

CODEx ALIMENTARIUS COMMISSION

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Food and Agriculture
Organization of the
United Nations



World Health
Organization

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REP20/FH

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEx ALIMENTARIUS COMMISSION

43rd Session

FAO Headquarters, Rome Italy

6 – 11 July 2020

REPORT OF THE 51st SESSION OF THE CODEx COMMITTEE ON FOOD HYGIENE

Cleveland, Ohio, United States of America

4 - 8 November 2019

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SUMMARY AND STATUS OF WORK

Responsible Party	Purpose	Text/Topic	Code	Step	Para.
Members, CCEXEC79 and CAC43	Adoption	Draft Code of Practice on Food Allergen Management for Food Business Operators	-	8	26, App.II
		Proposed draft revision of the <i>General Principles of Food Hygiene</i>	CXC 1-1969	5/8	88, App. IV
		Proposed Draft Guidance for the Management of Biological Foodborne Outbreaks	-	5	103, App.III
	Approval	New work on Guidelines for the Safe Use and Reuse of Water in Food Production			116, App.V
CCFL46	Information	Status of the work regarding the Draft Code of Practice on Food Allergen Management for Food Business Operators			26
Brazil, Honduras, Jamaica, and Thailand CCFH52	Redrafting	Diagram to the decision tree in the Proposed Draft Revision of the <i>General Principles of Food Hygiene</i>	CXC 1-1969	2/3	88
PWG (Denmark, Chile and the European Union) CCFH52	Revising	Draft Guidance for the Management of Biological Foodborne Outbreaks		7	103
EWG (Chile, France, New Zealand, the United States of America) CCFH52	Redrafting	Proposed Draft Guidelines for the Control of Shiga Toxin-Producing <i>Escherichia coli</i> (STEC) in Raw Beef, Raw Milk and Raw Milk Cheeses, Fresh Leafy Vegetables, and Sprouts		2/3	109
EWG (Honduras, Chile, Denmark, the European Union and India) CCFH52	Drafting	Guidelines for the Safe Use and Reuse of Water in Food Production		2/3	116
Members PWG (the United States of America) CCFH52	Comments/ Discussion	New work proposals / Forward workplan			120, App.VI
Codex Secretariat CCMAS41	Action Information	Provide links to the relevant CCFH texts containing methods of analysis for inclusion in CXS 234			8
Brazil CCFH52 CCMAS41	Review / Discussion Information	Review the methods of analysis in CXS 231 to determine their fitness for purpose and their possible conversion to performance-based criteria			8
Japan and New Zealand CCFH52	Review / Drafting	Discussion paper on revision of the <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood</i> (CXG 73-2010)			118
Canada and The Netherlands	Review / Drafting	Discussion paper on revision of the <i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food</i> (CXG 79-2012)			118
FAO/WHO (JEMRA) CCFH52	Request	Scientific advice on STEC in raw beef, raw milk and raw milk cheeses, fresh leafy vegetables and sprouts			107

LIST OF ACRONYMS

CAC	Codex Alimentarius Commission
CCEXEC	Executive Committee of the Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCFL	Codex Committee on Food Labelling
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCP	Critical Control Point
COP	Code of Practice
CRD	Conference Room Document
EU	European Union
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FBOs	Food Business Operators
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point
INFOSAN	International Food Safety Authorities Network
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
OIE	World Organization for Animal Health
PWG	Physical Working Group
RRA	Rapid risk assessment
STEC	Shiga toxin-producing <i>Escherichia coli</i>
U.S	United States of America
WHO	World Health Organization
WG	Working Group
WGS	Whole genome sequencing

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its 51st Session in Cleveland, Ohio, the United States of America, from 4 – 8 November 2019, at the kind invitation of the Government of the United States of America. Dr Jose Emilio Esteban, Chief Scientist, Food Safety and Inspection Service, Office of Public Health Science, United States Department of Agriculture (USDA) chaired the Session, which was attended by 59 member countries, one member organisation and 15 observer organizations. The list of participants is included in Appendix I.

