CODEX ALIMENTARIUS COMMISSION

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Food and Agriculture Organization of the United Nations

World Health Organization

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REP18/FH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-first Session

Rome, Italy

2 – 6 July 2018

REPORT OF THE FORTY-NINTH SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Chicago, Illinois, United States of America

13 – 17 November 2017

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LIST OF ABBREVIATIONS

CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CCP	Critical Control Point
CRD	Conference Room Document
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point
ISO	International Organization for Standardization
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
OIE	World Organization for Animal Health
PWG	Physical Working Group
SFP	Scombrotoxin fish poisoning
STEC	Shiga toxin-producing *Escherichia coli*
VTEC	Verotoxigenic *E. coli*
WHO	World Health Organization
WG	Working Group

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its 49th Session in Chicago, Illinois, the United States of America, from 13 to 17 November 2017, at the kind invitation of the Government of the United States of America. Dr Emilio Esteban of the United States of America Department of Agriculture (USDA), chaired the Session. The Session was attended by participants from 65 member countries, one member organization, 12 observer organizations, and FAO and WHO. The list of participants, including the Secretariats, is contained in Appendix I to this report.

OPENING OF THE SESSION[1]

2. Ms Mary Frances Lowe, U.S. Codex Manager, USDA opened the Session. Mr Ted McKinney, Under Secretary for Trade and Foreign Agricultural Affairs (TFAA), USDA, in his opening remarks, expressed his strong commitment to Codex and highlighted the importance of the science-based approach in the development of Codex standards. Dr Robert Brackett, Vice President and Director, Institute for Food Safety and Health, Illinois Institute of Technology, as keynote speaker, talked about the unique challenges for small and developing economies in addressing food safety.

Division of Competence[2]

3. The Committee noted the division of competence between the European Union (EU) and its Member States, according to paragraph 5, Rule II, of the Rules of Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda item 1)[3]

4. The Committee adopted the Agenda.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX SUBSIDIARY BODIES TO THE FOOD HYGIENE COMMITTEE (Agenda item 2)[4]

5. The Committee noted the matters for information and took the following decision.

Relationship between dried aromatic herbs and culinary herbs

6. Noting the clarification provided by CCSCH3, the Committee requested the Secretariat to replace “aromatic herbs” by ““culinary herbs” in the *Code of Hygienic Practice for Low-Moisture Foods* (CXC 75-2015) and for adoption by CAC41.

MATTERS ARISING FROM THE WORK OF FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 3)

Progress Report on the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) and Related Matters (Agenda item 3(a))[5]

7. The Representatives of FAO and WHO highlighted key activities since CCFH48.

Shiga toxin-producing *Escherichia coli* (STEC)

8. The Representative of FAO reported on the deliberations and outputs of the second FAO/WHO expert meeting on STEC convened in September 2017. Highlighting the key findings, it was noted that: (i) STEC poses a health burden worldwide as well as an economic burden and also impacts on trade; (ii) results of the source attribution work (based on expert elicitation and outbreak data) indicated beef, vegetables/fruits, dairy (primarily from unpasteurized products), and small ruminants’ meat as the most important sources of foodborne STEC illness; (iii) the use of virulence factors (genes) to predict the risk of severe illness associated with STEC in foods was recommended; and (iv) where STEC is identified as a food safety risk, monitoring should be risk-based, target high-risk foods and be implemented at points in the food chain where effective intervention is possible. The Representative noted the difficulties of having data from all regions and urged countries to provide any data they had on STEC outbreaks and/or case control studies of sporadic cases as soon as possible, for incorporation into the source attribution study to improve its global representativeness.

Conclusion

9. The Committee noted the information (see Item 6).

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1 CRD17 (Speeches of opening session)
2 CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)
3 CX/FH 17/49/1
4 CX/FH 17/49/2; CRD15 (Dominican Republic)
5 CX/FH17/49/3; CRD7 (ISO)

Water quality

10. The Representative of WHO reported on the preliminary findings of the FAO and WHO meeting of a core expert group established to address the request of CCFH48. She noted the conclusion of the group that there is no universal definition for clean water and highlighted the recommendation to take a risk-based approach with the objective of achieving "fit-for-purpose" water. The Representative noted that this risk-based approach was consistent with the WHO Guidelines for Drinking-Water Quality. It was also highlighted that moving towards this approach may require the Committee to consider how it addresses water safety in its texts in the future.

Conclusion

11. The Committee in general supported the approach being developed by FAO and WHO noting that it would be further developed in the coming months. The Committee noted that once the report was available, it would be possible to make an informed decision on how to address the issue of water safety in the context of Codex texts.

Histamine in fish and fishery products

12. The Representative of FAO reported the key findings of the comprehensive literature review regarding the risk of histamine development in Salmonidae which highlighted that under appropriate time-temperature control, and within the sensory shelf-life of the product, histamine development to the level that would cause scombrotoxin fish poisoning (SFP) was unlikely to occur. She also noted that the epidemiological evidence for histamine related illness linked to Salmonidae is scant and that the available evidence suggest that histamine in Salmonidae is not a significant public health risk.

Conclusion

13. The Committee thanked FAO and WHO for the report and noted that it would be considered under agenda item 5.

Other related issues

14. The Committee was informed on other FAO and WHO activities, including work on: guidance on shellfish sanitation programme; updating the risk assessment methodology; antimicrobial resistance; whole genome sequencing and food safety; good hygienic practices; and risk-based meat inspection.

15. The Committee was also informed on the activities being undertaken and information prepared by FAO, WHO and OIE for the World Antibiotic Awareness Week (13-19 November 2017).

Information from the World Organisation for Animal Health (OIE) (Agenda item 3(b))[6]

16. The Observer from OIE highlighted key activities since CCFH48, including: the decision of the OIE World Assembly of Delegates, at the 2017 General Session, to disband the Working Group on Animal Production Food Safety (APFS) in view of the integration of APFS in the work of OIE and the inclusion of APFS in the FAO/WHO/OIE Tripartite collaboration; the adoption of the two new chapters on *Salmonella* in pig and bovine production systems, respectively, published in the 2017 edition of the OIE *Terrestrial Code*; the ongoing work on the review of the *Terrestrial Code* chapters on the Role of veterinary services in food safety and the Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

17. The Observer noted the high level of collaboration between Codex and OIE at the international and national levels and the high priority on food safety related issues in OIE standard setting work. The Observer also noted that the OIE would consider work on STEC when Codex will undertake new work.

Conclusion

18. The Committee thanked OIE for the information and congratulated them for the excellent collaboration.

[6] CX/FH 17/49/4; CRD8 (Ghana); CRD 12 (Senegal); CRD13 (African Union)

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969) AND ITS HACCP ANNEX (Agenda item 4)[7]

19. The United Kingdom, as Chair, introduced the report of the PWG (CRD2) and explained that a general agreement had been reached on fundamental starting points on the further development of the ongoing revision.

20. While the Committee supported the points in CRD 2 as fundamental starting points to guide the revision, it noted that point vi. regarding hazard analysis, would need further consideration.

Conclusion

21. The Committee agreed to:

- consider the points in CRD2 as a basis for the further development of CXC 1-1969;
- establish an EWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and United States of America, working in English, French and Spanish to:
  - continue revision of the three parts of the document (Introduction, GHPs, HACCP) taking into account the discussions at CCFH49 and the written comments submitted;
  - clarify the relationship of the three types of control measures: GHPs, control measures essential for safety that are applied at Critical Control Points (CCPs), and control measures essential for safety that are not applied at CCPs, using examples; and
  - clarify how food business operators come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.
- establish a PWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and United States of America, to be held immediately prior to CCFH50 and working in English, French and Spanish, to consider all comments received and to prepare a revised proposal for consideration by the plenary.

