaluate the veterinary public health related elements of the national food control system.

Appendix III

DRAFT AMENDMENTS TO THE

PRINCIPLES AND GUIDELINES FOR THE EXCHANGE OF INFORMATION IN FOOD SAFETY EMERGENCY SITUATIONS

(CAC/GL 19-1995)

(for adoption)

Notes:

Only paragraphs and items where changes have been proposed in the existing Codex text are shown. Additions are presented in **bold/underlined font** and deletions in **bold/strikethrough font**.

SCOPE

Paragraph 3

These Principles and Guidelines apply to situations where the competent authorities in either the importing and/or exporting countries become aware of a food safety emergency situation, and communication of the information and risks surrounding the emergency situation must be undertaken. <u>The guidance applies to</u> feed¹ whenever the use of the feed may result in an unsafe food.

Paragraph 5

The Principles and Guidelines apply to food safety emergencies associated with imported or exported food or food that may potentially be imported or exported. The Principles and Guidelines may also apply to such emergencies where feed**stuffs** for food producing animals are implicated.

PRINCIPLES

Paragraph 7, point (a)

7. a) Its nature and extent should, where possible, be clearly and completely described by the relevant competent authorities. If the basis for the food safety emergency situation is related to the use of feed, the specific nature of the feed related problem and its impact on food safety should be indicated.

NATURE OF THE FOOD SAFETY EMERGENCY

Paragraph 9

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 is 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 given geographical area, all affected foods should be identified. If the food safety hazard is associated with feed, the feed should be clearly identified.

Paragraph 11, second sentence.

Necessary information includes the name of the competent authority and the contact details including name, address, phone numbers, facsimile numbers, and email addresses of the persons or offices that are responsible for managing the emergency situation and who can provide further details about the hazard, the foods <u>or, as appropriate, the feed</u> concerned, actions taken and other relevant information.

INFORMING ALL KNOWN AFFECTED AND POTENTIALLY AFFECTED COUNTRIES

Paragraph 12.

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(s) and all countries from which the potentially contaminated food <u>or</u>, <u>when appropriate</u>, <u>feed</u> 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 thus identified.

¹ 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)

INFORMATION TO BE EXCHANGED

Paragraph 16, Point (a)

a) The **origin and** nature of the food safety emergency including the hazards and risks identified, the methodology used and any assumptions made;

Paragraph 16, Point (b)

b) Detailed identification of the food or foods <u>or, if appropriate, the feed</u> concerned including <u>its origin</u>, product markings, certificate information;

Paragraph 22

In deciding on the appropriate communication measures to apply, the competent authorities should consider the quantity of food <u>or as appropriate, feed</u> that is involved, the extent of its distribution and the level (e.g. wholesale, retail) at which it has been distributed. In some cases, the affected food may not yet have entered the importing country and communication will focus on the importers. However, in other cases the food will have entered and been distributed within the country or transshipped to other countries. The competent authority should take account of whether the food has been, or is likely to have been, distributed at the wholesale, retail or consumer level, and implement risk management and communication measures accordingly, including a notice of recall at one or more of these levels of food distribution.

ANNEX

STANDARD FORMAT FOR INFORMATION EXCHANGE IN FOOD SAFETY EMERGENCY SITUATIONS

Item 2.

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

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