JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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7–12 July 2019

REPORT OF THE FIFTIETH SESSION OF THE
CODEX COMMITTEE ON FOOD HYGIENE

Panama City, Panama

12 - 16 November 2018
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# LIST OF ABBREVIATIONS

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<th>Abbreviation</th>
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<tr>
<td>CAC</td>
<td>Codex Alimentarius Commission</td>
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<td>CCEXEC</td>
<td>Executive Committee of the Codex Alimentarius Commission</td>
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<td>CCFH</td>
<td>Codex Committee on Food Hygiene</td>
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<td>CCFICS</td>
<td>Codex Committee on Food Import and Export Inspection and Certification Systems</td>
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<td>CCMAS</td>
<td>Codex Committee on Methods of Analysis and Sampling</td>
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<td>CCP</td>
<td>Critical Control Point</td>
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<td>CRD</td>
<td>Conference Room Document</td>
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<td>EU</td>
<td>European Union</td>
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<td>EWG</td>
<td>Electronic Working Group</td>
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<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
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<td>FBOs</td>
<td>Food Business Operators</td>
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<td>GHP</td>
<td>Good Hygienic Practice</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>HACCP</td>
<td>Hazard Analysis and Critical Control Point</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>JEMRA</td>
<td>Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment</td>
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<td>OIE</td>
<td>World Organization for Animal Health</td>
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<td>PWG</td>
<td>Physical Working Group</td>
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<td>SFP</td>
<td>Scombrotoxin fish poisoning</td>
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<td>STEC</td>
<td>Shiga toxin-producing <em>Escherichia coli</em></td>
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INTRODUCTION
1. The Codex Committee on Food Hygiene (CCFH) held its 50th Session in Panama City, Panama, from 12 to 16 November 2018, at the kind invitation of the Governments of Panama and the United States of America. Dr Emilio Esteban of the United States of America Department of Agriculture (USDA), chaired the Session, which was attended by 56 member countries, one member organization and 13 observer organizations. A list of participants is contained in Appendix I.

OPENING OF THE SESSION
2. Eng. Eduardo Carles, Minister of Agriculture of Panama and Dr Eric Ulloa, Vice Minister of Health of Panama, addressed the Committee and extended their warmest welcome to all participants. They emphasized the importance of the mandate of Codex to protect the health of consumers and ensure fair practices in the food trade and wished the Committee successful deliberations.

3. Ms Anita Katial, Regional Agricultural Counselor of the U.S. Embassy San Jose, Costa Rica, Ms Mary Frances Lowe, U.S. Codex Manager, and Ms Sarah Cahill, Senior Food Standards Officer of the Codex Alimentarius Commission also addressed the Committee, expressed their appreciation to Panama for co-hosting the Session and congratulated CCFH on its achievements over the past 50 years. Ms Cahill also thanked the United States of America for successfully hosting the Committee since 1964.

Division of Competence
4. The Committee noted the division of competence between the European Union (EU) and its Member States, in accordance with paragraph 5, Rule II, of the Rules of Procedure of the Codex Alimentarius Commission.

ADOPTION OF THE AGENDA (Agenda item 1)
5. 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)
6. The Committee noted the matters referred including matters arising from the 24th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS).

Matters from CCFICS24
7. The Committee noted that: (i) with regard to the request of the Executive Committee of the Codex Alimentarius Commission (CCEXEC) on the need for guidance similar to those for the management of (micro)biological foodborne crises/outbreaks, CCFICS24 agreed to await the result of the discussions at CCFH before considering this issue and (ii) that CCFICS would consider the possibility of developing new work on food fraud after conducting a comprehensive analysis of existing relevant Codex texts.

MATTERS ARISING FROM THE WORK OF FAO AND WHO (INCLUDING THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) (Agenda item 3)
8. The representatives of FAO and WHO highlighted key activities since CCFH49.

Water quality
9. The representative of FAO reported the preliminary findings of the second FAO/WHO expert meeting on the Safety and Quality of Water Used in Food Production and Processing, highlighting that the use of water is diverse and complex. He noted the conclusion of the expert meeting that the water used in food production and processing should not compromise the safety of the final product and that “fit-for-purpose” water should be determined by a risk-based approach. Noting that several decision analysis tools (decision trees) were developed to assist in the assessment of the quality of water used in fresh produce and fishery food production/processing, he indicated that the next step was to pilot test these tools in the field and encouraged countries to engage with FAO/WHO on this activity. The representative noted that further work was needed to define microbiological criteria for “fit-for-purpose” water and strengthen decision tools for water reuse.

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1 CRD15 (Opening Remarks Mary Frances Lowe – U.S. Codex Manager); CRD16 (Opening Remarks Sarah Cahill - Codex Secretariat); CRD17 (Opening Remarks Anita Katial – USDA’s Regional Agricultural Counsellor); CRD18 (Opening Remarks Dr. Eric Ulloa – Vice Ministro de Salud Panama)
2 CRD1 (Annotated Agenda – Division of competence between the EU and its Member States)
3 CX/FH 18/50/1
4 CX/FH 18/50/2
5 CX/FH 18/50/3
Shiga toxin-producing *Escherichia coli* (STEC)

10. The representative of FAO reported the additional work on source attribution undertaken since CCFH49. Highlighting the key findings, he noted that in most (56%) outbreaks, the source was never identified, but that among identified sources, beef and produce each account for about 30% of all outbreaks. He further noted that an evaluation of case-control studies reinforced the role of beef as a cause of sporadic cases of STEC illness and that these results justify prioritization of work on the control of STEC in specific food commodities, notably beef and produce.

Other related issues

11. The Committee was informed of other FAO and WHO activities, including work on: validating/revising existing risk-assessment models for *Vibrio parahaemolyticus* and *Vibrio vulnificus* and identifying implications for risk management; updating and consolidating existing guidance on risk assessment methodology; reviewing existing pathogen-commodity risk assessments; and the role of environment, crops and biocides in foodborne antimicrobial resistance.

12. The representative of WHO reported the recent activities of the International Food Safety Authority Network (INFOSAN) which promotes rapid exchange of information during international food safety related events and highlighted the increase in active participation of member states.

Conclusion

13. The Committee noted the information provided by FAO and WHO and thanked them for their contribution.

14. The Chairperson reminded the Committee that it was important to identify any requests for scientific advice as early as possible given that generally 15 months was required for FAO and WHO to address requests.

INFORMATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE) (Agenda item 4)\(^6\)

15. The Codex Secretariat introduced the document on behalf of OIE. The Committee noted the key activities since CCFH49, including the confirmation of the adequacy of the current mechanisms for Tripartite collaboration on standard setting and related scientific advice by the 24th FAO/OIE/WHO Tripartite Annual Executive Coordination Meeting, and the adoption of the revised Chapter 6.2 of the Terrestrial Code, “The role of the Veterinary Services in food safety systems” to better reflect the developments and changes in the roles and responsibilities of veterinarians and veterinary services in food safety.

16. The Committee also noted that OIE would continue to address food safety-related issues as a high priority in its standard-setting work.

Conclusion

17. The Committee thanked OIE for the information provided and the ongoing collaboration.

PROPOSED DRAFT REVISION OF THE GENERAL PRINCIPLES OF FOOD HYGIENE (CXC 1-1969) AND ITS HACCP ANNEX (Agenda item 5)\(^7\)

18. The United Kingdom, as Physical Working Group (PWG) Chair, introduced its report (CRD2). After summarizing the consensus reached by the PWG, he explained that: (i) the section on water had been re-drafted in order to apply the concept of “fit for purpose”; (ii) the section on hand washing had been simplified in order to be less prescriptive, in line with the level of information in the rest of the document; and (iii) additional definitions had been included. He further explained that after a detailed discussion on paras. 4-6, of which the intention was to indicate that HACCP was not required in all instances, agreement had been reached on paras. 4 and 5, but not on para. 6. The PWG agreed not to use the term “review of hazard.”

19. The Committee noted that in addition to CRD2, the co-Chairs had drafted new text on para. 6 and a definition for water for consideration by the plenary.

\(^6\) CX/FH 18/50/4

\(^7\) CX/FH 18/50/5; CX/FH 18/50/5-Add.1 (Argentina, Brazil, Chile, Canada, Colombia, Costa Rica, Cuba, Ecuador, Egypt, Gambia, Guyana, India, Iraq, Jamaica, Japan, Kenya, Mauritius, Morocco, Norway, Nicaragua, Panama, Peru, Philippines, Senegal, Switzerland, Thailand, the United States of America, Uruguay, African Union, FoodDrinkEurope, International Dairy Federation and Safe Supply of Affordable Food Everywhere); CX/FH 18/50/5-Add.2 (Australia, Brazil, European Union, New Zealand and African Union); CRD2 (Report of PWG on HACCP); CRD5 (Proposed draft revision of the *General Principle of Food Hygiene (CXC 1-1969)* and its HACCP annex (Revised)-Prepared by the EWG chairs); CRD8 (Nigeria); CRD9 (Dominican Republic); CRD11 (Indonesia); CRD12 (El Salvador); CRD14 (Panama)
Discussion

20. The Committee considered the proposals in CRD2 and agreed with: (i) not including FAO/WHO reference documents under the subsection Hygienic Production of Food Sources; (ii) deleting the word “control” from the subsection heading “Temperature control” to clarify the text in the subsection was on facility rather than process monitoring; (iii) replacing “sanitation” with “cleaning and disinfection” in the heading of Section 3 and subsequently throughout the texts to address translation issues; (iv) retaining the current wording in CXC 1-1969 for Principles 3 and 6; and (v) moving the comparison table and the decision tree into annexes.

21. The Committee discussed those sections of the document that the PWG Chair considered the Committee needed to reach consensus in order to progress. In addition to editorial corrections, amendments for flexibility, clarity and consistency, the Committee made the following comments and decisions.

Introduction – Para. 4

22. Members expressed the view that the words “generally speaking” in the third line should be deleted since all Food Business Operators (FBOs) should implement Good Hygiene Practices (GHPs). Responding to an observation that this reduced the flexibility for FBO’s, who might in some cases only implement the WHO Five Keys to Safer Food rather than GHPs or HACCP; it was highlighted that even the Five Keys implied the use of basic GHPs.

23. The Committee agreed to the revised para. 4 as follows:

“FBOs need to be aware of any potential hazards that may affect their food. FBOs need to understand the consequences of these hazards for consumer health, and should ensure that they are properly managed. GHPs are the basis of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety.”

Introduction – Para. 5

24. Following the concerns about the appropriateness of the term ‘greater attention’, the Committee considered a range of different terms e.g. “greater control”, “greater focus” or “warrant a higher frequency of monitoring”, and agreed to replace “greater attention” in para. 5 as contained in CRD2 with “greater focus” in the first sentence.

Introduction – Para. 6

25. Following intensive discussions on the situations where HACCP should be applied and the appropriate means to reference resources to support the implementation of HACCP, the Committee agreed to simplify the text as follows:

“In some circumstances, the implementation of GHPs may be insufficient to ensure food safety, such as due to the complexity of the food operation and/or the product, technological advances (e.g. extending shelf-life through modified atmosphere packaging) or end use of the product (e.g. products destined for a special dietary purpose). In that case, when there are significant food safety hazards identified through hazard analysis, the HACCP principles should be applied.”

Definition – Water

26. The Committee agreed with the following definition:

“Water: water, including ice and steam, which is fit for purpose and that does not compromise safety and/or suitability of the food.”

Subsection – Water

27. The Committee noted the views that: (i) deleting many of the paragraphs under the subsection on water and changing potable water and clean water to water fit for purpose, as proposed in CRD2, might result in losing useful guidance; and (ii) the decision on this subsection should be deferred to the next session when the report of the Joint FAO/WHO Expert Meeting on the Safety and Quality of Water Used in Food Production and Processing became available.

28. In response to the questions raised by members, the representative of FAO clarified that the definitions of waters were complex while the use of the term “fit-for-purpose” allowed for the simplification of the definition. He noted that “purpose” was the same as the intended use and “fitness” was determined by a risk assessment for each specific purpose.

29. The Committee agreed to include the following text under the section:

“An adequate supply of water with appropriately maintained facilities for storage, distribution and temperature control, should be available, as appropriate.”
Definition – Others

30. The Committee agreed with:
   - the definitions of “Contaminant”, “Contamination” and “Food suitability” as contained in CRD2; and
   - the revised definitions of “Disinfection” and “Food hygiene system” as follows:

   **Disinfection**: reduction by means of chemical agents and/or physical methods in the number of viable microorganisms on surfaces to a level that does not compromise food safety and/or suitability.

   **Food hygiene system**: The combination of good hygiene practices (GHPs), and control at CCPs, as appropriate, that when taken as a whole, ensures that food is safe and suitable for its intended use.

31. The Committee agreed to further consider the definitions of “Acceptable level”, “Food business operator”, “Competent authority” and “Good Hygiene Practices (GHPs)”, noting (i) the proposals on the inclusion of exposure aspects in the definition of “Acceptable level”; (ii) the views that “Competent authority” should include both legislative and enforcement agencies for food hygiene; (iii) the definition of “Good Hygiene Practices (GHPs)” should be differentiated from that for “Food hygiene system”; and (iv) the definition of “Food business operator” should include transporters.