22. The Committee noted that the report of the EWG would be made available to the Codex Secretariat at least three months before CCFH50 for circulation for comments at Step 3.

PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CXC 52-2003) (Agenda item 5)[8]

23. Japan, co-chair of the EWG, introduced the item and explained that the draft guidance focused on fishing vessels, which is the critical point for the control of histamine formation. The comments submitted highlighted some outstanding concerns, in particular, the challenge in implementing HACCP principles. The co-chairs had prepared a revised proposal (CRD6) based on all written comments and proposed to use this as a basis for discussion.

Discussion

24. The Committee agreed with most of the proposals in CRD6, and in addition made editorial corrections, amendments for flexibility, clarity and consistency with other sections and definitions of the Code (e.g. definition for chilling and relation with the section 18: processing of fish sauce) and made the following comments and decisions.

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7 CX/FH 17/49/5; CX/FH 17/49/5-Add.1 (Argentina, Australia, Brazil, Canada, Chile, Colombia, Ecuador, Japan, New Zealand, Norway, Paraguay, Philippines, Switzerland, United States of America, Uruguay, FoodDrinkEurope, IAF, SSAFE); CX/FH 17/49/5-Add.2 (El Salvador, European Union, India, Japan, Kenya, Panama, Senegal, Thailand, AU); CRD2 (Report of PWG on HACCP); CRD5 (Australia); CRD8 (Ghana); CRD10 (Mali); CRD11 (Indonesia); CRD14 (Morocco); CRD15 (Dominican Republic); CRD16 (ISO)

8 CX/FH 17/49/6; CX/FH 17/49/6-Add.1 (Argentina, Brazil, Canada, Ecuador, European Union, Kenya, Morocco, New Zealand, Paraguay, USA); CRD6 (Proposed draft guidance for histamine control in the *Code of Practice for Fish and Fishery Products* (CXC 52-2003), (Revised) - prepared by the EWG Chairs); CRD 8 (Ghana), CRD9 (Republic of Korea); CRD10 (Mali); CRD14 (Morocco); CRD15 (Dominican Republic)

Preamble

25. The Chair of the Committee recalled the decision of CCFH48 to create a table/list based on Table 2.3 of the Joint FAO/WHO Expert Meeting report (2013), in the draft guidance with species associated with histamine formation, but could not agree whether Salmonidae should be included. In view of this, the Committee had agreed to request FAO/WHO to conduct a literature review related to histamine development in fish of the family Salmonidae and provide this information to CCFH49. FAO/WHO did this review and provided its summary and conclusions in CX/FH 17/49/3. He reiterated that the key findings indicated: (i) few confirmed cases of illness over a long period of time; (ii) low levels of histidine; (iii) formation of histamine albeit at levels generally below existing Codex limit; and (iv) a high volume of production and trade with no identified rejections linked to histamine, suggesting that the family Salmonidae do not present a significant risk of histamine poisoning.

26. In considering the inclusion of Salmonidae, the Committee was reminded that, as risk managers, the Committee should make a risk management decision commensurate to the risk, bearing in mind that there is no such thing as zero risk. The options presented to the Committee were whether or not to retain a list and if so, whether the list should include only those species which present the greatest potential for histamine development or include all species identified in the hazard identification table (Table 2.3) of the report of the FAO/WHO Expert meeting. The Committee was further reminded that the table was not a risk-based list, but rather a list of species that represented potential sources of histamine hazard; inclusion of all the species from this table in this guidance on histamine control would not be risk-based and could present an unnecessary burden to both industry and regulators.

27. The Committee first agreed that a list should be included in the guidance as it would enable the user to understand to which species the guidance applied.

28. Different views were expressed regarding the composition of the list. Some delegations were of the opinion that the list should include only those species that presented the highest potential for developing histamine and causing scombrotoxin fish poisoning (SFP), which would mean excluding Salmonidae from the list. This would ensure that risk management measures taken would be proportionate to the risk.

29. Others expressed preference for an exhaustive list with all species identified in the FAO/WHO Expert Meeting report (2013), including Salmonidae, noting that small quantities of histamine could also constitute a risk, particularly for susceptible individuals. They noted that the FAO/WHO Literature Review had confirmed that Salmonidae contains histidine, has been linked to SFP and levels of histamine exceeding current limits had been detected and on this basis, as risk managers, it was necessary to take risk management measures to control histamine in salmon.

30. It was subsequently highlighted that the FAO/WHO Literature Review also noted that: (i) histidine levels in Salmonidae were lower than in other species; (ii) only a small number of cases of SFP were identified in a 40 year period and it was not always clear if the SFP was linked to histamine or other biogenic amines; and (iii) when higher levels of histamine in Salmonidae were detected, the product was at the end of its shelf-life or data on the state or storage condition of the fish were not available. It was further pointed out that the aim of Table 2.3 in the report was for hazard identification, the first step of risk assessment, and not for risk management purposes.

31. The Committee noted that this guidance would be part of the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) which states that the "*Code will assist all those engaged in the handling and production of fish and fishery products or concerned with the storage, distribution, export, import and sale in attaining safe and wholesome products that can be sold on national or international markets and meet the requirements of Codex standards*." The levels set in related standards for safety was 20 mg/100 g. The Committee further noted that in some sections of the Code (e.g. Section 13: Smoked fish, smoke-flavoured fish and smoke-dried fish) and related fish and fishery product standards, reference was made to six families associated with SFP (i.e. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae) and the Committee thus considered whether to list only these families.

Conclusion

32. In a spirit of compromise, the Committee agreed to list the six families already referenced in CXC 52-2003 and noted that the list could be expanded in future.

33. Morocco and Mauritania expressed their reservation to the non-inclusion of Salmonidae in the list despite the numerous justifications, notably that in their view: (i) the decision was dictated more by economic legitimacy than for public health reasons; (ii) the FAO/WHO Expert Meeting report had confirmed several cases of histamine poisoning caused by salmon; (iii) in the case of scientific uncertainty, the precautionary principle should apply; (iv) and the low content of histamine in any case cannot justify its exclusion from the list of species causing SFP.

Other sections

34. The Committee amended the section on vessel operations to highlight that such operations are primary production and therefore do not need to apply HACCP principles as GMP was sufficient to control histamine. The Committee further recognised that in the absence of information to document on-vessel histamine control then testing at the receiving establishment was appropriate.

35. The guidance was made applicable to all fishing vessels, including artisanal boats, by deletion of reference to HACCP principles with a focus on control measures, such as temperature control, and the need for record keeping and documentation.

36. The Committee noted the importance of having text to emphasise that implementation of histamine control measures was more important for ensuring safety of the product than histamine testing. Histamine testing needed to be statistically meaningful which in turn could be resource intensive.

37. In order to avoid the possible confusion and misuse of the typical histamine level in freshly harvested scombrotoxin forming fish and the achievable histamine level by applying HACCP, the Committee agreed to revise section X.2.4.1, including the title, and to include a chapeau which explained the reason for a receiving establishment to set an acceptable histamine level, and highlighted the information that could assist in establishing this level. The levels were moved to a footnote and attributed to the FAO/WHO Expert report.