OPENING¹

2. Dr. Mindy Brashears, Deputy Under Secretary for Food Safety, USDA, delivered the opening address titled “Merging Science with Policy to Ensure Food Safety”. She drew attention to importance of science-based and data-driven decisions and having access to the data to develop appropriate policies to ensure food safety.
3. Ms. Mary Frances Lowe, U.S. Manager for Codex Alimentarius, also addressed the Committee.
4. The Committee observed a minute’s silence in memory of the late Dr Amy Gassama, who had served on the delegation of Senegal and made tremendous contribution to CCFH for many years.

Division of competence²

5. 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)³

6. The Committee adopted the agenda.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX SUBSIDIARY BODIES TO THE COMMITTEE (Agenda Item 2)⁴

7. The Committee noted the matters for information and took the following decisions.

Matters from CCMAS40

8. The Committee noted that the requests from the Codex Committee on Methods of Analysis and Sampling (CCMAS) would help make *Recommended Methods of Analysis and Sampling* (CXS 234 – 1999) a more user-friendly single source of information for all analytical methods in Codex and agreed:
 - to request the Codex Secretariat to provide links to the relevant CCFH texts containing methods of analysis for inclusion of the links in CXS 234; and
 - In principle to transfer the methods in the *General Methods for the Detection of Irradiated Foods* (CXS 231 - 2001) to CXS 234; and noted the offer of Brazil to review the methods in CXS 231 to determine their fitness for purpose and their possible conversion to performance-based criteria for consideration by CCFH52.
9. The Committee also noted that the above decisions would not impact on the terms of reference of CCFH with regard to methods of analysis.

MATTERS ARISING FROM THE WORK OF FAO AND WHO (INCLUDING JEMRA) (Agenda Item 3)⁵

10. The FAO representative, on behalf of FAO and WHO, provided a summary of work performed since CCFH50 and future joint FAO/WHO work related to CCFH. Short summaries of each activity are available in the document CX/FH 19/51/3-

International Food Safety Authorities Network (INFOSAN)

11. The Representative reported that INFOSAN continues to rapidly respond to food safety events worldwide. The second Global INFOSAN meeting will be held in December 2019.

Report back on FAO/WHO and JEMRA activities

12. The Representative informed the Committee that:
 - JEMRA published, in 2019, meeting reports on source attributions of Shiga toxin-producing *Escherichia*

¹ CRD22 (Opening speeches)

² CRD1 (Division of competence between the European Union and its Member States)

³ CX/FH 19/51/1

⁴ CX/FH 19/51/2

⁵ CX/FH 19/51/3

coli (STEC), and *Safety and Quality of Water Used in Food Production and Processing*. A third document, *Foodborne Antimicrobial Resistance: Role of Environment, Crops and Biocides*, would be published in 2019.

- three JEMRA meetings were held in 2019 on the following topics: i) methodologies for microbiological risk assessment, ii) *Vibrio parahaemolyticus* and *Vibrio vulnificus* in seafood, and iii) microbiological quality of water used in production and processing of fresh fruits and vegetables. The document on methodologies for microbiological risk assessment would be available for public comment prior to its finalization. The results of the *Vibrio* meeting identified new information that the Committee might wish to review and consider new work to revise the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010).

Future JEMRA schedule

13. The Representative reported that in response to requests for scientific advice from CCFH50, JEMRA had scheduled meetings for 2020 on i) STEC control and intervention, and ii) allergens. JEMRA would also be convening a meeting on *Listeria monocytogenes* to provide an updated synthesis of attribution and methods of analysis applied to food safety for this pathogen.
14. The Committee was informed that meeting planning for 2021 was already underway. Tentative topics under consideration include i) water used in food production; ii) microbiological safety of fresh fruits and vegetables; and iii) follow-up meetings on *Listeria monocytogenes* and allergens, as needed.
15. A meeting on microbiological risk assessment of STEC in sprouts was foreseen for 2022.
16. The Representative underscored the timeline and forward planning required to arrange meetings for scientific advice and urged the Committee towards forward thinking about new work that might be required to inform decisions anticipated in future meetings.
17. The Representative, on behalf of both FAO and WHO, expressed appreciation to all the Member countries who supported the work of the Joint FAO/WHO Scientific Advice Programmes, notably JEMRA.