Conclusion

32. The Committee agreed to:
   - return the proposed draft document to Step 2 for redrafting;
   - establish an EWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and the United States of America, working in English, French and Spanish to:
     a. Review and revise the texts in Appendix 1 of CRD 2, taking into account the discussions at CCFH50 and excluding those texts agreed by CCFH50, and to focus on:
        i. the tracked changes (that were based on the written comments) in the sections that were not discussed at CCFH50;
        ii. texts in square brackets; and
        iii. sections on “General Principles” and “Management Commitment”; and the Comparison Table, to ensure the text reflects discussions at CCFH50 and is aligned with the revised texts;
     b. Consider the inclusion and revision, as appropriate, of the original diagrams from CXC 1-1969:
        i. logic sequence for application of HACCP;
        ii. example of a HACCP worksheet in CXC 1-1969 as Annexes; and
        iii. decision making sequence for the identification of CCPs; and
   - establish a PWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and the United States of America, to be held immediately prior to CCFH51 and working in English, French and Spanish, to consider all comments received and to prepare a revised proposal for consideration by the plenary.

33. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH51 for circulation for comments at Step 3.

REVISION TO THE CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (CXC 52-2003): THE PLACEMENT FOR THE GUIDANCE ON HISTAMINE CONTROL; THE AMENDMENTS TO OTHER SECTIONS, AND THE REVISIONS OF THE SECTION ON SAMPLING, EXAMINATION AND ANALYSES RELATED TO HISTAMINE FOOD SAFETY (Agenda item 6) ⁸

⁸ CX/FH 18/50/6; CX/FH 18/50/6/Add.1 (Argentina, Australia, Brazil, Canada, Colombia, Cuba, Ecuador, European Union, Gambia, Iran, Iraq, Japan, Mexico, Morocco, New Zealand, Norway, Panama, Peru, Senegal, Thailand, United States of America, IUFOST); CX/FH 18/50/6/Add.2 (Australia, European Union, Nicaragua, African Union and FoodDrinkEurope); CRD6 (Revision of related Codex Fish and Fishery product Commodity Standards(Revised)-Prepared by the EWG chairs); CRD7 (Revision to the Code of Practice for Fish and Fishery products (CXC 52-2003) (Revised)-Prepared by the EWG chairs); CRD8 (Nigeria); CRD9 (Dominican Republic); CRD11 (Indonesia); CRD12 (El Salvador); CRD14 (Panama)
34. Japan, co-Chair of the EWG, introduced the item and explained that the co-Chairs had prepared revised proposals (CRD6 and CRD7) based on all written comments and proposed to use these as a basis for discussion.

The placement of the newly adopted histamine guidance in CXC 52-2003

Conclusion

35. The Committee agreed with the recommendation of the EWG that the newly adopted histamine guidance should be a separate section in the Code located directly after Section 9 (Processing of Fresh, Frozen and Minced Fish).

Consequential amendments to other sections of CXC 52-2003

36. The Committee agreed with most of the proposals in CRD7, and in addition to editorial corrections, made the following amendments:

- deletion of the third sentence in para. 1 of Section 12 to avoid confusion as the intent was already covered in the first sentence;
- deletion of “scombrotxin” as a potential hazard and “decomposition” as a potential defect in Section 12.2.1 as this Section was only relevant to species from the Gadidae family, which are not susceptible to scombrotxin formation;
- revision of the text added in Section 13.2 to read “To prevent scombrotxin formation during smoke flavour treatment, proper temperature should be maintained”; and
- change “micro-organism” to “microorganism” throughout the Code.

37. Following a discussion on whether the added text to Section 13.1 should refer to “hot smoking” or just smoking, the Committee agreed to retain “hot smoking” as “cold smoking” was already adequately addressed in CXC 52-2003.

Conclusion

38. The Committee agreed to forward the consequential amendments to other sections of CXC 52-2003 for adoption by CAC42 (Appendix II).

39. The revised CXC 52-2003 including the histamine guidance will be published on the Codex website after adoption of the amendments.

Sampling guidance in eleven commodity standards for fish and fishery products

40. The Committee noted the work that had been undertaken by the EWG, the revision of the sampling guidance by the co-Chairs as presented in CRD6 and the request of the Chairperson to reflect on the Terms of Reference for this work to develop sampling plans for different purposes, bearing in mind that sampling plans should be practical and feasible while still ensuring food safety using a risk-based approach.

41. In line with this, the co-Chair highlighted the two sampling purposes that were described in CRD6; the first purpose for determining acceptability of lots with unknown history, or from sources with unreliable implementation of histamine controls, or for settling disputes, and the second purpose for lots from sources with established Good Manufacturing Practices (GMPs) and HACCP controls to confirm that histamine levels remain indicative of adequate controls. Given that management of time and temperature were key to histamine control, he indicated that the second purpose represented the most common situation, while the first purpose represented exceptional situations.

42. Delegations expressed different views on the sampling plans including that:

- the two-class attributes sampling plan proposed for determining acceptability of lots with unknown history, unreliable controls, or settling disputes suggested that:
  - histamine apparently was considered a severe hazard, when in fact it is a moderate hazard and therefore, a three-class attributes sampling plan would be more appropriate; and
  - a sampling plan involving 59 units was impractical and costly, and would lead to an unnecessary burden on producers and competent authorities and did not therefore reflect the spirit of the Terms of Reference for this work;
- histamine is not life-threatening, does not provoke sequelae, and symptoms disappear after treatment;
experience in implementing a three-class attributes sampling plan with a lower number of samples than proposed in Section 7.1.1 (CRD6) demonstrated that such plans were practical, feasible and effective; 

the sampling plan mentioned in bullet 3 of Section 7.1.1 refers to the sampling plans mentioned in Section 2.5.3 of the General Guidelines on Sampling (CAC/GL 50-2004) about sampling plans for inspection of critical nonconformity. 

Section 7.1.2 (CRD6) was out of the scope of this work as it focussed on verification of control measures rather than sampling plans for safety of specific commodities; and 

the guidance on sampling plans proposed in Section 7.1.2 was ambiguous and would lead to further confusion on the appropriate plans to be applied, and for ease of implementation the document should focus on the development of a single sampling plan for histamine.

43. The co-Chairs clarified that:

- histamine, while a moderate hazard, was the most-commonly reported fish-borne illness in the United States of America;
- the histamine safety limit is near the level that causes illness, and there is no margin of safety, and this was considered in the sampling plan proposed in Section 7.1.1;
- it was not within the scope of work to consider the Codex histamine decomposition quality provision for a 3-class sampling plan for the safety provision;
- the primary approach for control of histamine was through time and temperature control and not sampling;
- in situations where GHPs or HACCP were implemented, the document provided greater flexibility on the sampling plan to be applied;
- when there is no prior knowledge on the lot, or illnesses are traced back to the producer, the sampling plan needs to be more stringent to protect consumers;
- the sampling plan proposed in Section 7.1.1 was based on consideration of different levels of protection as presented in Table 1 of CX/FH 18/50/6 and considered an appropriate balance between public health protection and feasibility in this case, 1 in 20 (5%) of the available sample units in the lot exceed the 200 mg/kg histamine safety limit;
- it was not severity of the hazard but the level of protection that determined the stringency of the sampling plan;
- feasibility and cost should not be based on number of samples alone but also frequency of application of the sampling plan;
- rapid screening methods and composite sampling reduce cost; and
- the Terms of Reference indicated that sampling plans be developed for different purposes as earlier discussions in the Codex Committee on Fish and Fishery Products (CCFFP) determined that a single sampling plan for all situations was not possible.

44. In efforts to move forward it was proposed that the circumstances in which the different sampling plans would apply be further clarified and the sampling plans revised for each of the scenarios.

45. However, given the divergent opinions expressed during the discussion, the co-Chairs indicated that they considered progress was unlikely and proposed to postpone this work for a few years when more data might be available and Codex Committee on Methods of Analysis and Sampling (CCMAS) may have revised the General Guidelines on Sampling (CXG 50-2004). The Committee was in agreement with this proposal.

46. In response to concerns that this left countries with no guidance on sampling plans, it was noted that countries should continue to use the sampling plans as defined in the commodity standards, in which no sample unit can exceed 200mg/kg.
Conclusion

47. In view of the lack of consensus, the Committee agreed

- to postpone consideration of the work until such time as CCMAS had completed its amendments to the General Guidelines on Sampling (CXG 50-2004);
- to inform CAC that the Committee had difficulty to agree on sampling plans for histamine at this time; and
- to inform CCMAS of the challenges faced by the Committee in developing sampling plans for histamine in fish commodities that achieved an acceptable balance between consumer protection, feasibility and practicality, with the view that they could take this into consideration in the revision of CXG 50-2004.

PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS (Agenda item 7)

48. Australia, co-Chair of the EWG, introduced the item, explained the draft guidance and noted that, based on the comments submitted, the main issues to be addressed related to thresholds for allergens, risk assessment methodologies, and the use of the term ‘precautionary allergen labelling’. The co-Chairs had prepared a revised proposal (CRD4) based on all written comments and proposed to use this as a basis for discussion.

Discussion

49. The Committee agreed with most of the revisions in CRD4, and in addition made editorial corrections, amendments for flexibility, clarity and consistency within the Code (e.g., clarification, addition or deletion of examples; inclusion of transporters in the list of FBOs for completeness; including reference to re-packaging as well as re-labelling) and made the following comments and decisions.

50. The Committee noted that allergen management measures could prevent as well as minimize allergens and agreed to use both terms throughout the text.

51. As information on risk of allergen cross-contact may not be available, the Committee agreed to replace ‘risk’ with ‘likelihood’ where appropriate.

52. The Committee also included reference to undeclared as well as unintended allergens in food in the hazard characterization section in recognition that both situations were possible; clarified in Section 5.2.1.4 that the review of suppliers extended to suppliers’ operations and suppliers of processing aids; deleted reference to recognizing and responding to customer allergic reactions under Section 5.6, noting that although very important it was not part of allergen management; and added “and Resolution” to the title of Section 5.8.1 “Consumer complaints” to demonstrate that action needed to be taken.

List of foods that can cause allergic reactions (Para. 9 of CRD4)

53. Responding to the requests for clarification on the list of foods that can cause allergic reactions, the co-Chair of the EWG noted that while the list in the draft was related to allergic reactions and the list in the General Standard for Labelling of Pre-packed Foods (CXS 1-1985) was related to hypersensitivity, the two lists had been aligned as much as possible. In addition, a footnote had been added to clarify the inclusion of oats, given that this cereal does not contain gluten but that oats are commonly produced in the same location as gluten-containing cereals, resulting in cross-contact. The Committee agreed to put para. 9 in square brackets and send the list, with this modification, to CCFL for their advice.

Precautionary allergen labelling (Paras. 14, 28, 72, 152, 160, 161 of CRD4)

54. Recognizing that there may be situations in which the use of a precautionary allergen statement may be warranted, the Committee noted that such labelling should not replace the implementation of measures to prevent or minimize the presence of allergens. In this context, the co-Chair of the EWG informed the Committee that some general text on precautionary allergen labelling and the related use of risk assessment/thresholds had been developed and inserted in relevant sections of the document.

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9 CX/FH 18/50/7; CX/FH 18/50/7/Add.1 (Argentina, Brazil, Canada, Colombia, Costa Rica, Cuba, Ecuador, Egypt, Gambia, Guyana, India, Iraq, Japan, Kenya, Malaysia, Morocco, New Zealand, Norway, Panama, Peru, Philippines, Thailand, the United States of America, AOECS and IDF); CX/FH 18/50/7/Add.2 (Australia, European Union, Nicaragua, African Union and FoodDrinkEurope); CRD4 (Proposed draft Code of practice on food allergen management for food business operators (revised)-prepared by EWG chairs); CRD8 (Nigeria); CRD9 (Dominican Republic); CRD12 (El Salvador); CRD13 (Russian Federation); CRD14 (Panama)
55. While there was general agreement on the inclusion of these texts, the Committee agreed to seek the advice of CCFL on the appropriateness of the precautionary labelling statements and put all relevant paras. in square brackets. Furthermore, in order to include advice to FBOs on the use of risk assessment to support decisions related to allergen management, the Committee agreed that they would need to seek scientific advice, particularly on risk assessment approaches, from FAO and WHO. The Committee also noted that the proposed use of risk assessment was not intended to be burdensome for small FBOs but rather to highlight the importance of FBOs reviewing their processes for allergen management rather than using precautionary labelling and thereby restricting products for consumers.

Conclusion

56. The Committee agreed to:

- forward the proposed draft code for adoption by CAC42 at Step 5 (Appendix III);
- seek the advice of CCFL on the following:
  a. the appropriateness of the use of a precautionary allergen labelling statement (Paras. 14, 72, 152, 160, 161 of Appendix III) and the related definition (Para. 28 of Appendix III);
  b. the list of foods which cause allergic reactions (Para. 9 of Appendix III).
- submit the food labelling provisions to CCFL for endorsement (Paras. 158 and 159 of Appendix III);
- request FAO/WHO convene an expert consultation to provide scientific advice and inform CCFL of this request.

Terms of Reference for FAO/WHO expert consultation on risk assessment of food allergens relating to the work of CCFH

a. what are the threshold levels for the priority allergens (cereals containing gluten, crustaceans, eggs, fish; milk, peanuts, soybeans, and tree nuts) below which the majority of allergic consumers would not suffer an adverse reaction?

b. how can thresholds be used by FBOs to determine:
   ▪ the extent to which a cleaning procedure removes an allergen to a level that prevents or minimises the risk to the majority of allergic consumers from allergen cross-contact; and
   ▪ whether an ingredient that contains a low level of an allergen (e.g. an ingredient with a precautionary allergen label) warrants control of its use to prevent or minimise allergen cross-contact?

c. for the priority allergens, what are appropriate analytical methods for testing food and surfaces?

d. what methods/tools are available for FBOs to determine:
   ▪ whether allergen cross-contact is reasonably likely to occur in a food after a cleaning procedure;
   ▪ whether allergen cross-contact is reasonably likely to occur from equipment used for foods with different allergen profiles; and
   ▪ the level of allergen in a food resulting from cross-contact?

PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF (MICRO)BIOLOGICAL FOODBORNE CRISSES/OUTBREAKS (Agenda item 8)

57. Denmark, Chair of the EWG, introduced the item and proposed to discuss the scope and key areas on which consensus was needed to progress the work. The Committee was informed that the co-Chairs had prepared a revised proposal (CRD10) based on all written comments and proposed that this would be the basis for further work.

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10 CX/FH 18/50/8; CX/FH 18/50/8-Add.1 (Argentina, Brazil, Canada, Colombia, Cuba, Ecuador, Egypt, Gambia, Guyana, India, Iran, Japan, Malaysia, Morocco, New Zealand, Norway, Philippines, Senegal, Thailand, USA and IUFOST); CX/FH 18/50/8-Add.2 (Australia, European Union and African Union); CRD8 (Nigeria); CRD9 (Dominican Republic); CRD10 (Proposed draft guidance for the management of (micro) biological foodborne crises/outbreaks (revised)- prepared by EWG chairs); CRD11 (Indonesia); CRD13 (Russian Federation); CRD14 (Panama); CRD19 (Points for discussion of Agenda item 8 prepared by EWG chairs)
Discussion

References to FAO/WHO documents

58. In reply to the question on referencing FAO/WHO documents in the draft guidance, the Codex secretariat clarified that there was currently no specific rule in Codex on this but noted that references to external documents should be kept to a minimum and inclusion be considered on a case-by-case basis. She also reminded the Committee that the relevant information could be incorporated into the draft guidance, with the objective of removing the references in the final text.

59. The Committee agreed to incorporate relevant information from references where feasible.

Scope

60. The co-Chairs proposed that the guidance focus on foodborne outbreaks and not extend to situations of contamination without human illness cases, and that the term “crises” was subjective and therefore did not add to the clarity of the scope.

61. Responding to proposals that a broader approach to cover the whole continuum of food safety events, including contamination events, would be more appropriate, the co-Chairs noted that the Guidance would cover some of these aspects as they are linked to outbreak management.

62. The Committee agreed to limit the scope to foodborne outbreaks, and to delete the term “crises” in the title.

Definitions of foodborne outbreak

63. The co-Chairs proposed a definition, based on two existing definitions (CRD19) and comments received, highlighting that the objective was to be as inclusive as possible.

64. The Committee agreed to the following definition of foodborne outbreak:

“The observed number of cases of a particular illness that may be foodborne exceeds the expected number, OR the occurrence of two or more cases of a similar foodborne illness resulting from the ingestion of a common food and epidemiologic analysis implicates the food as the source of the illness.”

The use of the term “biological” or “(micro)biological”

65. The Committee agreed to use the term “biological” in the guidance and defined “biological hazards” as follows:

“Biological hazards are biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria, viruses and parasites.”

The use of “Rapid risk assessment” and/or “Outbreak assessment”

66. The Committee agreed to use “Rapid risk assessment” rather than “Outbreak assessment” and defined “Rapid risk assessment” as follows:

“Rapid risk assessment is a risk assessment, based on the information available on the foodborne outbreak, which needs to be carried out urgently to quickly support (provisional) risk management measures and therefore may not always contain all the full development of the four steps of a classical risk assessment.”

Use of graphic explanations/diagrams in the guidance

67. The Committee was informed that an example to illustrate the connection between national, regional and international networks would be prepared for further consideration on the use of graphic explanations at the next session.

Conclusion

68. The Committee agreed to:

- return the proposed draft document to Step 2 for redrafting; and
- establish an EWG, chaired by Denmark and co-chaired by Chile and the European Union, and working in English and Spanish, to:
  a. Review and revise the texts contained in CRD10 taking into account the discussions and agreements at CCFH50, and comments received in writing; and
  b. Provide a revised version for consideration at the next session.

69. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH51 for circulation for comments at Step 3.
DISCUSSION PAPER ON FUTURE WORK ON SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) (Agenda item 9)\textsuperscript{11}

70. This item was considered under agenda item 10.

OTHER BUSINESS AND FUTURE WORK (Agenda item 10)\textsuperscript{12}

New Work / Forward Workplan

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

72. The Committee considered the recommendations of the PWG and made the following comments and decisions.

New work

Control of Shiga Toxin-Producing Escherichia coli (STEC) in Beef, Unpasteurized Milk and Cheese produced from Unpasteurized Milk, Leafy Greens, and Sprouts

73. The Committee noted the following views expressed by members:

- the guidelines should be developed using a step-wise approach and that beef and leafy greens could be the first priorities;
- the proposed structure of the document to include overarching guidance followed by commodity specific guidance was appropriate;
- the term “unpasteurized milk” should be replaced with the term “raw milk” to avoid confusion with milk that may have received thermal treatment but not pasteurization.

74. In response to comments on the specific type of beef meat to be included, the Chairperson clarified this could be defined in the development of the guidelines.

75. The Committee agreed to revise the project document, in line with the comments above, including the proposed time-line for completion to reflect the stepwise elaboration of the work.

Conclusion

76. The Committee agreed to:

- start new work;
- request Chile and the United States of America to revise the project document in line with the discussion and to submit through the Codex Secretariat the revised project document to CAC42 for approval as new work; and
- establish an EWG, co-chaired by Chile and the United States of America, working in English and Spanish, to prepare, subject to the approval of the Commission, the proposed draft guidelines for circulation for comments at Step 3 and consideration at CCFH51.

77. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH51 for circulation for comments at Step 3.

Forward Workplan

78. The Committee reviewed the forward workplan and agreed to:

- remove the work on Control of Shiga toxin-producing \textit{E. coli} as this work would be submitted for endorsement by CAC42;
- move the work on principles for the safe use of water in food processing to the top of the table following its evaluation against the criteria for new work priorities;
- include the \textit{Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods} (CXG 61-2007) in response to information from recent outbreaks; and

\textsuperscript{11} CX/FH 18/50/9; CRD8 (Nigeria); CRD3 (Report of the PWG on CCFH work priorities); CRD8(Nigeria); CRD9 (Dominican Republic); CRD13 (Russian Federation); CRD14 (Panama)

\textsuperscript{12} CL 2018/35-FH; CX/FH 18/50/10; CRD3 (Report of the PWG on CCFH work priorities); CRD9 (Dominican Republic)
• insert a footnote indicating the reference to the project document on the development of the code of hygienic practice for the storage of cereals for ease of reference.

79. The Committee noted the need for a discussion paper on principles for the safe use of water in food processing to progress this work and welcomed the offer of Honduras, with the support of Chile, EU, India and Denmark, to prepare a discussion paper on this subject for consideration by CCFH51.

80. The Committee agreed to:
  • endorse the revised forward workplan (Appendix IV);
  • request the Codex Secretariat to issue a Circular Letter requesting proposals for new work; and
  • establish a PWG on CCFH Work Priorities, to be held in conjunction with CCFH51, working in English, French and Spanish, and chaired by the United States of America.

DATE AND PLACE OF THE NEXT SESSION (Agenda item 11)

81. The Committee was informed that its fifty-first session would be held in the United States of America from 4 to 8 November 2019, with the final arrangements subject to confirmation by the host Government in consultation with the Codex Secretariat.
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**ALIGNMENT OF THE CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (CXC 52-2003) WITH THE NEW SECTION ON HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION**

Edits shown in **bold underline** and **strike-through** font.

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**SECTION 2 – DEFINITIONS**

2.1 **General definitions**

**Disinfection** The reduction by means of chemical agents and/or physical methods in the number of microorganisms in the environment to a level that does not compromise food safety or suitability. 

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**SECTION 4 – GENERAL CONSIDERATIONS FOR THE HANDLING OF FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES**

4.1 **Time and temperature control**

Temperature is the single most important factor affecting the rate of fish and shellfish deterioration and multiplication of microorganisms. For species prone to scombrotoxin production, time and temperature control may be the most effective method for ensuring food safety. It is therefore essential that fresh fish, fillets, shellfish and their products that are to be chilled, be chilled rapidly and held at a temperature as close as possible to 0 °C. **Refer to Section 9-bis for further information on control of scombrotoxin.**

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**SECTION 5 – HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) AND DEFECT ACTION POINT (DAP) ANALYSIS**

5.3.3.1.1 **Hazards**

...However, as with all foods, there are some health risks associated with the consumption of certain products, which may be increased when the catch is mishandled during and after harvest (e.g. scombrotoxin). **Refer to Section 9-bis for scombrotoxin control guidance.**

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**SECTION 9 – PROCESSING OF FRESH, FROZEN AND MINCED FISH**

...As in the further processing of fresh fish in a MAP product, or minced or frozen fish, the section labelled “Fish preparation” is used as the basis for all the other fish-processing operations (Sections 9-bis, 10, 12, 13, 17 and 21), where appropriate.

For fish susceptible to scombrotoxin formation, refer to Section 9-bis “Harvesting, Processing, Storage and Distribution of Fish and Fishery Products at Risk for Scombrotoxin (Histamine) Formation” for information on the control of histamine, including guidance for harvest vessel operations.

9.1.1 **Raw, fresh or frozen fish reception (Processing Step 1)**

**Potential hazards:** microbiological contamination, viable parasites, biotoxins, scombrotoxin\(^\text{10}\), chemicals (including veterinary drug residues) and physical contamination.

\(^\text{10}\)Refer to Section 9-bis for scombrotoxin control guidance.

9.1.5 **Washing and gutting (Processing Steps 6 and 7)**

**Potential hazards:** microbiological contamination, biotoxins and scombrotoxin

**Potential defects:** presence of viscera, bruising, off-flavours, cutting faults, decomposition
9.2.2 Vacuum or modified atmosphere packaging (Processing Step 11)

Potential hazards: subsequent microbiological contamination and biotoxins, subsequent scombrotoxin produced subsequent to packaging, physical contamination (metal)

Potential defects: subsequent decomposition

9.3.1 Freezing process (Processing Step 15)

Potential hazards: viable parasites, scombrotoxin

Potential defects: texture deterioration, development of rancid odours, freezer burn, decomposition

9.4.2 Washing of minced fish (Processing Step 22)

Potential hazards: microbiological contamination and scombrotoxin

Potential defects: poor colour, poor texture, excess of water, decomposition

9.4.3 Blending and application of additives and ingredients to minced fish (Processing Steps 23 and 24)

Potential hazards: physical contamination, microbiological contamination, non-approved additives and/or ingredients, scombrotoxin

Potential defects: physical contamination, incorrect addition of additives, decomposition

9.4.4 Wrapping and packaging (Processing Steps 17 and 25)

Potential hazards: microbiological contamination, scombrotoxin

Potential defects: subsequent dehydration, decomposition

SECTION 9-bis – HARVESTING, PROCESSING STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE FORMATION)

[Placeholder for newly adopted histamine control guidance]

SECTION 10 – PROCESSING OF FROZEN SURIMI

10.1.1 Hazards

If scombrotoxin-forming fish such as tuna or mackerel or tropical reef fish that may accumulate ciguatera toxin are utilized for surimi, appropriate controls for these hazards should be developed.

Refer to Section 9-bis for scombrotoxin control guidance.

10.2.1 Raw fresh and frozen fish reception (Processing Step 1)

Potential hazards: unlikely when using marine groundfish as the raw material, scombrotoxin

Potential defects: decomposition, protein denaturation

10.2.2 Chilled storage (Processing Step 2)

Potential hazards: unlikely scombrotoxin

Potential defects: protein denaturation, decomposition

10.4 Washing and dewatering process (Processing Step 10)

Potential hazards: microbiological contamination, scombrotoxin

Potential defects: decomposition, protein denaturation, residual water-soluble protein

10.5 Refining process (Processing Step 11)

Potential hazards: microbiological contamination, scombrotoxin, metal fragments

Potential defects: objectionable matter, protein denaturation, decomposition

Technical guidance:
- Temperature of the minced fish flesh in the refining process should be adequately controlled to prevent the growth of pathogenic bacteria and scombrotoxin formation.
- Product should be processed promptly to minimize possible pathogenic microbial growth and scombrotoxin formation.

10.6 Final dewatering process (Processing Step 12)
Potential hazards: microbiological contamination, scombrotoxin
Potential defects: decomposition, protein denaturation

10.7 Mixing and addition of adjuvant ingredients process (Processing Step 13)
Potential hazards: microbiological contamination, scombrotoxin, metal fragments
Potential defects: improper use of food additives, protein denaturation, decomposition
Technical guidance:
- Temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria and scombrotoxin formation.
- Product should be processed promptly to minimize possible pathogenic microbial growth and scombrotoxin formation.

10.8 Packaging and weighing (Processing Step 14)
Potential hazards: microbiological contamination, scombrotoxin
Potential defects: foreign matter (packaging), incorrect net weight, incomplete packaging, denaturation of protein, decomposition
Technical guidance:
- Temperature of the product should be adequately controlled during packaging to avoid the growth of pathogenic bacteria and scombrotoxin formation.
- Product should be packaged promptly to minimize possible pathogenic microbial growth.
- Packaging should be conducted rapidly to minimize the risk of contamination, pathogenic microbial growth, scombrotoxin formation, or decomposition.

10.9 Freezing operation (Processing Step 15)
Potential hazards: unlikely scombrotoxin
Potential defects: protein denaturation, decomposition
Technical guidance:
- After packaging and weighing, the product should be promptly frozen to maintain the quality of the product, and to prevent scombrotoxin formation.
- Procedures should be established that specify maximum time limits from packaging to freezing.