Further work on histamine

38. The Committee noted that work was still necessary to identify an appropriate place for the guidance in CXC 52-2003, and to consider whether the inclusion of the new guidance would require amendment of other sections of CXC 52-2003, which contain technical guidance on histamine.

39. The Committee recalled that further work was still needed on the revision of sampling, examination and analyses section in standards for fish and fishery products related to histamine food safety (see project document in CX/CAC 16/39/7).

Conclusion

40. The Committee:

- agreed to establish an EWG, chaired by Japan and co-chaired by the United States of America, working in English, to continue working on the outstanding issues identified in paragraphs 38 and 39;
- noted the offer of Chile to assist with translation of documents into Spanish and the offer of France to explore the possibility to translate documents into French; and
- agreed to forward the guidance for adoption by CAC41 at Step 5/8 (Appendix II) and noted that the guidance would be published only once consequential alignment amendments to relevant sections of CXC 52-2003, if any, were finalised and adopted by the Commission.

41. The Committee noted that the report of the EWG would be made available to the Codex Secretariat at least three months before CCFH50.

OTHER BUSINESS AND FUTURE WORK (Agenda item 6)[9]

New Work / Forward Workplan

42. The United States of America, as Chair of the PWG, introduced CRD3 and provided an overview of the discussions and recommendations.

43. The Committee considered the recommendations of the PWG and took the following decisions.

Revision to the Process by Which the Codex Committee on Food Hygiene Will Undertake its Work

44. The Committee agreed with the revised document for posting on the Codex website (Appendix III).

New work

a) *Code of practice on food allergen management for food business operators*

45. Australia, noted that while the PWG had agreed to develop a discussion paper they were still willing to start the new work as this would still align, as appropriate, with the ongoing discussions on allergen labelling in CCFL.

[9] CL 2017/68-FH; CX/FH 17/49/7; CRD3 (Report of the PWG on CCFH work priorities); CRD4 (Proposal by the Chair of the PWG on CCFH work priorities); CRD7 (ISO); CRD8 (Ghana); CRD10 (Mali); CRD12 (Senegal); CRD13 (African Union); CRD14 (Morocco); CRD15 (Dominican Republic)

46. The Secretariat noted, that should new work be agreed, then the project document would need to be revised by: i) clarifying the relationship with food labelling; ii) identifying the need for expert scientific advice; iii) completing the information on an assessment against the five criteria applicable to general subjects as requested in the Procedural Manual.

47. Noting the high priority accorded to this work in the Committee's ranking, and that the agenda of the Committee could accommodate new work, the Committee clarified the purpose and scope as follows:

> "*The purpose of the Code of Practice (CoP) will be to provide guidance to food business operators and governments to manage allergens in food production, including controls to prevent cross-contact. Food allergen management also involves allergen labelling which is addressed by the GSLPF.*"

Conclusion

48. In view of the agreement on the scope, the Committee agreed to:

- start new work;
- request Australia and the United States of America to submit the revised project document to the Codex Alimentarius Commission (through the Secretariat) for approval as new work; and
- establish an EWG, chaired by Australia and co-chaired by the United Kingdom and the United States of America, working in English only, to prepare, subject to the approval of the Commission, the proposed draft Code for circulation for comments at Step 3 and consideration at CCFH50.

49. The Committee noted that the report of the EWG would be made available to the Codex Secretariat at least three months before CCFH50 for circulation for comments at Step 3.

b) *Guidance for the management of (micro)biological foodborne crises/outbreaks*

50. The European Union highlighted that this proposal was also accorded a high priority and clarified that the work, was intended to supplement FAO/WHO guidance and Codex texts, and that the guidance would also be addressed to food business operators. The option of a discussion paper would unnecessarily delay this urgently needed work and proposed that the Committee agree to start new work.

51. The Secretariat noted, that should new work be agreed, then the project document would need to be revised in particular to explain the relation between the proposal and other Codex documents, such as CCFICS and CCFH texts.

52. Delegations in favour of starting the new work were of the view that the guidance would assist the management of crises/outbreaks at national level and should not be delayed, while delegations in support of developing a discussion paper first, indicated that a detailed gap analysis of existing mechanisms (INFOSAN) and FAO, WHO and Codex documents would help defining the need for this work. More information was necessary to take into account the needs for addressing crises/outbreaks management in other regions.

53. Noting the high priority accorded to this work in the Committee's ranking, and that the agenda of the Committee could accommodate new work, the Committee clarified the purpose and scope as follows:

> *"The purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crises, including the communication between national programmes with "INFOSAN. The guidance intends to address preparedness, detection, response and recovery with the intent of limiting the extent of such events. The scope is limited to biological hazards. This guidance intends to provide a supplement and a link to documents developed by FAO/WHO and Codex texts, as appropriate. The document will define the role of competent authorities and collaboration with food business operators and other stakeholders during foodborne outbreaks/crises."*

Conclusion

54. In view of the agreement on the scope, the Committee agreed to:

- start new work;
- request the European Union to submit the revised project document to the Codex Alimentarius Commission (through the Secretariat) for approval as new work; and
- establish an EWG, chaired by Denmark and co-chaired by Chile and the European Union, working in English and Spanish, to prepare, subject to the approval of the Commission, the proposed draft guidance for circulation for comments at Step 3 and consideration at CCFH50.

55. The Committee noted:

- the request for supporting the participation of francophone countries; and
- that the report of the EWG would be made available to the Codex Secretariat at least three months before CCFH50 for circulation for comments at Step 3.

Other

Discussion paper on future work on STEC

56. The Committee confirmed the CCFH48 decision that a discussion paper on future work on STEC would be prepared by the United States of America, Uruguay and Chile for consideration at CCFH50. The Committee agreed that the discussion paper should address all categories of foods associated with human STEC illnesses identified as a major risk by the report of the FAO/WHO Expert meeting.

Forward Workplan

57. The Committee agreed to:

- the forward workplan (Appendix IV);
- request the Secretariat to issue a Circular Letter requesting proposals for new work; and
- establish a PWG on CCFH Work Priorities, which will be held in conjunction with CCFH50, working in English, French and Spanish, and chaired by the United States of America and co-chaired by Panama.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 7)

58. The Committee was informed that the next Session was scheduled to be held on 12 to 16 November 2018, and would be co-hosted by Panama, the final arrangements being subject to confirmation by the Secretariats.

Appendix I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

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Appendix II

PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CXC 52-2003)
(SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION)

(At Step 5/8)

SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION

Preamble

This section complements other sections of the Code by providing detailed control recommendations for the prevention of scombrotoxin fish poisoning (SFP). This section only applies to specific marine finfish species (Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae) that present the greatest potential for developing hazardous levels of histamine. This section contains specific guidelines for preventing SFP; however, within the scope of this Code, it is not possible to provide all the appropriate controls and alternatives that may apply to every operation because these will vary with each particular operation.

SFP is a worldwide food safety challenge that, in some parts of the world, accounts for the largest proportion of fish-borne illness cases. Individuals suffering from SFP may show one or more symptoms including flushing, swelling, rash, itching, headache, heart palpitations, abdominal cramps, diarrhoea, and vomiting. In some cases, exacerbation of asthma and more serious cardiac manifestations may occur. Symptoms typically develop rapidly (from 5 minutes to 2 hours after ingestion of implicated fish), with a usual duration of 8–12 hours, although symptoms may persist for up to several days. SFP is rarely fatal. Scombrotoxin poisoning is generally a mild disorder where the symptoms disappear quickly after an anti-histamine treatment and where no known long-term sequelae were reported.

Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish that have been subjected to conditions that are favourable for the multiplication of bacteria and development of scombrotoxin, such as time-temperature abuse. Generally, this takes place at a temperature of more than 25°C over a period of more than six hours or for longer at lower temperatures.

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these bacteria migrate into the previously sterile fish musculature where they multiply if time and temperature are not controlled. When histamine-producing bacteria multiply in fish flesh, they produce histidine decarboxylase (HDC) enzymes, that convert histidine (naturally present in muscle tissue flesh of at risk fish) into the toxic metabolite histamine.

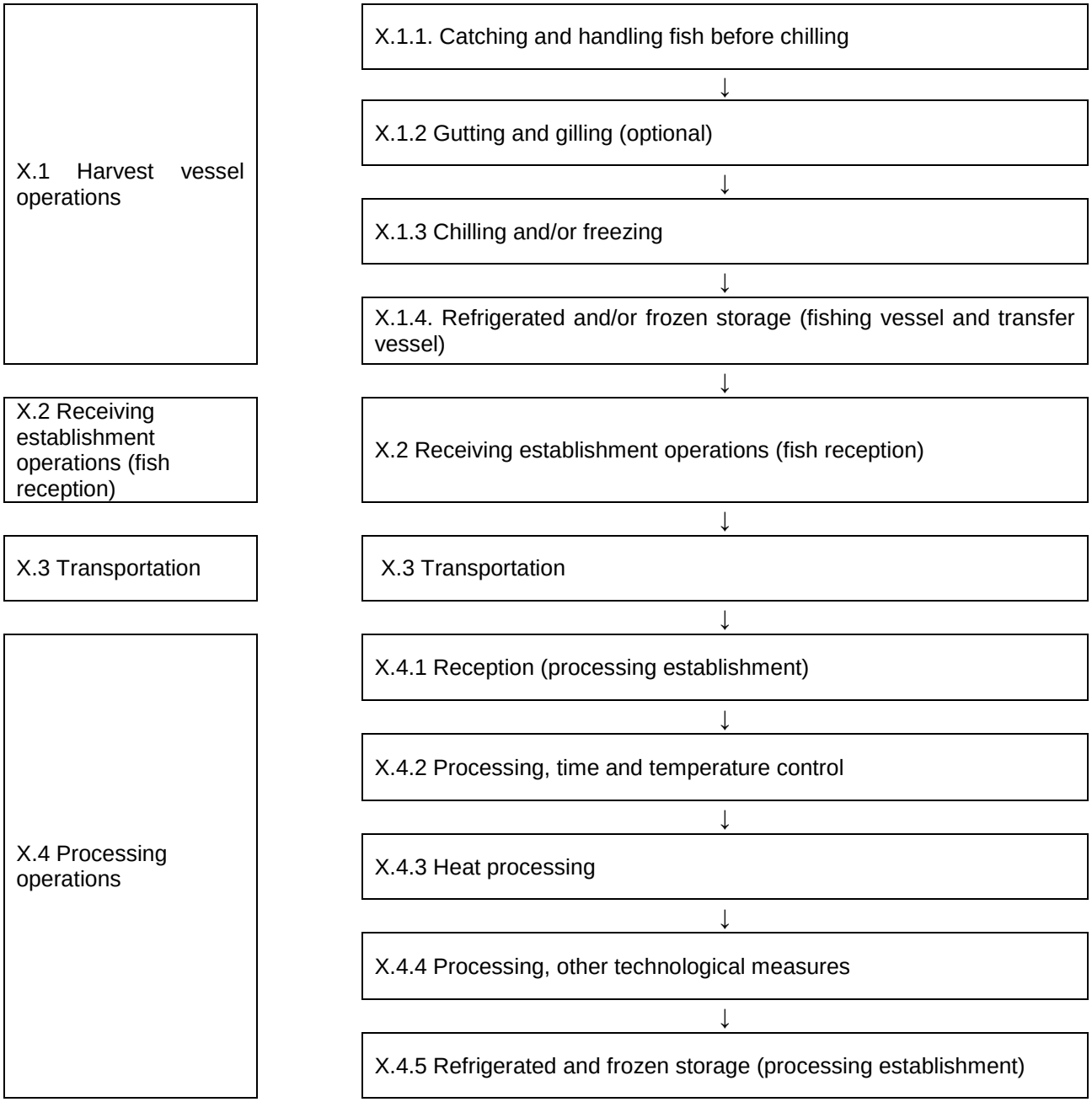
Rapid multiplication of histamine-producing bacteria can be prevented or delayed by chilling fish immediately after death and maintaining the fish in a chilled, or frozen, state from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histidine decarboxylase, enzymatic activity can continue to produce histamine slowly at refrigeration temperatures.

The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing operations).

The relevant sections of the guidelines in this section may also apply to aquacultured fish.

Figure X.1. Example flow chart for the production of fish at risk of scombrotoxin formation

This flow chart is for illustrative purposes only. A complete and comprehensive flow chart has to be drawn up for each product.



X.1 Harvest vessel operations

Fishers use many different harvesting methods throughout the world, employing hooks, nets, and traps. In all cases, live retrieval or quick retrieval of dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at cold temperatures, are critical to prevent histamine formation.

The fishing vessel and equipment, and the methods used, should be designed or adapted to prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in hygienic practices and temperature control methods and understand their importance for histamine control. Where HACCP principles are used, persons responsible for developing HACCP documentation should be trained in HACCP principles used to control histamine formation.

Harvest vessel operations are considered primary productions and GMPs are sufficient to control histamine at this level. However, in the absence of information to document on-vessel histamine control, for example, records of temperature, the shore-based receiving establishment should perform histamine testing on each vessel delivery to monitor and to document that the histamine levels in the raw material received are acceptable. If vessel operations provide documented evidence that histamine was controlled on the vessel, then the receiving establishment may choose to examine the vessel monitoring records as an alternative to testing each lot. The control of fish time-temperature exposure on harvest vessels and associated evidence of control provide more reliable consumer protection than testing histamine levels after delivery.

X.1.1 Catching and handling fish before chilling

- Limits should be established for the time period between death of the fish and the start of chilling that will effectively minimize histamine production. The time period may be adjusted according to water and air temperatures, the size and species of fish caught, and other relevant factors of the operation. The types of histamine-producing bacteria present and how rapidly they produce histamine can also change, therefore established limits should take into account the worst-case scenario. The FAO/WHO Expert Report (Section 6.1.1 Chilling)[1] provides examples of time limits from fish death to chilling for medium to large fish.
- Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.
- The time period that nets or hooks are left in the water, and the number and rate of fish caught, should be optimized to allow live landing of fish where practical.
- Fish should be removed from nets and hooks as quickly as possible to prevent death or to minimize the period from death until chilling of the fish.
- If captured fish are held in the sea for too long following death, decomposition commences, and histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit signs of decomposition, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified to allow proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with signs of decomposition will be brought on board in the future.
- The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling system to achieve and maintain established limits.
- Rough handling, overcrowding and over stacking of fish should be avoided where practical because crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish muscle.
- Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contamination of fish (see Section 3.4 Hygiene control programme), and the chilling medium should be ready and at the target temperature.