Conclusion

18. The Committee noted the information provided by FAO and WHO and thanked them for their contribution.
19. The Chairperson highlighted that JEMRA was already planning meetings as far in advance as 2022. He also urged the Committee to consider proposing new work to review relevant Codex documents while the scientific advice documents were most up-to-date.

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

20. The Committee noted that there was no updated document provided on this item.

DRAFT CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS (Agenda Item 5)⁷

21. The United States of America introduced the item and recalled that the draft Code of Practice on Food Allergen Management for Food Business Operators had been adopted at Step 5 by CAC42 and advanced to Step 6 for comments. She further recalled that CCFH50 had agreed to request that FAO/WHO convene an expert consultation to provide scientific advice and to request advice from the Codex Committee on Food Labelling (CCFL) on the appropriateness of the use of precautionary allergen labelling.
22. In view of the feedback from CCFL and the new work underway in that Committee, plus the fact that scientific advice was needed to finalise the work in CCFL and the Code of Practice (COP), the draft COP could remain at Step 7 for some time. However because the COP already contained a great deal of information on managing food allergens, the United States of America, Australia and the United Kingdom were proposing revisions as presented in CRD4 to assist in progressing the document to Step 8. She noted that the COP could be revised in the future once FAO/WHO had completed its scientific advice and CCFL had completed its work on precautionary allergen labelling and updating the list of foods and ingredients in section 4.2.1.4 of the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985).
23. The United States of America further informed the Committee that a revised draft COP had been prepared

⁶ CX/FH 19/51/4

⁷ REP19/FH Appendix III; CX/FH 19/51/5; CX/FH 19/51/5-Add.1 (European Union, India, New Zealand, Nigeria, Senegal, Tanzania, East African Community and Economic Community of West African States (ECOWAS)); CRD4 (Draft code of practice on food allergen management for food business operators proposed draft (Proposal by the Chairs of the EWG on sections related to precautionary food allergen labelling)); CRD5 (Proposed draft Code of practice on food allergen management for food business operators (revised)); CRD13 (Dominican Republic); CRD14 (Uganda); CRD16 (Philippines); CRD17 (Benin); CRD19 (Senegal); CRD20 (AU); CRD21 (Mali); CRD24 (Egypt)

taking into account comments submitted at Step 6 (CRD5) and proposed that the Committee consider CRD5 as the basis for discussion.

Discussion

24. The Committee considered the revised draft COP (CRD5) section by section, agreed with most of the revisions in CRD5, including the proposals related to deletion of text related to precautionary allergen labelling throughout the COP (including the definition of precautionary allergen labelling). In addition the Committee made editorial corrections, and several amendments to improve accuracy, clarity and consistency within the Code.
25. The Committee further:
 - converted para. 8 describing Coeliac disease into a footnote to a statement in para. 10 that gluten can cause adverse reactions in persons with Coeliac disease, since the disease is not the focus of the COP.
 - noted a proposal to delete “spelt” from the list of foods in para. 9 (and elsewhere in the Code), recalling the advice from CCFL that CCFH should continue to use the list in 4.2.1.4 of *General Standard for the Labelling of Prepackaged Foods* (CXS 1 – 1985) until further advice was obtained from FAO/WHO.
 - Included a bullet in the Objectives section about controls to prevent or minimise the potential for unintended allergens to be present in the food due to errors along the food chain.
 - noted that the content of para. 18 did not fit under the section on *Factors contributing to exposure*, but related more to food business responsibilities and agreed to put this paragraph under a new section titled *FBO responsibilities*.
 - considered a proposal to include food safety culture under the section *Factors contributing to exposure*, but agreed that it was adequately covered by the *General Principles of Food Hygiene* (CXC 1-1969) (see Agenda item 6), noting that this Code should be used in conjunction with CXC 1-1969.
 - noted that street foods were included in food service. In response to a concern that the same level of control should not be applied to street foods as for other food services, e.g. restaurants, it was clarified that the Code should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969), which provided sufficient flexibility for small and/or less developed food businesses.
 - Added “allergen map” and “HACCP documentation” as manufacturing records.

Conclusion

26. The Committee agreed:
 - to forward the draft COP to CAC43 for adoption at Step 8 (Appendix II);
 - to inform CCFL of the status of the work; and
 - that the COP could be revised upon completion of the work on precautionary allergen labelling in CCFL and advice from FAO/WHO.