10.13 Frozen storage (Processing Step 19)
Potential hazards: unlikely scombrotoxin
Potential defects: decomposition, protein denaturation
Technical guidance:

SECTION 11 – PROCESSING OF QUICK-FROZEN COATED FISH PRODUCTS

11.3.1 Reception

11.3.1.1 Fish
Potential hazards: chemical, and biochemical and microbiological contamination, histamine scombrotoxin
Potential defects: tainting, block irregularities, water and air pockets, packaging material, foreign matter, parasites, dehydration, decomposition
**11.3.5.2. **Application of additives and ingredients

Potential hazards: foreign material, microbiological contamination, *scombrotoxin*

Potential defects: incorrect addition of additives, *decomposition*

Technical guidance:
- The temperature of the product in the mixing process should be adequately controlled to avoid the growth of pathogenic bacteria, and *scombrotoxin formation*.

**11.3.5.3** Forming

Potential hazards: foreign material (metal or plastic from machine) and/or microbiological contamination/*scombrotoxin* (fish mixture only)

Potential defects: poorly formed fish cores, cores subjected to too much pressure (mushy, rancid), *decomposition*

**11.3.7.1** Wet coating

Technical guidance:
- controlled within certain parameters to *affect* the proper amount of breading pick-up.

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**SECTION 12 – PROCESSING OF SALTED AND DRIED SALTED FISH**

This Section applies to fresh, all species of salted and dried salted fish, of the *Gadidae* family, intended for human consumption, have the following scientific and common names: Cod (*Gadus morhua*), Pacific cod (*Gadus macrocephalus*), Polar cod (*Boreogadus saida*), Greenland cod (*Gadus ogac*), Saithe (*Pollachius virens*), Ling (*Molva molva*), Blue ling (*Molva dypterygia*), Tusk (*Brosme brosme*), Haddock (*Gadus aeglefinus/Melanogrammus aeglefinus*), Forkbeard (*Phycis blennoides*) and Pollock (*Pollachius pollachius*). **Measures to control scombrotoxin are not relevant for species that are not susceptible to scombrotoxin formation, such as species in the Gadidae family.**

**12.1** General

Refer also to Section 9.1 for general handling prior to processing and Figure 12.1 for an example flow chart of a salted and dried salted fish-processing line. **Refer to Section 9-bis for technical guidelines for the control of scombrotoxin.**

**12.2** Preparing for salting

**12.2.1** Splitting, washing and rinsing (Processing Step 7)

Potential hazards: unlikely

Potential defects: improper splitting

**12.2.4** Nobbing (Processing Step 10)

Potential hazards: unlikely *scombrotoxin*

Potential defects: remaining gut content and intestines other than roe or milt, decomposition

**12.2.5** Gibbing (Processing Step 11)

Potential hazards: unlikely *scombrotoxin*

Potential defects: remaining gut content, decomposition

**12.4** Salting and maturing

Salted fish should be salt-matured, sound and wholesome. The salting process, including the temperature, should be sufficiently controlled to prevent the development of *C. botulinum*, or the fish should be eviscerated prior to brining. **The temperature should also be sufficiently controlled to prevent the formation of histamine in susceptible species.**
Salting of fish either by brining, brine injection, wet-salting, dry-salting or pickling should be carried out with full understanding of their effects on the quality of the final product and should be done under strict hygienic conditions and temperature control.

Two particular conditions that can adversely affect the quality of salted fish are the occurrence of bacteria and mould. Both defects can be combated by maintaining a temperature lower than 8 °C (ideally below 4 °C for fish that may form scombrotoxin). Salt produced from marine sources may contain halophilic bacteria, which continue to live in the salt and salted fish. In order to minimize such microbial contamination of salted fish, previously used and/or contaminated salt should be removed from the plant.

12.4.1 Brining (Processing Step 14)

*Potential hazards:* viable parasites, scombrotoxins, botulinum toxin

12.4.2 Brine injection (Processing Step 15)

*Potential hazards:* viable parasites, scombrotoxins, injection needle fragment, botulinum toxin

12.4.3 Wet-salting (Processing Step 16)

*Potential hazards:* viable parasites, scombrotoxins, botulinum toxin

12.4.4 Dry-salting (Processing Step 17)

*Potential hazards:* viable parasites, scombrotoxins, botulinum toxin

12.4.5 Pickling (Processing Step 18)

*Potential hazards:* viable parasites, scombrotoxins, botulinum toxin

*Potential defects:* decomposition

**Technical guidance:**
- The amount of salt must be adjusted to the quality of the fatty (primary) fish (fat content). Salt, sugar and spices should be weighed/measured and be evenly distributed.
- Cured fatty fish should be kept in brine or pickle.
- Fatty fish should always be covered with pickle during curing.
- Pickling is primarily used for fatty fish. Under certain conditions, dry-salting of small fatty fish, such as anchovy and small herring, may be used.

12.4.6 Maturing (Processing Step 19)

*Potential hazards:* viable parasites, microbiological contamination, scombrotoxins, botulinum toxin

*Potential defects:* decomposition, rancidity and discolouring of the flesh or surface bacteria and mould

**Technical guidance:**
- The first part of curing period for fish that accumulate histamine should be done at temperatures between 0 °C and 5 °C to prevent growth of microbial pathogens and development of histamine.
- Fatty fish such as herring may be kept in a temperature range of 5–10 °C during the maturing period provided the salt concentration is sufficient to inhibit scombrotoxin formation. The length of this period will vary from weeks to several months depending on the specific products. If the containers are to be held at lower temperatures, the maturing period will increase.

12.5.2 Drying (Processing Step 21)

*Potential hazards:* unlikely scombrotoxin

12.5.3 Weighing, wrapping and packaging (Processing Step 22)

**Technical guidance:**
- Barrels in which fatty fish are ready to be marketed should be clean, whole and hygienic.
SECTION 13 – SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH

13.1 Processing of Smoked Fish

This Section provides…

The recommendations made for the production of fresh fishery products in Section 9 are valid for the preparation of fish used as raw material for the production of fish products covered by this section.

For fish at risk of scombrotoxin formation, the times of product exposure between refrigerated and hot smoking temperatures should be monitored to control histamine formation (refer to Section 9-bis for technical guidelines on histamine control).

13.1.1 Reception of raw materials

Refer to Section 9.1.1, Refer to Section 9-bis.1 for fish susceptible to scombrotoxin.

13.1.2 Salting

Potential Hazards: microbiological, chemical and physical contamination, scombrotoxin, presence of metal, broken needles

Potential Defects: decomposition, physical contamination, undesired texture, physical damage

Technical guidance:

- Fish for cold smoking are dry salted, wet salted, combined salted or salted by brine injection of a medium-strength salt brine to enhance flavour and for safety purposes. To ensure a uniform salt distribution throughout the fish, it can be left for up to 24 hours under refrigeration to equilibrate. The equilibration time should be adapted to the salting technique used, to the temperature (e.g. 8–12 °C), and depending on the fish species.
- Salting time and temperature and fish temperature should be selected so as to control the development of histamine, where fish of susceptible species are concerned (e.g. Scombridae, Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae).

13.1.3 Hanging and racking

Potential hazards: microbiological contamination, scombrotoxin

Potential defects: physical damage, drying/smoking defects due to inadequate separation, decomposition

13.1.4 Drying

Refer also to Section 12.5.2

Potential hazards: microbiological contamination, physical contamination, and histamine formation, scombrotoxin

Potential defects: decomposition, fungal contamination, physical contamination

Technical guidance:

- Drying should not result in prolonged exposure to ambient temperature as this may lead to unwanted microbiological growth and the formation of histamine in susceptible species.

13.1.10 Hot smoking

Potential hazards: parasites and microbiological contamination, scombrotoxin, chemical contamination from smoke

Potential defects: physical contamination (tar, ash), poor colour, flavour and texture, decomposition

Technical guidance:

- Time and temperature of the smoking process should be monitored to achieve the desired colour, taste and texture, and to ensure control of microbiological contamination, and scombrotoxin formation in susceptible species. Continuous monitoring devices are...
recommended to ensure that time and temperature conditions are met.

13.1.11 Cold smoking

Potential hazards: chemical contamination from smoke, growth of Clostridium botulinum, scombrototoxin

Potential defects: physical contamination (tar, ash), poor colour, flavour and texture, decomposition

Technical guidance:

- In the cold smoking process the temperature of the products is kept below the coagulation temperature for the proteins of the flesh of the fish, usually under 30 °C, but can vary between 27 °C and 38 °C. Time and temperature of the smoking process should be monitored to achieve the desired colour, taste and texture. Continuous monitoring devices are recommended to ensure that time and temperature conditions are met.

13.1.12 Cooling

Potential hazards: microbiological contamination, scombrototoxin

Potential defects: poor taste and texture, decomposition

Technical Guidance:

- Following smoking, the fish should be cooled rapidly and thoroughly to a temperature that minimizes microbiological growth over the determined shelf-life.

13.1.13 Slicing

Potential hazards: microbiological contamination, scombrototoxin

Potential defects: physical contamination, poor slices, decomposition

Technical guidance:

- The flow of products should be maintained to avoid undue accumulation of products along the processing line.

13.1.14 Packaging

Potential hazards: microbiological, chemical and physical contamination, scombrototoxin

Potential defects: physical contamination, decomposition

13.1.15 Cooling or freezing

Potential hazards: microbiological contamination, scombrototoxin, survival of parasites

Potential defects: poor taste and texture, decomposition
13.1.16 Storage

Potential hazards: microbiological contamination, scombrotoxin

Potential defects: poor taste and texture, decomposition, freezer burn

13.2 Smoke-flavoured fish

Potential hazards: microbiological, physical and chemical contamination from smoke flavours, growth of Clostridium botulinum, scombrotoxin

Potential defects: too little or too much smoke flavour, non-homogenous distribution of smoke flavour, physical contamination, poor colour, flavour and texture, decomposition

- To prevent scombrotoxin formation during smoke flavour treatment, proper temperature should be maintained.

13.3 Pre-drying

Potential hazards: microbiological and physical contamination, scombrotoxin

Potential defects: decomposition, physical contamination

13.3.2 Smoke-drying

Potential hazards: parasites and microbiological contamination, scombrotoxin, chemical contamination from smoke

Potential defects: physical contamination (filth), burnt parts, poor texture, decomposition

SECTION 17 – PROCESSING OF CANNED FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

17.2.1 Hazards

A2 Scombrotoxin

Histamine

Since histamine is heat stable, its toxicity it remains practically intact in containers following fish processing at high temperatures. Good practices for the conservation and handling from capture to heat processing retorting are essential to prevent histamine production. Refer to Section 9-bis for further information about histamine control. Codex adopted maximum levels for histamine in standards.

17.3.1 Fish and shellfish (Processing Step 1)

Potential hazards: chemical and biochemical contamination (DSP, PSP, scombrotoxin, heavy metals, etc.)

Potential defects: species substitution, decomposition, parasites

Technical guidance:

Refer to Section 9.1.1 (and Section 9-bis.4.1 for scombrotxin-forming fish), and other relevant sections; and also:

17.3.3 Unwrapping, unpacking (Processing Steps 3 and 4)

Potential hazards: unlikely scombrotoxin

Potential defects: foreign matter, decomposition

Technical guidance:

- During unwrapping and unpacking operations, precautions should be taken to limit product contamination and the introduction of foreign matter into the product. To avoid microbial proliferation, waiting periods before further processing should be minimized.
17.3.5.1 Fish preparation (gutting, trimming, etc.)

**Potential hazards:** microbiological contamination, biochemical development (histamine scombrotoxin)

**Potential defects:** objectionable matter (viscera, skin, scales, etc. in certain products), off-flavours, decomposition, presence of bones, parasites, etc.

**Technical guidance:**

Refer to Sections 9.1.5 and 9.1.6, and 9-bis and:

17.4 Precooking

**Potential hazards:** chemical contamination (polar components of oxidized oils), microbiological or biochemical (scombrotoxin) contamination, scombrotoxin

**Potential defects:** water release in the final product (for products canned in oil), abnormal flavours, decomposition

17.4.1 Filling

**Potential hazards:** microbiological contamination and scombrotoxin (waiting period or, after heat processing owing to incorrect filling or defective containers)

**Potential defects:** incorrect weight, foreign matter, decomposition

17.4.3 Handling of containers after closure – staging before heat processing (Processing Step 9)

**Potential hazards:** microbiological contamination and scombrotoxin (waiting period or owing to damaged containers)

**Potential defects:** unlikely, decomposition

SECTION 18 – PROCESSING OF FISH SAUCE

Salt is an essential ingredient in fish sauce production in order to support the growth of halophilic microorganisms that produce effective fermentation, and prevent growth of bacterial pathogens and other undesirable microbial activity, yielding a high quality, safe fish sauce product.

**General considerations of hazards and defects**

**Hazards**

The raw material used in the fermentation to make fish sauce may include both freshwater and marine fish. Some marine fish, such as mackerel, sardines or anchovies, pose a risk of scombrotoxin formation; for these it is necessary to refer to Section 9-bis of this Code. Fish may be contaminated with undesirable microorganisms, including pathogenic bacteria, thus it is necessary to control raw material on the harvest vessel in compliance with Sections 3, 4, and 9-bis of this Code.

Water Phase Salt concentrations of 20 percent or higher should be achieved and maintained throughout the fermentation to prevent growth and activity of undesirable microorganisms, including pathogens.

SECTION 20 – TRANSPORTATION

20.1 For fresh, refrigerated and frozen products

**Potential hazards:** biochemical development (histamine scombrotoxin), microbiological contamination

**Potential defects:** decomposition, physical damage, chemical contamination (fuel)

**Technical guidance:**

Refer to Section 9-bis.3 for fish at risk of scombrotoxin formation.

- Check product temperature before loading.

SECTION 21 – RETAIL
21.1.1 Reception of chilled products at retail

Potential hazards: microbiological contamination, chemical and physical contamination, scombrotoxin formation, C. botulinum toxin formation

Potential defects: spoilage (decomposition), contaminants, filth

Technical guidance:

- Product temperature should be taken from several locations in the shipment and recorded. Chilled fish, shellfish and their products should be maintained at or below 4 °C (40 °F). MAP product, if not frozen, should be maintained at or below 3 °C (38 °F).