X.1.2 Gutting and gilling (optional)

- Histamine-producing bacteria are universally present in the gut, gills, and skin of fish at the point of capture. Rapid removal of guts and gills, and rinsing of the gut cavity, significantly delays histamine formation in the muscle.
- For large fish, removing the gut aids chilling by allowing chilling media (e.g. ice, refrigerated seawater) access to the visceral cavity, resulting in more rapid chilling of this bacteria-laden part of the fish.
- Care should be taken and hygienic practices should be maintained during gutting and gilling in order to minimize the spread of bacteria from the guts, gills, skin, and other contamination sources, into the muscle.

[1] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

X.1.3 Chilling and/or freezing

Rapid chilling as soon as possible after death is the most crucial aspect of histamine control because bacterial growth and histamine formation accelerate exponentially with time under unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at refrigeration temperatures, and the growth rates of those that do are much reduced.

- Temperature limits and monitoring frequencies should be established for the onboard chilling/freezing process. For example, limits may be established for maximum loading volumes and rates, and maximum starting temperature for refrigerated seawater (RSW) and/or brine tanks to ensure an adequate chilling environment is maintained for each harvested set[2] of fish.
- Sufficient ice to completely surround the fish, or preferably, ice/seawater slurries or RSW should be used to bring the internal temperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enzymatic activity. For fish used to produce fish sauce, refer to Section 18.
- Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[3].
- For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden part of the fish.
- Freezing fish is more effective in preventing histamine formation than chilling and maintaining fish below 4°C. It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.
- Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamine-producing bacteria and enzymes, which can become active when temperatures increase again, such as during processing or meal preparation.
- Crew members responsible for chilling should provide feedback to the catching operation to ensure that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time-temperature limits and maintain the fish in a chilled state.
- Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the time limit established for the temperature conditions.
- Refrigeration and other chilling equipment should be in good repair, and operated in a manner that quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries and brine tanks to allow good circulation and rapid cooling.

X.1.4 Refrigerated and/or frozen storage (fishing vessel and transfer vessel)

- Refrigerated fish should be stored at a temperature as close as possible to 0°C. The storage temperature should be kept below 4°C until off-loading. Storage at these temperatures will inhibit or slow the growth and enzyme production for most histamine-producing bacteria.
- Ice, where used, should completely surround the stored fish and be regularly monitored throughout the trip and replenished as necessary.
- Refrigerated seawater and/or brine temperature should be regularly monitored throughout the trip and controlled in order to maintain inhibitory storage temperatures.
- Continuous temperature recording devices, or thermometers, should be used in refrigerated and frozen storage compartments to ensure that inadequate holding conditions are identified and appropriate actions taken to minimize consumer risk.

X.1.5 Monitoring records

- Records of histamine control monitoring activities should be maintained in a way that they can be readily retrieved for trace-back to possible causes if elevated levels of histamine are detected later.
- Records should be made available to the receiving establishment that offloads the fish from the vessel to provide evidence that histamine controls were implemented effectively by the vessel.

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[2] A "set" means the fish from one set net, or the fish from one set long-line, etc.
[3] *FAO Fisheries Technical Paper 436* (“The use of ice on small fishing vessels.”) Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

- Vessel records should include documentation of actual observed activities pertinent to onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip.
- The records of histamine control monitoring activities depend on the operation and may include:
  - Dates and times of earliest fish death, and times to get fish into appropriate chilling media;
  - Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during storage of the fish for the duration of the fishing trip;
  - Water and ambient temperature.
- A responsible crew member should review the monitoring records daily to confirm that limits were met, and that appropriate corrective actions were taken when necessary.
- Where onboard record keeping is impractical, such as for small artisanal day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to ensurehistamine control (e.g. time of departure and return, air and water temperature, adequacy of ice and fish internal temperature, etc.), and avoid the need to test histamine levels at receipt.
- If some of the fish on the vessel are determined based on monitoring records to be at risk for unacceptable histamine levels, then these fish should be segregated and identified in order to allow targeted testing and/or proper disposition at unloading.

X.2 Receiving establishment operations (fish reception)

Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an important control point for histamine. This is where 1) fish temperatures, 2) signs of decomposition, and 3) histamine levels and/or vessel records are best monitored.

Reception controls may need to be specific to both the harvest vessels as well as to any collection/transfer vessels that deliver the fish to the receiving establishment.

If deficiencies in vessel controls are found at receiving, feedback should be provided to the vessel operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from the fishing vessel are considered. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.

During offloading of fish from the vessel (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be maintained in the frozen state.

X.2.1 Temperature monitoring

- Fish internal temperatures should be measured at reception to ensure reception temperature limits are met, and to help provide confidence that fish were properly stored onboard the fishing and transfer vessel.
- For fish stored in ice, the adequacy of ice surrounding the fish should be observed and recorded at the time of offloading the fishing vessel, along with internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.
- Sampling should be done randomly throughout the fishing vessel delivery lot. The number of fish temperatures monitored and results recorded should be sufficient to provide reasonable assurance that the temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be taken into account when taking samples.
- Fish on the vessel should have been stored at a temperature as close as possible to 0°C (4°C or below). If an internal temperature in a sample fish exceeds 4°C (or the established temperature limit based on elapsed time from death) then this indicates a lapse in histamine control. The cause of the deviation should be determined and corrected, and histamine testing of the entire vessel delivery lot performed, or the delivery rejected. For fish used for producing fish sauce, refer to Section 18.

- Higher temperatures usually correspond to higher histamine risk; however, higher deep core temperatures may need to be allowed for in larger fish that have been delivered soon after harvest and have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to establish proper fish reception temperatures in these circumstances.

X.2.2 Sensory evaluation

Sensory evaluation of fish at reception is a useful screening method to identify fishing vessel delivery lots that have been mishandled or subjected to time-temperature abuse and, hence, are at risk of elevated histamine levels. Neither histamine formation nor decomposition occurs in the absence of time-temperature abuse. However, the correlation between histamine level and sensory evidence of decomposition is not absolute, and histamine formation often occurs without readily detectable sensory indicators of decomposition. Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and reliable vessel control records or histamine testing, along with temperature monitoring, should be part of a complete receiving control system.

- Fish for sensory evaluation should be chosen randomly from throughout the vessel delivery lot. Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling plan. It may be appropriate to select more fish from portions of the delivery lot identified by vessel records or temperature examination to be at greater risk for histamine formation.
- The number of fish examined should be sufficient to provide assurance that the vessel crew appears to have been vigilant about time-temperature exposures of the fish. The number of samples taken should be increased when conditions or fishing methods are more likely to introduce variable time-temperature exposures of fish, e.g. longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc.
- Evidence of abuse that may be conducive to histamine formation is indicated when the fish sensory attributes indicate marginal quality, not only when the sensory attributes show advanced decomposition. See FAO “Sensory Assessment of Fish Quality”[4] and Codex “Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories”[5] for guidance on sensory evaluation of fish.
- If sensory evidence of decomposition is detected at reception, it indicates that controls on the vessel may have been inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural changes, and improvement to facilities or equipment verified. It is justifiable to reject the entire delivery lot based on evidence of inadequate time-temperature control; however, if further evaluation is used to determine if some of the fish are suitable for human consumption, then intensified histamine sampling and testing should be performed on the entire delivery lot. The testing should also include the decomposed fish found to determine if the type of decomposition detected was conducive to histamine formation.

X.2.3 Review of vessel control records (receiving establishment)

If vessel operators monitor and document histamine control, review of vessel histamine control records, when available, is an effective control method at receipt to ensure that appropriate procedures were followed on the vessel to minimize histamine formation in the fish while on the fishing vessel and is more effective than routine histamine testing.

- Refer to Section X.1.5 Monitoring records
- Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel, unless the information is available by other means, to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel limits were met.