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CXC 1-1969) AND ITS HACCP ANNEX (Agenda item 6)⁸

27. The United Kingdom, as Physical Working Group (PWG) Chair, speaking also on behalf of the co-chairs, France, Ghana, India, Mexico and the United States of America, introduced its report (CRD2). After summarising the consensus reached by the PWG, he explained that due to time constraints, the PWG had not completed its review of (i) sections 2, 3.1 to 3.7, and 3.11.2 to 3.13 of Chapter 2; (ii) the annex and diagrams; and (iii) the structure of the guidelines. It was further highlighted that the PWG was unable to reach consensus on two aspects i.e. the definition of food business operator (FBO) and new texts in Section 7.2.1 in relation to estimation of shelf life of food.
28. The Committee noted that the PWG Chair had also led informal discussions on the annex and diagrams in the margins of the meeting with the purpose of incorporating all the comments received if appropriate.

⁸ CX/FH 19/51/6; CX/FH 19/51/6-Add.1 (Argentina, Brazil, Canada, Chile, Colombia, Egypt, Gambia, Guatemala, Honduras, India, Iraq, Japan, Morocco, New Zealand, Nicaragua, Peru, Thailand, Uruguay, the United States of America, CCTA, FoodDrinkEurope, IAF, IDF/FIL and ISO); CX/FH 19/51/5-Add.2 (Ecuador, European Union, Ghana, Nigeria, Senegal, Tanzania, ECOWAS); CRD2 (Report of PWG on HACCP); CRD8 (Guatemala); CRD9 (Republic of Korea); CRD10 (Indonesia); CRD12 (Morocco); CRD13 (Dominican Republic); CRD14 (Uganda); CRD18 (El Salvador); CRD19 (Senegal); CRD20 (AU)

Discussion

29. The Committee considered the revised document contained in CRD2 section by section.
30. The Committee agreed to replace: (i) “disposing” and “disposal” with “disposition” where appropriate; (ii) “loss of control” with “deviation”; and (iii) “the next person/FBO”, the next user in the food chain or consumer should be replaced with “the next FBO” throughout the entire document where appropriate.
31. The Committee agreed with most of the revisions in CRD2 and in addition to editorial corrections, amendments for flexibility, clarity, completeness and consistency, the Committee made the following comments and decisions.⁹

General Principles – (vii)

32. In response to the suggestion to insert the wording reading “in the process or processing environment” in the second line after “a significant change” and “or new legislation” in the fourth line after “new scientific knowledge”, the PWG Chair clarified that the first proposal would limit the intent of the statement; and the matter of new legislation was already addressed in para. 14.

The Committee agreed to retain the original text.

Definitions – Food business operator (FBO)

33. Noting some countries defined FBO as an individual person(s) while others expanded FBO to include an entity in their jurisdictions, the Committee considered different options, i.e. either to delete the definition or to elaborate it as “a person and/or entity”, “an entity” or “a party”.
34. It was explained that “entity” also is understood as a “person”. Therefore, the Committee agreed to the revised definition as follows:

“Food business operator (FBO): An entity responsible for operating a business at any step in the food chain.”

Definitions – Monitor

35. The Committee considered a proposal to replace the words reading “to assess whether a control measure is under control” in the last part of the definition with “detect deviations from a critical limit” as the definition was from HACCP Chapter, and did not reflect its use in Good Hygienic Practices (GHPs).
36. The Committee did not agree with the proposal, and noted that the terminology was from *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and should remain unchanged.

Definitions – Validation

37. The Committee agreed to remove the definition for “validation”, while keeping the definition of “validation of control measures”.

Section 2.2 Hygienic Production – bullet points 2 and 3 of para. 28

38. The Committee considered deletion of “control of zoonotic diseases” from bullet point 3, as this was already covered by the concept of animal health. However, views were expressed that such deletion would remove an important example. The Committee agreed to delete this from bullet point 3 and insert in bullet point 2 “e.g. zoonotic foodborn agents” as more appropriate.