- **For fish susceptible to scombrotoxin formation, retailers should measure fish internal temperatures and perform sensory examination of representative fish before accepting delivery, and retailers should ensure that fish are purchased from suppliers that use HACCP or similar systems to prevent histamine formation.**

- **For fish susceptible to scombrotoxin formation, retailers should ensure that fish are purchased from suppliers that use HACCP or similar control systems to prevent histamine formation. In case the fish being received is likely to be susceptible to scombrotoxin formation, retailers should evaluate if fish are surrounded by ice or other cooling media, measure fish internal temperatures when appropriate, and perform sensory evaluation of representative fish samples before accepting delivery.**
ANNEX I — POTENTIAL HAZARDS ASSOCIATED WITH FRESH FISH, SHELLFISH AND OTHER AQUATIC INVERTEBRATES

1.2 Bacteria

…Examples of indigenous bacteria that may pose a health hazard are *Aeromonas hydrophila*, *Clostridium botulinum*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, *Vibrio vulnificus* and *Listeria monocytogenes*.

…Other species that cause foodborne illness and that have occasionally been isolated from fish are *Edwardsiella tarda*, *Plesiomonas shigelloides* *Plesiomonas shigelloides* and *Yersinia enterocolitica*.

1.5 Scombrotoxin

Scombroid intoxication, sometimes referred to as histamine poisoning or scombrototoxin fish poisoning, results from eating fish that have been incorrectly chilled during and/or after harvesting and/or during subsequent processing and handling. Scombrotoxin is attributed mainly to bacteria in the Enterobacteriaceae family, which can produce high levels of histamine and other biogenic amines in the fish muscle when products are not immediately chilled after catching and retained in a chilled state. The main susceptible fish are the scombroids (Scombridae family) such as tuna, mackerel and bonito, although it can be found in other fish families such as Clupeidae, Engraulidae, Coryphaenidae, Pomatomidae, Scomberesocidae. The intoxication is rarely fatal and symptoms are usually while typically mild, can be severe. Rapid refrigeration after catching and a high standard of handling during processing should prevent the development of the toxin. The toxin is not inactivated by normal heat processing. In addition, fish may contain toxic levels of histamine without exhibiting any of the usual sensory parameters characteristic of spoilage.
Appendix III

PROPOSED DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

(At Step 5)

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Introduction

1. Food allergies, an immune-mediated food hypersensitivity, are an increasing food safety issue globally and have emerged as a major public and personal health burden. While food allergies may affect a relatively small proportion of the population, an allergic reaction can be severe or potentially fatal. Furthermore, it is increasingly apparent that people with food allergies experience a very significant reduction in quality of life, some of which could be mitigated by a harmonised approach to the management of allergens in the food chain.

2. Allergens are an ongoing food safety concern for allergic consumers, those who have people with food allergies in their care, growers, transporters, food business operators (FBOs) and competent authorities.

3. With the increasing health burden posed by food allergens, comes the expectation that FBOs take steps to accurately declare the presence of allergenic ingredients, prevent and manage unintended allergen presence and that Competent Authorities provide guidance, oversight and advice, where necessary, to FBOs on food allergen complaint investigations. FBOs including producers, processors, wholesalers, distributors, importers, exporters, retailers, transporters, and food service operators all have a role in managing allergens.

4. In a global market, it is crucial that there is international understanding of this issue and of the measures required to address it. Allergen management practices should be part of good hygiene practices (GHPs), and, where appropriate, HACCP systems, in manufacturing, retail and food service.

5. Allergens need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, can minimise the allergenicity, but should not be relied upon to eliminate or completely destroy allergenic proteins.

Hazard characterisation

6. The allergenic nature of some foods should be identified as a food safety hazard for susceptible individuals. Food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. Allergies to food can be classified by their immune mechanism:
   - immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
   - non-IgE mediated (cell-mediated, or delayed hypersensitivity), and
   - mixed IgE and non-IgE mediated.

7. IgE-mediated symptoms typically develop within minutes to 1-2 hours of ingesting the food. Non–IgE-mediated and mixed IgE- and non–IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms of IgE-mediated food allergy may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea and, in its most severe form, anaphylaxis; and may result in death.

8. Coeliac disease is a serious lifelong illness where the body’s immune system attacks its own tissues when gluten is consumed. This causes damage to the lining of the gut and results in the inability of the body to properly absorb nutrients from food.

9. While many different foods can cause allergic reactions in susceptible individuals, the majority of food allergies on a global basis are caused by a variety of proteins in eight foods/food groups (and derived products). These are
   - cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these)
   - crustaceans;
   - eggs;
   - fish;
   - milk;

---

1 [The listed allergens, with some exceptions (e.g. sulphites), are also referred to in the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) with respect to labelling.]
2 While oats do not contain gluten, they are commonly produced in the same location as gluten-containing cereals such as wheat, resulting in cross-contact.
10. The most common allergic reactions to tree nuts involve almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, cereal grains such as wheat, barley and rye contain gluten, which can cause adverse reactions in persons with Coeliac disease, as well as those with specific allergies to those cereals.

11. While the allergens listed above are the most common, other food allergens such as sesame seeds, buckwheat, celery, mustard, molluscs and lupin are recognised as important in many countries. The list of recognised food allergens varies among countries and there is the potential for additional major allergens to be identified in the future. The controls outlined in this Code of Practice (Code) would be similar for any other allergens, and FBOs should apply these as appropriate to their own business requirements and applicable legislation. This includes being aware of the food allergens recognised as important in countries they are exporting their product to, managing those allergens and ensuring the necessary allergen labels are applied.

12. Poor allergen management (including insufficient or inaccurate labelling) can result in the presence of varying levels of undeclared and/or unintended allergens in food, which may pose a risk if consumed by an allergic individual. The doses that provoke reactions vary among individuals and depend in part on the type of allergen. The risk of allergic reactions among a larger proportion of the allergic population increases with increasing concentration of undeclared allergen.

13. Allergen cross-contact can result from a number of factors in processing, preparing and handling foods, some of which pose a greater potential for cross-contact than others. The control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on risk.

14. [In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventive measures and GHPs, and in such situations, the application of a precautionary allergen statement such as “may contain” is substantiated. However, it may be possible to minimise cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that would cause an adverse reaction in the majority of consumers allergic to the specific allergen. In these instances, the use of scientifically based threshold levels is a tool to evaluate risk for consumers with food allergies. Threshold levels can be used to reduce precautionary allergen labelling, in turn making precautionary labelling much more meaningful for consumers with food allergies.]

15. It is important that FBOs are able to identify the allergenic nature of the foods, including ingredients, and processing aids they handle and take steps to manage any potential presence of undeclared allergens.

Factors contributing to exposure

16. A variety of situations may result in the exposure of allergic individuals to undeclared allergens. These include the following:

**For harvesting, handling, storage and transportation:**
- inadequate or ineffective cleaning of containers, including reusable bags, and transport vehicles;
- inadvertent inclusion of foreign particulates (e.g. grains, nuts or seeds);
- inadequate physical separation or storage of commodities with different allergen profiles; and
- inadequate or a lack of employee training and awareness on managing food allergens.

**For packaged food manufacturing facilities:**
- labelling errors (e.g. mistakes during label development, label misprints, outdated labels, lost labels, wrong label applied to package, incorrectly translated labels or omitting the declaration of an allergen, product in the wrong package);
- unintentional presence of an allergen due to in-process or post-process cross-contact;
- inappropriate design of the establishment in terms of separation of areas, location of equipment, traffic patterns, and the ventilation system, among others;
- errors in handling of rework;
• production sequences (scheduling) that result in the unintentional presence of an allergen from a product produced earlier;
• inadequate or ineffective equipment cleaning/sanitation procedures at product changeover;
• lack of change management for changes in formulation, ingredient supply and documentation processes;
• improper use of an allergen-containing ingredient;
• undeclared allergen in a supplier ingredient; and
• inadequate or lack of employee training/education on managing food allergens.

For retail and food service establishments:
• failure of the establishment to receive accurate information from supply chain or lack of allergen information with ingredients or foods received;
• failure to receive timely notification of ingredient changes or order substitution;
• labelling errors for allergenic foods;
• lack of adequate storage or preparation areas to prevent or minimise the potential for allergen cross-contact;
• inappropriate flow or separation of operations or improper equipment lay-out or utensils;
• absence of, or inadequate, food preparation and service procedures to avoid allergen cross-contact;
• inadequate or lack of employee training/education on managing food allergens, including lack of understanding of the serious nature of food allergies;
• inability of FBOs to clearly communicate allergen information to customers;
• food delivery websites which fail to communicate allergen presence in food items to the consumer, as well failure of a delivery service to communicate a consumer’s dietary requirements, with respect to allergens, to the FBO preparing the food; and
• food allergic individuals not making their allergies known to food service personnel.

17. Cross-contact can occur at many points in the food chain. Potential points where cross-contact can occur are outlined in relevant sections within this Code.

18. FBOs are encouraged to have documented and detailed allergen management policies and procedures specific to the food business. Implementing allergen management policies and procedures, and compliance with these:
• allows a business to demonstrate it is taking all necessary steps to reduce the likelihood of an allergen being unintentionally present in a food;
• increases accuracy of allergenic ingredient declarations;
• provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management; and
• reduces the risk to the allergic consumer from the presence of an unintended allergen.

SECTION I - OBJECTIVES

19. This Code provides guidance to FBOs, including primary producers, to develop policies and procedures to identify allergens in all areas of food production, preparation and service, and then implement allergen management practices, including controls to:
• prevent or minimise the potential for cross-contact that is of risk to the allergic consumer;
• ensure the correct allergen label is applied to pre-packaged foods; and
• ensure that accurate information can be provided to consumers at point of sale when the food is not pre-packaged.

20. The management tools and guidance in this Code are a proactive approach for effectively managing allergens in food production, preparation and service and reducing risk for consumers, rather than a reactive response once a food safety hazard has been detected in a food.
21. Food allergen management also involves allergen labelling. While this Code addresses controls to ensure that the correct label is applied during manufacturing of a product or when labelled at retail for the customer, labelling requirements for food products are addressed by the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) and the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CXS 118-1979).

Section II – Scope, Use and Definitions

2.1 Scope

22. This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service end points. It complements GHP in manufacturing and food preparation practices in food service.

23. This Code covers IgE-mediated, non Ig-E-mediated food allergies and hypersensitivities (e.g. Coeliac disease) that can be triggered by small amounts of the offending food allergen (thus requiring attention to GHPs in addition to labelling). There are eight foods/food groups (and derived products) that cause the majority of food allergies on a global basis, these are cereals containing gluten; crustaceans; eggs; fish; milk; peanuts; soybeans; and tree nuts. However, since the complete list of recognised food allergens varies among countries, it is important to consider which allergens are applicable when exporting food.

24. This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food, such as a lack of an enzyme to process foods effectively (e.g. the absence or deficit of lactase in those with lactose intolerance). While intolerances are not explicitly mentioned in the following text, some of the controls described here could be applied to protect those with food intolerances.

2.2 Use

25. This Code follows the format of the General Principles of Food Hygiene (CXC 1-1969) and should be used in conjunction with it, as well as with other applicable codes and standards such as the General Standard for Labelling of Prepackaged Foods (CXS 1-1985) and Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001).

26. The provisions in this document should be applied as appropriate for the food business (e.g. manufacturing, retail, food service), with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of public health risks associated with allergenic ingredients/foods.

27. The document has been structured to outline the principles of food allergen management which apply broadly to food business operators, as well as identify those which should be specifically applied to retail and food service sectors.

2.3 Definitions

28. Refer to definitions in the General Principles of Food Hygiene and other applicable Codes. In addition, for the purpose of this Code, the following expressions have the meaning stated:

Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction in certain individuals. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.

Allergen cross-contact occurs when an allergenic food, or ingredient, is unintentionally incorporated into another food that is not intended to contain that allergenic food.

Allergen profile means the food allergens present via intentional addition as well as those inadvertently present (or the absence of any allergens) in a food.

Food service means a food business or institution that produces, prepares and serves food for direct consumption.

[Precautionary allergen labelling means a label indicating the allergens (other than those that are listed as ingredients) that may be present in the product because of unavoidable cross-contact (e.g. “may contain”).]

Retail means a food business primarily involved in selling pre-packaged or non-prepackaged food directly to consumers for off-site or future consumption.

Rework means clean, unadulterated food that has been removed from processing at any point up to and including final packaging for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food or a food component.

Visibly clean means having no visible food, debris and other residues..
29. This section is focused on primary production of cultivated commodities where there is a likelihood of allergen cross-contact (often referred to as adventitious presence).

Section III – Primary Production

3.1 Environmental hygiene

30. Depending on the crop, growers should consider the potential for allergen cross-contact from the growing environment. In order to assess the likelihood of allergen cross-contact, growers should know the history of the specific growing area (i.e., previous crops), and what other crops are being grown in close proximity. Where the adventitious presence of an allergen needs to be managed to ensure the allergen profile of the final food (e.g. gluten free), particular crop measures may be required to remove, to the extent practicable, the physical remains of previous crops prior to re-planting.

3.2 Hygienic production of food sources

31. During growing, prevent or minimise the potential for maintenance machinery (e.g. used for weeding) to contain other plant material which could result in allergen cross-contact.

3.3 Handling, storage and transport

32. Prior to harvest, inspect equipment used for harvesting of crops to determine if the equipment is clear of visible plant debris and signs of previous crops/food material.

33. Harvested commodities should be cleaned to the extent possible using various methods such as sifting via size, aeration, and mechanical cleaning to remove foreign allergenic matter where feasible and consistent with applicable Codex standards.