[4] FAO/Torry Advisory Note No. 91, “Sensory Assessment of Fish Quality.” Link: http://www.fao.org/wairdocs/tan/x5989e/x5989e00.htm

[5] CXG 31-1999, *Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories*. Link: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B31-1999%252FCXG_031e.pdf

- If vessel records are reviewed and found to be incomplete and the receiving establishment cannot verify by other means, such as by intensified histamine sampling and testing, that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, the delivery should be rejected. (Refer to Section X.2.4 Histamine testing).
- The impact of a limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g. one brine well or one specific fishing set) and the affected fish were effectively segregated when the vessel was unloaded.

X.2.4 Histamine testing

When review of fishing vessel histamine control records is used as one of the histamine controls by a receiving establishment, then histamine testing should be performed periodically as verification that the control system is continuing to work effectively. If verification test results indicate elevated histamine levels, then the vessel control system should be reviewed and corrected, and the frequency of testing should be increased until testing results and other evidence suggest that the vessel control systems are being effectively implemented (e.g. a series of consecutive problem-free deliveries).

When a fishing vessel operation uses GMPs, but has not implemented a histamine control system including monitoring and record keeping that provide documented evidence of control, then histamine testing is an important monitoring procedure at the reception critical control point, rather than a verification procedure, and testing should be applied to every vessel delivery lot. If histamine levels exceed the established critical limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.

Note that histamine testing can be less reliable than receipt of appropriate vessel control records because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protection can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel.

The histamine testing guidance in this subsection can also be applied to intensified sampling or periodic verification of histamine controls throughout the supply chain.

X.2.4.1 Histamine Levels

In order to better use the test result, the receiving establishment should establish the acceptable histamine level for incoming fish. To do so, the following information should be taken into account:

- Information on histamine level in freshly harvested fish[6].
- Elevated histamine levels could indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and an elevated risk that some fish in a lot will have unacceptable histamine levels. In addition, they could indicate that histidine decarboxylase enzymes are present that can contribute to histamine formation during exposure to elevated temperatures further along the food chain, even without growth of histamine-forming bacteria.
- Additional increases in histamine levels are likely with time and exposure to non-refrigerated temperatures during further processing and handling.

X.2.4.2 Histamine testing, sampling strategies

- Sampling plans for testing histamine levels should be selected based on statistical performance parameters. Statistical tables and computer programs can provide the information needed to design a sampling plan based on the histamine limits, the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling Tool[7] is an example of an application designed for this purpose.

[6] *According to the FAO/WHO Expert Meeting Report 2013, freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[6].*

[7] *FAO/WHO Histamine Sampling Tool*. Link: http://tools.fstools.org/histamine/

- Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section 6.2.2.2)[8] suggests using histamine accept/reject levels ("value for m") that are lower than the acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.
- More sample units should be tested whenever vessel records, sensory analysis, or fish temperatures indicate possible lapses in time-temperature control that could result in elevated histamine.
- It is best to sample the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified for trace back to vessel lots. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.
- Samples taken should be representative of the lot.

X.2.4.3 Histamine testing, analytical methods

- Several reliable test methods exist for determining histamine levels in fish. The FAO/WHO Expert Report (Section 2.5 Analytical methods for histamine)[9] lists some of the available methods.
- The testing method used should be properly validated for the detection limits used. The staff responsible for the sampling and for sample analysis should receive training in the procedures used.
- The part of the fish selected for testing can significantly affect the test results. Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation of fish muscle should be collected to prepare for analysis (e.g. 100-250 grams). The weight of the representative sample unit may depend on the product and sampling strategy. For smaller fish, in addition to the lower anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected. For very small fish, multiple fish may need to be collected to acquire a representative sample unit. The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.
- To screen deliveries more economically, sample units from different fish can be optionally combined (composite sample) to reduce the number of histamine analyses required, provided that the histamine level critical limit is lowered proportionately.

X.2.5 Monitoring records (receiving establishment)

- Histamine control records should be maintained at the receiving establishment for trace-back to possible causes if elevated histamine level is discovered further along the distribution chain.
- Receiving establishment monitoring records may include, but are not limited to:
  - Relevant information about vessel delivery lot (e.g. vessel name and type, captain's name, date/time of offloading, type and volume (weight) of fish off-loaded);
  - Sensory evaluation results;
  - Internal temperatures at the time of offloading;
  - Histamine test results, when applicable;
  - Copies of the fishing vessel's monitoring records reviewed, when applicable.
- A responsible person should examine, as a part of verification activity, the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

[8] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July 2012, Rome (Section 6.2.2.2 Using the known standard deviation and the derived mean to design a sampling plan.)

[9] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July 2012, Rome (Section 2.5 Analytical methods for histamine.)

X.3 Transportation

- Refer to Section 20 (Transportation)
- Refer to Section X.1.4 (Refrigerated and/or frozen storage (fishing vessel and transfer vessel))
- Transport vehicles or vessels should be adequately equipped to keep fish cold by mechanical refrigeration or by completely surrounding the fish with ice or other cooling media.
- Vehicles or vessels should be pre-chilled before loading fish where applicable.
- Refrigerated compartment temperatures, or cooling media such as ice slurries, should be monitored during transportation between locations (e.g. receiving establishment, processing establishment, distributor, market) using continuous temperature recording devices (where practical), and the receiving establishment should review the temperature record from the device. Devices should be periodically calibrated for accuracy.
- At delivery, internal temperatures of a representative sample of fish, and adequacy of ice or other cooling media when applicable, should be monitored by receiving personnel as described in Section X.2.1 Temperature monitoring.
- If established fish reception or vehicle compartment temperature control limits are exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. If evidence indicates that temperature abuse leading to elevated histamine could have occurred, the affected lot may be rejected by the receiving personnel, or the receiver may perform intensified histamine analysis on representative fish collected throughout the lot, and the lot rejected if any fish exceed the established histamine limit.

X.4 Processing operations

This section applies to processing on land or at sea (e.g. factory vessel, mother ship)

X.4.1 Reception (processing establishment)

- If fish are delivered directly from the fishing vessel to the processing establishment, then also refer to Section X.2 Receiving establishment operation (fish reception).
- If fish are delivered by transport vehicle or vessel, then also refer to Section X.3 Transportation.
- If the processing establishment is a secondary processor receiving product from a primary processor (e.g. receiving establishment or factory vessel), then the secondary processor should confirm that the primary processor uses a HACCP system designed to prevent formation of unacceptable levels of histamine.
- When it is impractical for the initial receiving establishment to conduct all the necessary histamine controls listed in subsection X.2 (i.e. temperature monitoring, sensory evaluation, vessel records review~~,~~ and/or histamine testing), then the processing establishment should conduct these activities, and should ensure that, where practical, the controls and decisions are applied to intact fishing vessel lots that are not comingled with other lots. Note, however, that fish internal temperatures (and adequacy of ice, where applicable) should always be monitored at vessel delivery by the receiving establishment (to evaluate vessel control), as well as at receipt by the processing establishment (to evaluate land-transportation control). If lots are co-mingled and there may be unacceptable levels of histamine in fish, the entire lot should be considered when making decisions on disposition.

X.4.2 Processing time and temperature control

When fish undergo processing (e.g. thawing, cutting, re-chilling, salting, drying, pickling, cooking, smoking, canning) it is important that they are not subjected to time-temperature conditions where histamine-producing bacteria can grow and produce histamine to unacceptable levels.