Section 5.1.3 Monitoring of Effectiveness – para. 74

39. The Committee noted different views on whether the second part of the sentence reading “however, microorganisms are unlikely to develop resistance if recommended cleaning and disinfection procedures are explicitly followed” should be deleted.
40. France, as the PWG co-Chair, explained that the word “resistance” was often misused. When bacteria are inhibited by minimal concentration of disinfecting agents, the bacteria could gradually adapt to higher concentrations, which was “tolerance” rather than “resistance” which was the intent of this paragraph.
41. The Committee further considered the wordings in the sentence, e.g. “unlikely” vs “less likely” and “procedure” vs “instructions”, and agreed to revise this paragraph as follows:

“Microorganisms can sometimes become tolerant to disinfecting agents over time. Cleaning and disinfection procedures should follow the manufacturers’ instructions. Periodic review with disinfectant manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of

⁹ The paragraph numbers reflect the paragraph numbers in CRD2

different types of microorganisms (e.g. bacteria and fungi)."

Section 5.3.1 General – paras. 82 and 83

42. A Delegation proposed to include the sentence reading “hazardous waste should be disposed of by trained personnel” in para. 83 as basic training seemed insufficient and special training in this regard would be required. The United States of America, as PWG co-Chair, explained that in addition to a specified section on training in the document, the pertinent requirements for training personnel responsible for waste removal had been elaborated in para. 82.
43. In the spirit of compromise, the Committee agreed to add “including hazardous waste” in the last sentence of para. 82.

Section 6.1 Health Status – para. 85

44. In response to a proposal to insert a requirement that “all food handlers should periodically undergo medical screening as appropriate to prevent contamination of food”, the PWG Chair emphasized that this type of screening was ineffective to detect foodborne disease and thus should not be included. This view was confirmed by the Representative of WHO.
45. The Committee agreed not to include the proposed sentence in the paragraph.

Section 6.3 Personal Cleanliness – para. 91

46. A proposal was made to insert a reference to the use of “disposable paper towels” as the safest way to dry hands.
47. Noting this matter had had lengthy discussion at the previous session, and in view of the fact that disposable towels were not always readily available, the Committee reaffirmed its decision not to take up the proposal.

Section 7 Control of Operation – para. 95

48. Delegations expressed the view to replace the term “food hygiene system” in the paragraph with “Good Hygiene Practices” since “food hygiene system” implied that both GHP and HACCP were applied but in some operations GHP might be sufficient.
49. The PWG Chair clarified that this section was on control of operation and that the more generally applicable term “food hygiene system” was correct in this context.
50. The Committee agreed to retain the original text.

Section 7.1 Description of products and processes

51. One delegation was of the view that the text in the section may be read as implying the introduction of certain steps of the HACCP system into the application of GHP.
52. In order to clarify the specific conditions under which a GHP required greater attention, the Committee agreed to insert a new paragraph between Section 7.1 Description of products and processes and Section 7.1.1 Product description as follows:

“After consideration of the conditions and activities of the food business it may be necessary to pay greater attention to some GHPs that are particularly important for food safety. In this case, the following provisions could be considered.”

Section 7.1.4 Monitoring of process

53. The Committee agreed to remove the sub-heading of Section 7.1.4.1 Corrective action and correspondingly change the heading of Section 7.1.4 to “Monitoring and corrective action”.

Section 7.1.5 Verification – para. 103

54. Delegations expressed the following views:
- “assessment of efficacy” in bullet point 3 should be a part of validation and should not be included under this section; and
 - “sampling and testing” should be inserted as bullet point 4.
55. Noting assessment of efficacy was one example of verification activities to check the implementation of GHP and “sampling and testing” was part of efficacy, the Committee agreed not to make the revisions to the paragraph.

Section 7.2 Key Aspects of Food Hygiene Systems

56. The Committee agreed to change “Food Hygiene Systems” contained in the heading to “GHPs” in light of the

fact that the content of this section was related to GHP.

Section 7.2.1 Time and temperature control – para. 106

57. The Committee agreed to change the words “process control” in the second line to “operational control”.

New texts in Section 7.2.1 in relation to estimation of shelf life of food

58. The Committee considered several proposals to (i) move the proposed new texts on shelf life determination to other more relevant sections, e.g. Section 8.2; (ii) add a new subsection titled shelf life determination; and (iii) delete the information as not relevant to the text or because it might give the impression that FBOs must under all circumstances do their own shelf life determination whereas shelf life requirements might already be established by regulatory authorities.