34. To prevent or minimise the likelihood of allergen cross-contact, storage facilities that hold different commodities should be visually inspected and appropriately cleaned. When handling multiple commodities such as grains/pulses/seeds ensure that physical segregation is in place to prevent or minimise the potential for cross-contact. Having a clear “allergen map” (see section 5.2.1.1) of the storage facility will show where allergenic crops enter and are stored so the potential for cross-contact is managed.

35. Where a commodity is bagged, bags should be clean and those used for allergenic commodities should be identified (e.g. with different colours). Bags that have been used for an allergenic commodity should not be reused for a different commodity. For example, avoid the re-use of jute / canvas bags for non-allergenic commodities if they have already been used for allergenic commodities. Where grains or pulses are bagged and stored together, store allergens on the bottom shelves so that spillages can be easily managed from the perspective of preventing contact with non-allergenic commodities.

36. FBOs should ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.

37. Transportation of food stuff should be carried out using a clean transport vehicle that is dry and free of the previous load to prevent or minimise the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to prevent or minimise the potential for allergen cross-contact of the next load. The use of one-time packaging may be a useful option for some transporters. For more detail on transportation refer to Section 8.

3.4 Cleaning, maintenance and personnel hygiene at primary production

38. Refer to the General Principles of Food Hygiene (CXC 1-1969).

39. In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue.
Section IV – Establishment: Design and Facilities

**PRINCIPLE:** Establishment design should prevent or minimise the potential for allergen cross-contact with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.

4.1 Location

4.1.1 Establishments

40. FBOs producing food at more than one site should consider whether it is feasible to consolidate production, processing and storage of products containing specific allergens at one location. Although this may not always be feasible, particularly for small businesses, it could be used to limit allergen cross-contact. If dedication of production facilities is not possible, the production could be separated in time (see 5.2.1.) or space (separate rooms or lines for different allergens) and the establishment may be designed to have a linear flow in the production. Effective cleaning procedures, such as those outlined in Section 6, are also important in managing allergen cross-contact.

4.1.2 Equipment

4.1.2.1 Manufacturing

41. Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment. Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in all cases. Separation by time should be considered as an option, especially for small businesses. An analysis of the process, including the equipment design, should be conducted to determine the likelihood of allergen cross-contact and whether dedicated processing lines, equipment redesign, or other control measures are needed to prevent or minimise such cross-contact.

42. If separate production lines are used for foods with different allergen profiles (e.g. for foods that do not contain a particular allergen and for foods that do), manufacturers should provide sufficient separation to prevent or minimise the potential for cross-contact from one line to another based on the food, the process, and the likelihood of cross-contact. Manufacturers should eliminate cross-over points or provide a means to contain or shield food (e.g. closed pipes, enclosed or covered conveyors) to prevent food spilling from one line to another.

4.1.2.2 Retail and food service

43. Retail and food service operators also commonly handle multiple allergens, frequently on the same equipment. They should, where feasible, use equipment dedicated to foods with a particular allergen (e.g. use a separate slicer for cheese, which contains milk, and for meats that do not contain milk). Alternatively, equipment should be cleaned when switching between foods with different allergen profiles (see section 6.1).

4.2 Premises and rooms

44. Where feasible, FBOs (manufacturers, as well as retail and food service operators) should consider the need, based on the likelihood of allergen cross-contact resulting in a risk to the allergic consumer, to provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas, or use screens to set up temporary segregated areas, for foods with different allergen profiles. For example, an establishment that handles shellfish and fish could dedicate separate rooms or other areas for handling these foods. One that handles different types of protein powders such as soy protein and milk powder could dedicate separate areas for handling these powders. Alternatively, equipment should be thoroughly cleaned when switching between different food allergens (see section 6.1). Where applicable, the areas should be appropriately designed such that effective cleaning could be administered to reduce allergen cross-contact.

45. FBOs should consider having areas to store allergenic ingredients separately from other allergens, as well as separate them from non-allergenic ingredients or foods.

4.2.1 Manufacturing

46. Manufacturers should consider providing appropriate barriers (e.g. walls, partitions, curtains) or adequate separation (e.g., spacing) between lines, when necessary, to prevent allergen cross-contact when foods with different allergen profiles are processed at the same time.
47. When necessary, based on an assessment of risk to the allergic consumer, manufacturers should consider designing premises and rooms to ensure appropriate allergen dust removal or hood systems to mitigate the likelihood of airborne allergen cross-contact throughout the processing area, especially when powdered allergens such as wheat flour, dried milk powder, soy protein, etc. are used. Such controls could be important where powders are dumped into mixers, hoppers, or carts to prevent dust settling on surrounding equipment. Where dust removal systems are not in place, other controls such as cleaning surrounding areas following dumping could be used to mitigate the likelihood of allergenic proteins in powders being transferred to other foods (see section 5.2.1).

4.3 Equipment

4.3.1 Manufacturing

48. Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to provide for effective removal of allergens during cleaning. To prevent or minimise the potential for allergen cross-contact, ideally, equipment, tools and utensils should not contain areas where allergens, especially particulate allergens (e.g. peanuts, tree nuts, sesame seeds, crumbs from baked goods), could get caught in crevices and are difficult to remove by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be eliminated.

4.3.2 Retail and Food Service

49. Retail and food service operators should use equipment, tools, utensils and containers (other than single-use containers and packaging) that have been designed and constructed to ensure that allergens can be easily and effectively removed during cleaning.

4.4 Facilities

50. FBOs, including retail and food service, should place hand wash basins in appropriate areas to prevent allergen cross-contact via personnel. Having convenient hand wash basins will encourage personnel to wash hands with soap and water between handling foods that have different allergen profiles. FBOs should also consider, based on the risk to allergic consumers, facilities to enable change of protective clothing, especially when personnel are moving from particular areas within the manufacturing facility such as those handling powdered allergens.

Section V – Control of Operation

**PRINCIPLE:**
The unintentional presence of allergens in food is prevented or minimised by taking preventive measures through GHPs and HACCP-based controls at appropriate stages in the operation.

5.1 Control of food hazards

51. FBOs should control allergens by preventing or minimising the potential for allergen cross-contact, by ensuring that information identifying the allergens present in foods are clear, correct, and that retail and food service establishments are able to communicate the allergens present in the foods they prepare. Controls should be risk-based. Information helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the allergic consumer includes:

- allergens present in the facility;
- allergens that share the same processing line;
- the nature of the allergen (i.e. whether the food itself is an allergen, derived from an allergen, or the allergen is a component in an ingredient);
- whether allergens are, or may be, present, as notified by the supplier;
- whether the allergen is a particle, powder, liquid or paste;
- the processing steps where the allergen is used;
- ease of preventing allergen cross-contact between processing lines;
- ease of cleaning the equipment used to process foods with different allergen profiles; and
- If the information is available, the maximum amount of an allergen due to cross-contact.
52. It is important that FBOs educate and train personnel to have awareness of food allergens and their health impact in order to ensure they implement the necessary allergen controls.

53. FBOs should:
   - identify any steps in their operations that pose the likelihood of allergen cross-contact, assess the level of risk to the allergic consumer at those steps and ascertain the ones that are critical;
   - implement effective control procedures to prevent or minimise allergen cross-contact at those steps;
   - monitor, and when appropriate document, control procedures to ensure their continuing effectiveness;
   - review allergen control procedures periodically, particularly when the operations change;
   - ensure suppliers are familiar and comply with food allergen specifications;
   - notify customers in a timely manner of any changes to the allergen profile of the product; and
   - ensure personnel are aware of and follow allergen control procedures.

5.1.1 Manufacturing

54. Manufacturers should also identify steps in the operation that are critical to ensuring allergens are properly labelled including reviewing recipes and labels on compound ingredients, and ensuring that the correct product is packed in the correct package (i.e., with the correct label). When reviewing recipes, product enhancement processes, such as egg washes on baked products for glossy finish, should also be included.

5.2 Key aspects of hygiene control systems

5.2.1 Manufacturing

5.2.1.1 Minimising cross-contact during processing

56. If the same production area is used for foods with different allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles, e.g. process foods that do not contain allergens before foods with allergens. For instance, production schedules could be established in some cases whereby products that do not contain allergens are handled at the beginning of the schedule and different products containing the same food allergen profile could be run sequentially before products with different allergen profiles, to reduce the potential for allergen cross-contact (e.g. all frozen desserts containing only milk are run before those containing both milk and egg). Where possible, allergenic ingredients should be added as late in the production process as possible, or as far downstream as possible in the processing line (e.g. closest to the filling and packaging equipment), to minimise the amount of equipment in the production area that comes in contact with the allergen. This will help prevent or minimise potential allergen cross-contact and facilitate cleaning.

57. Manufacturers should design traffic flow of allergen-containing ingredients, packaging supplies and personnel during the manufacture of foods to prevent or minimise the potential for allergen cross-contact. This should include consideration for managing the movement for transient people such as managers, quality assurance personnel, inspectors, maintenance personnel, and visitors.

58. “Allergen mapping” (a diagram that identifies where allergens are stored, handled and prepared on site, overlaid with the processes involved) can be useful in identifying areas where controls should be applied to prevent or minimise allergen cross-contact.

59. Where there is a likelihood of allergen cross-contact by personnel, personnel working on processing lines that contain an allergen should be restricted from working on lines that do not contain that allergen. Manufacturers should consider a system to clearly identify personnel working on lines manufacturing foods containing different allergen profiles, e.g. different coloured uniform or hair net.

60. Containers and utensils used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen.
Where such dedication is not possible, effective cleaning procedures should be in place to clean containers before use for a food with a different allergen profile. Disposable liners can also be an effective strategy.

61. Manufacturers should provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpackaged product from allergen cross-contact. Dry ingredients should be physically contained by covering specific equipment, such as conveying equipment, hoppers, storage silos, shakers, and size graders. Where feasible, manufacturers should dedicate utensils and tools for processing lines with different food allergen profiles; these utensils and tools should be distinguishable (e.g. through marking, tagging or colour-coding) to prevent or minimise the potential for allergen cross-contact. Similarly, manufacturers could consider duplicating certain pieces of equipment (e.g. scales) and dedicating them for specific allergen-containing production runs.

62. Manufacturers should not use ingredients for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Allergen-containing ingredients should, if feasible and necessary to prevent or minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.

63. Dry ingredients that are, or contain, a food allergen should be added in a manner that minimises the potential for unintentional dispersion by dust. For example, the formation and dispersion of allergen dust can be minimised by adding liquid ingredients to mixers at the same time as powders, using dust collection systems (e.g. local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and/or covering equipment. The use of dry allergens with a propensity for dust formation should, where feasible, be scheduled at the end of a production/processing day.

64. Manufacturers should evaluate the potential for cross-contact due to cooking media, such as water or oil. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile.

65. Spills that contain food allergens should be cleaned up immediately, avoiding further dispersion (e.g., for liquids, spill kits could be used or vacuums for dust). Care should be taken not to generate aerosols with high pressure washers, or to re-suspend dust using compressed air hoses.

5.2.1.2 Rework and Work-in-Process

66. Rework and Work-in-Process (WIP) that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled with all food allergens specifically highlighted, and properly inventoried and accounted for during storage and when used, to prevent or minimise the potential for incorporation into the wrong product.

67. Manufacturers should implement a policy for rework to be added back to the same product whenever feasible.

5.2.1.3 Application of Product Labels

68. Manufacturers should implement procedures to ensure that allergen information and labels are accurate (see 5.3 Incoming Material Requirements)and verify that the correct product labels are used on the production line when packaging/labelling products. This could involve manual checks and/or automated checks such as bar code recognition or vision inspection systems to ensure the correct packaging is used.

69. Labels and labelled containers should be stored in a way that prevents or minimises the potential to pull incorrect labels or containers during production. All labels and labelled containers should be removed at the end of the production run and returned to their designated storage area.

70. Manufacturers should implement procedures to segregate and re-label food products that have been labelled incorrectly. If it is not possible to re-label such food, they should have a procedure to destroy the food.

5.2.1.4 Monitoring and verification

71. Regular internal audits of production systems should be conducted to verify that the product formulation, including changes to product formulation, matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented and that line personnel are appropriately trained.

72. [There should be a regular review of suppliers to ensure that all ingredients, including multi-component ingredients (e.g. sauces, spice mixes), processing aids, or operations, have not changed in a manner that introduces a new allergenic ingredient or that results in allergen cross-contact. Manufacturers should verify that precautionary allergen labelling is only applied in instances where allergen cross-contact cannot be reasonably prevented (e.g. disassembly of equipment that results in major loss of production time) through
GHPs and when such cross-contact could present a risk to allergic consumers. Periodic product testing for undeclared allergens may also be considered.]

5.2.1.5 Product development and change

73. When developing new products, or changing formulations or ingredient suppliers, manufacturers should consider whether it is feasible to use a non-allergenic ingredient to provide the same functionality as an allergenic ingredient to avoid introducing a new allergen into the establishment or a processing line.

74. Where the introduction of a new allergen into the establishment or a processing line is unavoidable e.g. during factory trials or consumer testing, care should be given to avoid cross-contact with existing products.

75. Procedures for preventing cross-contact, as well as relevant HACCP documents, operating procedures and associated personnel training, may need to be reviewed and revised to address a new product or formulation with a different allergen profile, especially when an allergen new to the production facility is involved.

76. Product labels should be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed in a manner that prevents accidental use. Where there is a change in the formulation which results in a change of allergenic profile, manufacturers should indicate this on the packaging and on their websites, with information such as "new formulation".

5.2.2 Retail and Food Service

77. Equipment that has been used for allergen-containing foods should be marked, tagged, or colour-coded to identify the allergen. Where this is not practical, equipment should be cleaned between use for foods with different allergen profiles.