- Scientific studies and microbial growth models[10] may be used to estimate the exposure times and temperatures that result in elevated histamine levels.
- Histamine formation is quite variable and strongly depends on the previous handling of the raw material and the different species of histamine-producing bacteria that are present; therefore, the worst case scenario should be considered when establishing critical limits.

[10] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July 2012, Rome (Section 6.1.9 Microbiological modelling.)

- The acceptable maximum histamine level used to establish processing time-temperature critical limits should take into consideration the point in the supply chain and any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption.
- The measure used for time-temperature critical limits should be the cumulative product non-refrigerated time-temperature exposure over all processing steps.
- Processing room temperature should be maintained as cool as practical during processing operations, and product exposure times should be minimized. For example, fish should be iced, or returned to refrigerated storage, during production breaks or production flow slow-downs.
- Controlled product flow and batch monitoring is an effective strategy to ensure product is not subjected to unacceptable time-temperature exposures. For example, periodically measure the ambient temperature and the time for a marked batch to begin and complete the processing step.
- Air thawing of raw material should occur at refrigerated temperatures to prevent excessive warming of the surface of the fish. Immersion in circulating cold water or spraying with cold water may be used to shorten thawing time. For re-chilling and refreezing, see Subsection X.1.3.
- When time-temperature critical limits are exceeded, the cause should be determined and corrected. In addition, intensified histamine testing should be performed (see Section X.2.4.2) before releasing affected product for human consumption. Alternatively, product should be rejected.

X.4.3 Heat processing

- Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate histidine decarboxylase enzymes. *Morganella morganii* is probably the most heat resistant of the histamine-producing bacteria, and in *Arripis trutta* at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012).
- Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine controls during harvesting, and during other steps prior to thermal processing, are critical to minimize the presence of histamine in the finished product.
- If the product is exposed to bacterial contamination and temperature abuse after initial heating, histamine formation may start again. Thus, for products such as hot smoked fish, care should be taken to avoid contamination after smoking. Additionally, refrigerated storage is essential unless the water activity is reduced sufficiently or some other means is used to prevent bacterial growth.
- For commercially sterile canned or pouched products, the container protects the product from bacterial recontamination, and no further histamine is produced when stored at ambient temperatures. However, once the product package is opened, histamine formation can occur again if the product is recontaminated in the absence of preventative time-temperature controls.

X.4.4 Processing, other technological measures

Time and temperature control is the recommended method for preventing histamine formation in fresh, frozen, and refrigerated processed fish products.

Some products and processes (e.g. fermenting, smoking, salting, drying, pickling, acidifying, preserving, modified atmosphere packaging) introduce other technological factors that may inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of these factors is complex and often unpredictable. For example, increased salt content, or increased acidity, may decrease or increase histamine production, depending on conditions.

Thorough scientific studies, and proper establishment and validation of control parameters for each specific process and product, are imperative to ensure the safe manufacture of foods that incorporate other technological measures as an element of histamine control. (See *Guidelines for the Validation of Food Safety Control Measures*, (CXG 69-2008))

The success of these treatments is dependent on the rapid chilling and maintenance of chilled temperatures of the raw fish from the time of death until the inhibitory effects from the treatments are achieved. In addition, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety.

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and/or frozen storage (fishing vessel and transfer vessel).
- For products whose preparation does not include a heating step or other means to eliminate histamine-producing bacteria and their enzymes, refrigerated storage will continue to be a critical control point to prevent histamine formation throughout the shelf-life of the products.

X.4.6 Monitoring records (processing establishment)

- Processing establishment monitoring records may include, but are not limited to:
  - Transport vehicle or vessel temperature records or adequacy of ice, and fish internal temperatures;
  - Temperatures and exposure times of product during unrefrigerated processing steps;
  - Critical control point monitoring records for other validated methods used to control histamine formation in processed fish;
  - Refrigerated storage temperature logs.
- A responsible person should examine the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.
- The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to Section X.2.4 Histamine testing).

Appendix III

PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE (CCFH) WILL UNDERTAKE ITS WORK

Purpose

1. The following guidelines are established to assist the CCFH to:

- Identify, prioritize and efficiently carry out its work; and
- Interact with FAO/WHO and their scientific bodies as the need arises.

Scope

2. These guidelines apply to all work undertaken by the CCFH and encompass: guidelines and procedures for proposing new work (including the revision of existing codes of hygienic practice); criteria and procedures for considering the priorities for proposed and existing work; procedures for implementing new work; and a process by which CCFH will obtain scientific advice from FAO/WHO.

Proposals for New Work

3. Proposals for new work to be undertaken by CCFH should follow the process outline below. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile[1], as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g. new or revised code of hygienic practice, risk management guidance document).

4. The proposals for new work will typically address a food hygiene issue of public health significance. It should describe in as much detail as possible, the scope and impact of the issue and the extent to which it impacts on international trade.

5. The proposal for new work may also:

- Address an issue that affects progress within CCFH or by other committees, provided it is consistent with the mandate of CCFH;
- Facilitate risk analysis activities; or
- Establish or revise general principles or guidance. The need to revise existing CCFH texts may be to reflect current knowledge and/or improve consistency with the *General Principles of Food Hygiene* (CXC 1-1969) or with other Codes of Practice.

Criteria for Evaluating and Prioritizing New Work

6. In addition to the provisions applying to the proposals for new work contained in the Codex *Procedural Manual,* the following criteria and associated weighting factors will be used in evaluating new work priorities to assist in determining the priority for new work to be undertaken by CCFH. Standards older than five years or those with duplication or inconsistency with existing codes should also be assessed by the criteria below to determine their need for revision.

[1] Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*). The elements of a risk profile are provided in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63-2007).

Criterion	Rating
Currency of Information – • Is there new information/data that would justify the need to review the existing code(s) or establish a new one? • Are there new technologies that would justify the need to review existing codes or establish a new one? • Is there duplication or inconsistency with existing codes that should be addressed?	Yes/No
Positive impact of new work on public health – • Would new work result in a document that could have a positive impact on public health? • How significant is the impact to public health, e.g. foodborne risk to public health?	High 20 Medium 14 Low 8
Impact of trade due to the public health risk*	Global Trade Impact, High Consumption: 10 Regional Trade Impact, High Consumption: 5 Global Trade Impact, Low Consumption: 4 Regional Trade Impact, Low Consumption: 2 No trade impact: 0

*Risk[2] is defined as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food. The hazard may be a biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect.

The criteria are applied in a stepwise manner.

Step 1:

Assess currency of information.

- Is there new information/data that would justify the need to review the existing code(s) or establish a new one?
- Are there new technologies that would justify the need to review existing codes or establish a new one?
- Is there duplication or inconsistency with existing codes that should be addressed?

If the answer is “yes” to any of these questions, proceed with Step 2. If the answer to all these questions is “No,” there is no justification for new work in the area at this time, and no need to apply the remaining criteria for prioritization. Standards older than five years for which there is no new information should be retained in the Forward Workplan (clearly separated within the table) for consideration at a later time.

Step 2:

Assess the public health impact:

Would the proposed new code, or the revisions to an existing code to be revised, result in a document that could have a positive impact on public health? How significant is the public health risk, e.g. foodborne risk to public health? The public health risk should be based on documented convincing or probable scientific evidence of adverse health effects or potential adverse health effects including morbidity and/or mortality due to a biological, chemical or physical agent in, or condition of the food. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*[3] should be referenced when determining the public health risk.