78. Allergen-containing food that is not in sealed packages, should also be stored separate from food that does not contain allergens, or from food with a different allergen profile (e.g., separation that prevents physical contact).

5.2.2.1 Minimising cross-contact during preparation

79. Retail and food service personnel should be aware of allergens in the foods provided to customers in order to provide appropriate information when a customer indicates they have a food allergy. They should also know and understand the likelihood of allergen cross-contact from the processes followed in the preparation of food items. Cross-contact during preparation primarily occurs in the following ways:

- food to food, e.g. by foods touching or one food dripping onto another food;
- food to hand to food, e.g. handling by cooking personnel, front service personnel or using hands in multiple containers of ingredients containing different allergen profiles without washing in between, such as adding toppings to pizzas, assembling sandwiches etc;
- food to equipment/utensils/surface to food, e.g. sharing of utensils, for example, using a whisk to stir a milk-based sauce and then using the same whisk to stir eggs, without thoroughly washing and drying the whisk between procedures, or using the same cutting board, griddle/frying pan, or other surface to prepare fish and shellfish; and
- food to cooking media, e.g. shared fryers or boiling vats for cooking food.

80. Preparation processes should be designed to prevent or minimise the potential for allergen cross-contact during food preparation, e.g. separate equipment and utensils that are used for foods with different allergen profiles, dedicate utensils/equipment for allergen-containing products, or clean equipment, utensils and preparation surfaces thoroughly between uses for foods with different allergen profiles.

81. Retail and food service operators should consider, where feasible, assigning one individual to prepare an allergenic food (e.g. deveining prawns/shrimp). Where this is not possible, allergen control procedures should be in place between preparation of foods with different allergen profiles (e.g., washing hands, changing disposable gloves).

82. Containers and tools used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or colour-coded to identify the allergen. Where such dedication is not possible, effective cleaning procedures should be in place to clean containers and tools before use for a food with a different allergen profile.

83. Food preparation operators should only use ingredients listed in the recipe, and not replace one ingredient with another unless the ingredient is known not to contain an allergen. To assist with the understanding of
foods or ingredients of allergenic significance to the FBO, there could be a list of relevant allergens available in the kitchen area. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present.

84. FBOs should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact, for example, not using oil to fry both battered/breaded fish and potatoes, as batter/breadcrumb particles could end up in the potatoes. It may be necessary to use an appropriate method to eliminate any allergen-containing particulate material present in frying oil if it is likely that such particles could end up in food with a different allergen profile.

85. Foods displayed for consumer purchase should be protected from cross-contact during display, e.g. by wrapping or by separation that could include plastic barriers. Designated serving utensils should be provided to handle foods with different allergen profiles, where feasible, and should only be used for that food, or the utensils should be cleaned between uses for foods with different allergen profiles.

86. Personnel handling product at display and consumer purchase, as well as servers in restaurants and other food service operations, should be knowledgeable about the allergens in products; alternatively, the personnel should know how to obtain the information about the allergens in products rapidly - especially when the food does not contain labelling that identifies the allergens.

5.2.2.2 Rework

87. Rework and WIP should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled to prevent or minimise the potential for incorporation into the wrong product. Food handlers should implement a policy for rework to be added back to the same product whenever feasible.

5.2.2.3 Application of Product Labels

88. In retail and food service operations that package and label foods sold directly to consumers, the label or allergen information is usually generated and provided on site, and often at the point of purchase. Retail and food service operators should implement procedures to ensure that product labels are accurate and the correct product labels/information are provided when packaging/labelling products. They should implement procedures to segregate, and re-package or re-label products, or destroy food products that have been labelled incorrectly.

5.2.2.4 Monitoring and verification

89. Supervisors of food preparation and service personnel in retail and food service operations should periodically verify that personnel are following the procedures established to prevent or minimise the potential for allergen cross-contact and inform the consumer about allergens in foods, including applying the appropriate label to packaged foods and providing the relevant information with respect to unpackaged foods. Regular review of ingredients, recipes, and labels, to ensure accuracy of allergen information should also be undertaken.

5.2.2.5 Product development and change

90. When introducing a new product or recipe with a different allergen profile, procedures for minimising cross-contact should be reviewed and possibly revised. Personnel that handle these foods, in particular those who have direct interaction with customers should be made aware of the changes in a timely manner. Allergen information on menus and websites should also be updated.

5.3 Incoming material requirements

5.3.1 Manufacturing

91. The source of an allergen unintentionally presenting in a finished product may be an ingredient obtained directly from a supplier, or an ingredient manufactured by a third-party supplier. Manufacturers should establish specifications for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.

92. Manufacturers should ensure that their suppliers have good allergen management practices to prevent or minimise the likelihood of cross-contact between foods with different allergen profiles. Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information or on the label of the finished product (e.g. milk in a spice blend ingredient used in a food) and should have processes in place to manage allergen labelling.

93. Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g. a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier’s site and the supplier’s allergen management plan, including cross-contact
controls and cleaning programs. A specification sheet, certificate of analysis, or vendor guarantee periodically or with each lot can also be useful in addressing a supplier’s control of food allergens, as well as periodic testing for undeclared allergens.

94. Manufacturers should have procedures/policies in place for suppliers to notify them, in a timely manner, of any changes in the supplier’s operation that could impact the allergen profile of the ingredient from the supplier (e.g., a change in formulation affecting the allergen profile or the introduction of a new allergen into the supplier’s establishment, particularly if that allergen will be used on the same line as the ingredient provided to the manufacturer). Manufacturers should have a procedure/policy for ensuring that any change in supplier is accompanied by a review of the product(s) being supplied with respect to that supplier’s allergen control program.

95. Incoming foods that are, or that contain, allergens should be labelled to identify the allergens that are present using common terms (e.g. ‘milk’ when casein is an ingredient). Manufacturers should review labels on, and documents accompanying, shipments of ingredients (including minor ingredients such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s). Particular attention should be given to multi-component pre-mixed ingredient packages. Manufacturers should have policies in place to address ingredients that contain advisory statements on the label with respect to the labelling of finished food containing that ingredient and controls to prevent or minimise allergen cross-contact based on the risk to the allergic consumer.

96. Manufacturers should inspect ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, manufacturers should inspect nearby containers for evidence of allergen cross-contact. Manufacturers should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that prevents or minimises the potential for allergen cross-contact (e.g. place a damaged container inside another container, or move the contents of the damaged container to a different container).

97. Manufacturers should clearly identify allergen-containing ingredients using a system that adequately distinguishes between ingredients with different food allergen profiles (e.g. tags or colour coding of cases/pallets/bags) to alert personnel that these materials are subject to special precautions and handling procedures throughout the establishment. The likelihood of allergen cross-contact from processing aids (such as pan-release agents that could contain soy) should be assessed to determine if special precautions and handling procedures are needed.

98. Secure, closable containers should be used to store allergen-containing ingredients and processing aids. Manufacturers should segregate allergen-containing ingredients based on allergen type and from ingredients that do not contain allergens e.g. in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, ingredients that contain allergens should be stored below those that do not contain allergens to prevent or minimise the opportunity for allergen cross-contact in the event of a spill or leak.

5.3.2 Retail and Food Service

99. Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g. packaged foods that list all ingredients. For example, if a bag of dried porcini mushroom and herb risotto mix does not list the contents, then the product should not be used. Sourcing ingredients from the same supplier may prevent or minimise changes in the allergen profile of foods supplied.

100. Retail and food service operators should:
   - inspect all raw materials/ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, operators should inspect nearby containers for evidence of allergen cross-contact;
   - reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact; and
   - handle damaged containers in a manner that prevents or minimises the potential for allergen cross-contact (e.g. place a damaged container inside another container, or move the contents of the damaged container to a different container).

101. The labels of incoming packaged ingredients used in the preparation of foods should be reviewed for allergens to ensure knowledge about the allergens present in the final prepared food. Retail and food service operators should store allergen-containing ingredients in a manner to prevent or minimise the
potential for allergen cross-contact e.g. store allergen-containing ingredients below those that do not contain allergens.

5.4 Packaging

102. FBOs should have procedures in place to review and approve all proposed product labels of all foods to ensure they are accurate with respect to allergens and that they are updated with any change in the formulation of the product. To avoid allergen labelling errors, there should be a procedure for destroying old packaging and labels (and to maintain electronic document control of old labels) when recipes/formulations have been changed.

5.5 Water

103. Water that has come in to contact with a food that is or that contains an allergen (e.g. water used for cooking or washing) should not be recirculated for use on a food that does not contain that allergen if such use could result in allergen cross-contact that could present a risk to allergic consumers.

104. Re-use of clean-in-place (CIP) solutions, including rinse water, from washing equipment containing an allergen should be avoided if this could result in allergen cross-contact that could present a risk to allergic consumers.

5.6 Management and supervision

105. FBO managers and supervisors need to have enough knowledge and understanding of allergen control principles and practices to be able to judge the potential for allergen cross-contact and determine the need for new or revised procedures to prevent the presence of undeclared allergens or the need to take corrective action when allergen control procedures are not properly implemented.

5.7 Documentation and records

106. Refer to the General Principles of Food Hygiene (CXC 1-1969).

5.7.1 Manufacturing

107. Records could include those for:

- suppliers’ allergen management (e.g. questionnaire, survey and/or an audit to assess the allergen profile of foods produced at the supplier’s site and the supplier’s allergen management plan, including cross-contact controls and cleaning schedules);
- suppliers’ allergen information / specification
- procedures for handling and storage of allergens;
- label review;
- label application;
- scheduling;
- batching (putting together the ingredients in a food);
- rework;
- cleaning (Standard Operating Procedures (SOPs)) and documentation that cleaning has been done);
- line clearance procedures for label and packaging material removal at changeover;
- packaging label and print manufacturing records;
- validation data for allergen cleaning efficacy;
- verification activities (including any analytical test results for allergens);
- corrective actions taken;
- training (personnel trained, type of training, and date of training); and
- SOPs to minimize/prevent allergen cross-contact.

5.7.2 Retail and Food Service

108. Records could include those for:
- allergenic ingredients associated with each menu item;
- label printing and application, where feasible;
- cleaning (SOPs);
- SOPs for handling allergic customer orders; and
- training (personnel trained, type of training, and date of training).

5.8 **Recall procedures**

109. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

110. FBOs should have recall procedures which address food allergens in their food recall plan.

111. A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Products tracing* as a tool within a *Food Inspection and Certification System* (CXG 60-2006) to enable the withdrawal of products where necessary. Procedures and processes should be in place that facilitate a one-step-back and one-step-forward traceability review in the case of a food allergen incident (e.g., an allergic reaction to an undeclared allergen).

5.8.1 **Consumer complaints and Resolution**

112. FBOs should have procedures in place for handling consumer complaints with regard to undeclared allergens in foods. The procedures should define the steps to be followed in handling complaints and include complaint collection, investigation, analysis, record keeping and reporting to relevant competent authorities where appropriate.

113. The complaint particulars should be evaluated and a decision made as to what action to take (e.g., recall of product, changes in manufacturing or preparation procedures, communicating publicly the details of the food allergen incident). The decision on action will consider the potential risk to consumers identified along with the timeliness, motivation and plausibility of the complaint. FBOs may need to contact the relevant competent authority for assistance in determining the most appropriate course of action.

114. The prime objective of an investigation into undeclared allergens in a food is to ensure that public health and safety are protected and the incident will not re-occur. The action plan depends on the outcome of the investigation. Action should always be taken in a timely manner to ensure further incidents do not occur, and public health and safety are protected.

**Section VI – Establishment: Maintenance and Sanitation**

**PRINCIPLE:**
The effective management of food allergens is facilitated by establishing effective maintenance and cleaning programs that prevent or minimise the potential for allergen cross-contact.

6.1 **Maintenance and cleaning**

6.1.1 **Manufacturing**

115. Inspect and remove any hand tools and utensils if they are damaged and not easily cleanable. Where feasible and appropriate, label or colour code maintenance tools to correspond with specific allergens.

116. Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to prevent or minimise the potential for allergen cross-contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the equipment, the food contact surface, the nature of the cleaning (e.g. dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled, where feasible, to adequately remove allergen residues, however some equipment cannot be disassembled. This should be taken into account in the allergen management program. Dust socks need to be removed and cleaned periodically.

117. When wet cleaning, low pressure water hoses should be used instead of high pressure water hoses for removing food residues from wet processing areas, since high pressure water hoses could spread and aerosolise food allergen residues during cleaning. When removing dry food residue from difficult-to-clean areas, scrapers, brushes and vacuum cleaners (that are fit for purpose) should be used, rather than compressed air, since compressed air can disperse food allergen residues from one area to another. If compressed air is used because vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue, manufacturers should take precautions to contain food residues that are removed by the compressed air. The need to clean the ductwork in ventilation systems
should be considered, where necessary, when cleaning the processing environment to prevent or minimise allergen cross-contact.

118. Bins, totes, and containers used for ingredients that are, or contain, a food allergen should be cleaned as soon as possible after being emptied to avoid being a source of cross-contact.

119. Where feasible, cleaning equipment, tools, cloths, sponges, and cleaning solutions should be designated for foods with specific allergen profiles and used in a manner that does not result in cross-contact. For example, freshly prepared cleaning solutions should be used rather than reusing cleaning solutions that have been used for foods with different allergen profiles to prevent recontamination of surfaces with allergenic food residues.

6.1.2 Retail and Food Service

120. Equipment, utensils, containers and preparation areas should be adequately cleaned (at a minimum visually clean) immediately after the preparation, storage, and dispensing of foods to prevent allergen cross-contact. Where feasible, cleaning equipment, tools, cloths, sponges, and cleaning solution should be designated for foods with specific allergen profiles and used in a manner that does not result in allergen cross-contact. For example, freshly prepared cleaning solutions should be used rather than reusing cleaning solutions that have been used for foods with different allergen profiles to prevent the recontamination of surfaces with allergenic food residues.

6.2 Cleaning programmes

6.2.1 Manufacturing

121. Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible. These procedures should specify the equipment, utensil, or area of the establishment to be cleaned; the tools and cleaning materials to be used; the sequence of steps to be followed; any disassembly required; the monitoring activities; and any actions to be taken if the procedures have not been followed or if food residues have not been adequately removed.

122. Validation of the cleaning process provides a means of assuring that cleaning processes are adequate to reduce or eliminate allergens and thereby prevent or minimise allergen cross-contact. The validation process should be specific to the allergen, process and matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible, through an analytical testing program (refer to section 6.5 of this Code).

123. Because introducing water into some facilities and equipment can result in microbial problems, some production procedures include a “push-through” technique in which the subsequent product, an inert ingredient, such as sugar or salt, or an allergen-containing ingredient, such as flour, that will be an ingredient in the subsequent product is pushed through the system to remove food residue. Where the use of allergen testing is feasible and appropriate, “push-through” material, or the first product through the line, should be evaluated to demonstrate that a food allergen from a previous production run has been adequately removed by this process.

124. Manufacturers should develop allergen clean up procedures for the manufacturing line to be followed in the event of spills of allergen-containing ingredients.

125. Manufacturers should maintain cleaning records, including any test results, and review them to verify that cleaning procedures have been conducted and adequately removed allergens.

6.2.2 Retail and Food Service

126. Retail and food service operators should develop allergen clean up procedures for the food service preparation, storage and presentation areas, to be followed in the event of spills involving allergen-containing foods.

6.3 Pest control systems

127. Refer to the General Principles of Food Hygiene (CXC 1-1969).

128. In addition, pest control systems should not use allergens (e.g. peanut butter, cheese) as bait in traps. It is important for FBOs to make pest control service providers aware of concerns about the use of food allergens and potential for allergen cross-contact.
6.4 Waste management

129. FBOs should place waste materials that contain food allergens in covered bins, totes, or containers that are identified as holding waste and handled in a manner to prevent or minimise the potential for allergen cross-contact.

6.5 Monitoring effectiveness

130. Manufacturers should verify cleaning procedures, where feasible, to demonstrate that if the procedures are followed, allergens are effectively removed. Equipment should be inspected after each cleaning to determine whether it is visibly clean; this is particularly useful with particulate allergens.

131. If a manufacturer uses CIP systems to clean pipe work, equipment and machinery, there should be verification that the CIP system is effectively removing allergens (e.g. testing rinse samples or swabs).

132. Manufacturers should periodically conduct tests to detect food residues that remain on surfaces after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix). Tests should be fit for purpose, i.e. appropriate for the targeted allergen, e.g. a casein (milk protein) test should not be used when whey (another milk protein) is the allergen of concern and the test should be validated to work with the matrix/food of concern. FBOs should know the limit of detection of the test used and the test specificity. If necessary, the FBO should obtain expert advice on interpretation of results (e.g. from the test kit supplier or an accredited testing laboratory).

Section VII – Establishment: Personal Hygiene

**PRINCIPLE:** Personal hygiene practices should manage the potential for food handlers to contribute to allergen cross-contact.

133. FBOs should consider the potential for cross-contact of products with allergenic materials via food handlers. For example, food handlers may become a vector for cross-contact if food allergens on their skin or clothing are transferred directly to foods. Allergens present as dry products (powders) are more likely to be transferred by food handlers than non-volatile liquids containing allergens.

134. FBOs should encourage personnel to wash hands between handling foods that have different allergen profiles, or after having been in contact with other sources of potential allergens. Where gloves are used, consider changing regularly to reduce the likelihood of allergen cross-contact.

7.1 Manufacturing

135. Where necessary, food handlers should wear dedicated clothing in areas where specific allergens are handled and there is a high likelihood of allergen cross-contact. The wearing of this clothing should be restricted to those areas. It may be appropriate to visually identify which personnel work on processing lines with different allergen profiles (e.g. different coloured clothing such as smocks or hair nets).

136. Personnel should not be permitted to bring food or drink into areas where product, ingredients or primary packaging is exposed, as these foods may contain allergens and result in allergen cross-contact.

7.2 Retail and Food Service

137. Where it is not feasible to assign one individual to prepare an allergenic food (e.g. deveining prawns/shrimp), ensure that the individual’s hands are thoroughly cleaned; that, if using gloves, the individual changes gloves; and, when appropriate, the individual changes outer clothing, before handling another food with a different allergen profile.

Section VIII – Transportation

**PRINCIPLE:** Foods containing allergens should be managed during transportation so that allergen cross-contact is prevented.

8.1 General

138. Foods that are being distributed should be adequately contained or packaged to protect against allergen cross-contact.
139. The FBO assigning the food to be transported should ensure that the transporter/haulier has clear instructions to follow regarding potential allergen cross-contact situations.

140. The transporter/haulier should have procedures in place to ensure the integrity of the items they are transporting.

8.2 Requirements

141. Foods should be arranged for transport in such a way that unpackaged products with different allergen profiles are transported separately. If this is not possible, consider other means of segregating the foods, such as inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the likelihood of allergen cross-contact, stacking non-allergenic food on top of allergenic food, or packaging the food using poly bags super sacks, or bags with plastic overwrap. Manufacturers should clearly communicate special instructions to their chosen transporter/haulier e.g. to not allow mixed transportation of goods, when there is the likelihood of cross-contact.

142. The food transportation unit and associated transport receptacles, should be suitably designed and constructed to facilitate inspection and cleaning, refer to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001).

143. The transporter/haulier should demonstrate a clear understanding of the food they carry and ensure personnel can identify and understand potential allergen cross-contact situations.

8.3 Use and maintenance

144. Vehicles such as bulk tankers used to transport liquids (e.g. raw milk, dairy mixes, juices, liquid egg, oil, water) must be adequately cleaned between loads to prevent or minimise allergen cross-contact. In some instances, dedicated bulk tankers may be best, for example, when transporting dry powders such as wheat flour.

145. Food transportation units (including relevant accessories, connections) and load carrying areas should be inspected and, if necessary, cleaned to remove any residue of the previous load, to the extent possible, before re-loading. The method of cleaning adopted should be appropriate to the type of commodity and type of allergen to be loaded in the unit.

146. Carts and trolleys used to transport food within a retail or food service establishment or to customers should be kept clean between uses; e.g. a meal of cheese omelette and toast spilled onto a cart and not properly cleaned between uses could contaminate a subsequent meal, utensils or cups transported to another customer that has allergies to egg, milk or wheat.

147. For commercial scale haulage, a record should be made when a vehicle has been inspected, even if cleaning is not needed. If feasible, designated vehicles should be used for transporting open or bulk allergenic ingredients e.g. raw tree nuts.

148. Spillages of foods containing allergens that occur during transportation should be cleaned up as soon as possible to ensure that there is no subsequent allergen cross-contact. If any incident occurs during loading, transportation or unloading which could result in allergen contamination, the circumstances should be reported to the owner of the goods or their customer for their consideration and for them to advise if specific measures are needed.

Section IX – Product Information and Consumer Awareness

PRINCIPLE:
Consumers should have access to adequate and correct information on the allergenic nature of a food. This should ensure that those with allergies can avoid allergic foods and ingredients.

9.1 Lot identification

149. Refer to the General Principles of Food Hygiene (CXC 1-1969).

150. The General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) applies.

9.2 Product information

151. Refer to the General Principles of Food Hygiene (CXC 1-1969).

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3 Food transportation unit (as outlined in the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001)) refers to food transport vehicles or contact receptacles (such as boxes, containers, bins, bulk tanks) in vehicles, aircraft, trailers and ships, and other transport receptacles in which food is transported.
9.2.1 Manufacturing

152. [All food products and ingredients should be accompanied by, or bear adequate information, to ensure other food manufacturers or processors and consumers can be informed whether the food is, or contains, an allergen. This includes any applicable information relevant to assess the likelihood of allergen cross-contact, such as that outlined in section 5.1, and may include precautionary allergen labelling as discussed in section 9.3. Such statements should be truthful, not misleading and not used in lieu of GHPs (see section 9.3).]

153. Manufacturers should have procedures in place to ensure that food is labelled appropriately, as per section 9.3.

9.2.2 Retail and food service

154. All food products and ingredients should be accompanied by or bear adequate information to ensure customers can be informed whether a food is, or contains (or may contain), an allergen. Restaurants should ensure that any allergen information, both on site (e.g. the menu, over the counter) and online, is current. Similarly, retail operations should make sure allergen information they make available, e.g. online, is current and correct and that the allergens in any pre-packaged products are correctly labelled.

155. Front of house personnel that serve food to customers should be knowledgeable about the allergens in menu items and preparation practices of the business that may result in cross-contact, or know how to obtain this information. Signage, whether within menus or located at the front counter, requesting that customers make dietary requirements with respect to allergens known to food service personnel, could also be used. Where the food service operators and personnel cannot ensure that a food does not contain an allergen, this should be clearly communicated to the customer.

156. Self-serve areas where consumers handle unpackaged food products may pose a particular risk for allergic consumers due to allergen cross-contact. Separation of allergenic food items and non-allergenic food, as well as provision of information on the likelihood of allergen cross-contact, should be considered in these instances (e.g. allergen alert signage or symbol/icons). Dedicated equipment, utensils and tools for handling allergenic food should not be used for non-allergenic food.

9.3 Labelling


158. The General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985) applies.

159. The General Standard for the Labelling of Pre-packaged Foods lists the foods and ingredients known to cause hypersensitivity that “shall always be declared” on the label.

160. [Precautionary allergen labelling should only be used after an assessment of the likelihood of allergen cross-contact has been carried out and a risk to consumers has been identified. Following risk assessment, all possible mitigation measures available to eliminate the likelihood should be explored prior to the use of a precautionary allergen label. Precautionary allergen labels that are necessary following this process can help to inform FBOs and consumers on the likelihood that the products might contain an allergen (other than those that are listed as ingredients) in situations where:

- allergen cross-contact for a specific food cannot be prevented using GHPs;
- allergen cross-contact occurs sporadically; and
- the allergen may be present at levels that, based on an assessment of risk, could result in adverse health consequences to the majority of allergic consumers.]

161. [However, in order to not limit food choices to allergic consumers, the use of precautionary allergen labelling should be restricted to those situations in which cross-contact cannot be controlled to the extent that the product does not present a risk to the allergic consumer.]

9.4 Consumer education

162. Refer to the General Principles of Food Hygiene (CXC 1-1969).

Section x – Training

PRINCIPLE:
Personnel engaged in food operations should have sufficient training in food allergen management to implement measures to prevent or minimise allergen cross-contact and ensure the correct label with appropriate allergen information is applied to food.
10.1 Awareness and responsibilities

163. All personnel involved in the production, manufacture, preparation, handling, distribution, retail and service of foods should understand their role in allergen management and the food safety implications of the presence of undeclared food allergens. This includes temporary and maintenance personnel.

10.2 Training programmes

164. All relevant personnel in a food business should receive food allergen training as appropriate to their job responsibilities, so they can contribute to the measures needed to prevent or minimise the likelihood of allergen cross-contact and labelling errors. Training programmes should be reviewed regularly to ensure they are up to date and appropriate. All appropriate personnel should be encouraged to report and/or take immediate action, if any labelling errors or an undeclared allergen is suspected.

165. Training programs should include, as appropriate to the person’s duties:

- general allergen awareness, including the serious nature and possible health consequences of the unintended or undeclared presence of allergens in products from a consumer perspective;
- awareness of the likelihood of allergen cross-contact identified at each stage of the food supply chain, and the preventive measures and documentation procedures applicable in the food business;
- GHPs, for example, appropriate clothing, hand washing, and minimizing hand contact with foods to prevent allergen cross-contact;
- hygienic design of facilities and equipment to prevent or minimise allergen cross-contact;
- cleaning of premises, equipment and tools, including clear between-product cleaning instructions, and its importance in preventing allergen cross-contact;
- handling of rework materials to prevent unintended allergens from being incorporated into a food;
- waste management, for example how waste should be handled to prevent allergen cross-contact;
- situations where potential allergen cross-contact can occur between products, production lines or equipment, and prevention measures;
- procedures for corrective actions when allergen cross-contact or labelling errors are suspected;
- procedures for managing people traffic patterns around the site to prevent or minimise allergen transfer from one area to another, for example people changing production line or site, movement to the canteen/break room and of visitors;
- equipment movement around the site, for example, maintenance tools, carts, food trays, etc. to prevent or minimise allergen transfer from one area to another;
- labelling and the awareness of allergen presence in raw materials, semi-finished goods and finished products; and
- sources of allergen information, e.g. supplier specifications, supplier audit records.

10.3 Instruction and supervision

166. Refer to the General Principles of Food Hygiene (CXC 1-1969).

10.4 Refresher training

167. Refer to the General Principles of Food Hygiene (CXC 1-1969).
# CCFH FORWARD WORKPLAN

<table>
<thead>
<tr>
<th>Title of Work</th>
<th>Last Revision</th>
<th>Information to Update (Yes/No)¹</th>
<th>Impact to Public Health (20/14/8)</th>
<th>Trade Impact (10/5/4/2/0)</th>
<th>Project document/ discussion paper (Yes/No)</th>
<th>FAO/WHO assistance needed? (Yes/No)</th>
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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.

² Discussion paper on development of Code of Hygienic Practice for the storage of cereals (prepared by India) FH/44 CRD 9, included in the Forward Workplan by the 44th session of the CCFH, 12-16 November 2012
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