Apply rating points as follows:

20 – the proposed new code or the proposed revisions to an existing code are likely to have a high public health impact (e.g., the hazard presents a high risk of illness/outbreaks or the provisions to be incorporated are reasonably likely to mitigate the risk from a hazard)

[2] Codex *Procedural Manual*
[3] Codex Alimentarius Commission, *Procedural Manual.*

14 – the proposed new code or the proposed revisions to an existing code are likely to have a medium public health impact (e.g., the hazard presents a medium risk (lower probability or severity than other hazards) or the provisions to be incorporated can reduce but not eliminate the risk from a hazard)

8 – the proposed new code or the proposed revisions to an existing code will have little or no impact on public health (e.g., the hazard presents a low risk (low probability and severity), the provisions to be incorporated have minimal impact on the risk from a hazard)

Step 3:

Assess the impact of the work on trade:

Is the food traded globally or only in particular regions? Is the food one that is frequently consumed or is consumption generally low?

In addition to ranking the project based on the criteria, the Forward Workplan should include information on whether the proposal contains a project document[4] or discussion paper (a project document must be submitted to the Codex Alimentarius Commission (CAC) for approval of new work) and whether the project requires FAO/WHO assistance (see "Obtaining Scientific Advice"). The need for FAO/WHO assistance may impact the timing of taking on new work due to FAO/WHO resource constraints.

Process for Considering Proposals for New Work

7. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities ("*ad hoc* Working Group") at each Session, in accordance with the Guidelines on Physical Working Groups.

8. The Committee on Food Hygiene will, normally, employ the following process for undertaking new work.

i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.

ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the ad hoc Working Group as well as the CCFH Host government and Codex Secretariats. Proposals should describe the new work and provide a rationale for taking up the new work. The proposal may include a project document to facilitate sending a request to the CAC for approval; the absence of a project document could delay approval of new work.

iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.

iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH, to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.

v. If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines presented above. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be "denied" or "returned for revision," a justification for this recommendation will be provided.

vi. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a project document, which may include amendments agreed upon by the Committee, will be prepared by the CCFH (or, if a project document was submitted with the proposed work, CCFH may recommend revisions) and submitted to the CAC with a request for approval of the proposed new work.

vii. The CCFH Workplan (see below) will be updated at each meeting of the *ad hoc* Working Group in order to maintain continuity and a historical record of CCFH's consideration of new work.

[4] The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual.*

CCFH Workplan

9. CCFH will maintain a forward-looking Workplan that will include new work proposals and, for the purpose of review, existing codes. The Workplan will list work in priority order based upon decisions made by CCFH and using the criteria for evaluating and prioritizing work (see above). The Workplan will be reviewed by the *ad-hoc* Working Group at each Session of CCFH when prioritizing proposals for new work. CCFH will progressively work down the prioritized list of items contained in the Workplan. CCFH may reassess the priority of each item on the Workplan; where new data or other information is available relating to an item on the Workplan, such data may be submitted for consideration and the priority for the work item reconsidered. It is intended for the Workplan to continue from Session to Session, updated and revised as appropriate based on CCFH's criteria for undertaking new work. If items are moved forward as new work, each item will require a Project Document and a clear indication of how the work is to be progressed (e.g. nominated delegation to lead work, use of a working group process).

Obtaining Scientific Advice

10. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g., through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies. When undertaking such work, the Committee should follow the structured approach given in the *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63-2007) and the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*

11. In seeking an international risk assessment to be conducted by FAO/WHO (e.g. through JEMRA), CCFH should consider and seek advice on whether:

i. Sufficient scientific knowledge and data to conduct the needed risk assessment are available or obtainable in a timely manner. (An initial evaluation of available knowledge and data will typically be provided within the Risk Profile.)

ii. There is a reasonable expectation that a risk assessment (if one is needed) will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.

iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

12. If the Committee decides to request that a microbiological risk assessment or other scientific advice be developed, the Committee will forward a specific request to FAO/WHO, the risk profile document (where available), a clear statement of the purpose and scope of the work to be undertaken, any time constraints facing the Committee that could impact the work, and, in the case of a risk assessment, the specific risk management questions to be addressed by the risk assessors. The Committee will, as appropriate, also provide FAO/WHO with information relating to the risk assessment policy for the specific risk assessment work to be undertaken. FAO/WHO will evaluate the request according to their criteria and subsequently inform the Committee of its decision on whether or not to carry out such work, together with a scope of work to be undertaken. If FAO/WHO responds favourably, the Committee will encourage its members to submit their relevant scientific data. If a decision is made by FAO/WHO not to perform the requested risk assessment, FAO/WHO will inform the Committee of this fact and the reasons for not undertaking the work (e.g. lack of data, lack of financial resources).

13. The Committee recognizes that an iterative process between risk managers and risk assessors is essential throughout the process described above and for the adequate undertaking of any microbiological risk assessment and the development of any microbiological risk management guidance document or other CCFH document(s).

14. The FAO/WHO will provide the results of the microbiological risk assessment(s) or other expert scientific advice to the Committee in a format and fashion to be determined jointly by the Committee and FAO/WHO. As needed, the FAO/WHO will provide scientific expertise to the Committee, as feasible, to provide guidance on the appropriate interpretation of the risk assessment.

15. Microbiological risk assessments carried out by FAO/WHO (JEMRA) will operate under the framework contained in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXC 30-1999).

Appendix IV

CCFH FORWARD WORKPLAN

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (20/14/8)	Trade Impact (10/5/4/ 2/0)	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Control of Shiga toxin-producing *E. coli*	N/A	Yes	20	10	No	Yes	Discussion paper planned for CCFH50	30
Code of Hygienic Practice for the Storage of Cereals	N/A	Yes	8	5	Yes			13
Code of Practice on Food Allergen Management for Food Business Operators	N/A	Yes	20	10	Yes	No	Project document submitted to CAC41	30
Guidance for the Management of (Micro)biological Foodborne Crises/ Outbreaks	N/A	Yes	20	10	Yes	No	Project document submitted to CAC41	30
Principles for the Safe Use of Water in Food Processing	N/A				No			
Code of Hygienic Practice for Meat (CXC 58-2005)	2005	No						
Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)	2009	No						
Code of Hygienic Practice for Eggs and Egg Products (CXC 15-1976)	2007	No						

[1] Information to Update (Currency of information): Is there new information/data that would justify the need to review the existing code(s) or establish a new one? Are there new technologies that would justify the need to review existing codes or establish a new one? Is there duplication or inconsistency with existing codes that should be addressed? If there is an existing code in place and a determination is made that the code is sufficient, no new work should proceed.

Title of Work	Last Revision	Information to Update (Yes/No)[1]	Impact to Public Health (20/14/8)	Trade Impact (10/5/4/ 2/0)	Project document/ discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CXC 39-1993)	1993	No						
Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001)	2001	No						
Code of Hygienic Practice for Low-acid and Acidified Low-acid Canned Foods (CXC 23-1979) *Code of Hygienic Practice for Aseptically Processed and Packaged Low-acid Foods* (CXC 40-1993) *Guideline Procedures for the Visual Inspection of Lots of Canned Foods for Unacceptable Defects* (CXG 17-1993) *Code of Hygienic Practice for Canned Fruit and Vegetable Products* (CXC 2-1969)	1993 1993 1993 1969	No						
Code of Hygienic Practice for Bottled/Packaged Drinking Waters (other than natural mineral waters) (CXC 48-2001)	2001	No						
Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf-life (CXC 46-1999)	1999	No						