59. The Committee agreed to delete the new text as this was not a key aspect of the food hygiene system.

Section 7.2.5 Physical contamination – para. 116

60. One delegation proposed to replace the word “calibrated” in the fifth line with “validated”. Another delegation indicated that “sieves” in line 7 which was listed as an example might cause confusion.

61. The Committee confirmed that “calibrated” was the correct word and agreed to delete “sieves”, noting that “sieves” could nevertheless be calibrated.

Section 7.5 Recall Procedures - removal from the market of unsafe food – para. 123

62. The following views were observed:

- This paragraph should be revised to reflect the obligation for FBOs to contact the competent authority as FBOs might not have the knowledge to estimate the risk correctly and conduct the withdrawal from the market properly;
- Food products could be recalled due to reasons other than safety and public warnings were only necessary if food products could lead to public health concerns; and
- There might be inadequate capacity for small businesses to implement these requirements.

63. The Committee agreed with revised text as follows with the aim of providing more flexibility to individual countries.

“Reporting to the relevant competent authority should be required and public warnings should be considered where product may have reached consumers and when return of product to the FBO or removal from the market is appropriate.”

Section 8: Product Information and Consumer Awareness – box

64. The Committee considered a proposal to add text reading “without confusing consumer” to the bullet point under Objective “be aware of the importance of reading and understanding the label”.

65. It was clarified that this requirement was sufficiently addressed in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) and the bullet point relating to “understanding the labelling” implied that the information on labels should not be confusing to consumers.

66. The Committee agreed not to insert that bullet point.

Section 8.1 Lot Identification and Traceability

67. The Committee considered a proposal to delete “Traceability” from the heading as traceability was not part of prerequisite programme.

68. The Committee agreed to retain the original heading and reinstate “and traceability” in the definition for prerequisite programme.

69. The Committee also concluded that it was unnecessary to develop a definition for traceability.

Introduction – para. 136

70. The Committee agreed to delete the last sentence reading “the application of HACCP is the system of choice to achieve food safety” in this paragraph as it appeared to contradict the flexibility provided in the document and that some GHPs alone can achieve food safety in some instances.

2.2 Flexibility for small and/or less developed food businesses – para. 142

71. The Committee revised this paragraph by incorporating the relevant information contained in the deleted paragraph under Introduction in order to provide more flexibility and retained a reference to the FAO/WHO *Guidance to governments on the application of HACCP in small and/or less-developed food businesses* as a

footnote.

3.3 Identify intended use and users (Step 3) – para. 154

72. Noting the explanation of foods produced for vulnerable populations as including for example food for hospital/infants, the Committee agreed to replace the words “institutional catering” in the fourth line with “hospital” and affirmed the necessity to provide a higher level of assurance of food safety for vulnerable populations.

3.6 List all hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1) – paras. 152, 155 and 158

73. The Committee also agreed to:

- change the word “hazards” in line 3 of para. 152 to “potential hazards” and make the change to the heading accordingly;
- include an additional bullet after bullet point 3 of para. 155 as follows:
“identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information;” and
- amend the placement of examples in para 158 to better exemplify how more than one control measure might be needed in some circumstances to control a single hazard, while one control measure could control more than one hazard.

74. The Committee also considered a proposal to develop a definition for “potential hazard” and concluded it was unnecessary to do so.

3.10 Establish corrective actions (Step 10/ Principle 5) – para. 171

75. The Committee considered a proposal to delete the second sentence starting from “in some cases...” as in the view of some delegation, if a validated critical limit was set correctly then failure of that meant the product would be unsafe and the reference to expert advice on safe use of affected product could be misused or misinterpreted.

76. The Committee agreed to delete the sentence, nevertheless noting that it would be possible that when a deviation occurred, the evaluation might determine that the product was still safe.

3.12 Establish documentation and record keeping (Step 12/ Principle 7) – para. 185

77. In response to a proposal to insert the words “empirical or legislative” after the word “scientific” in bullet point 4, the United States of America, as PWG co-Chair, pointed out that all those bullet points were listed as examples and it was expected that legislation should also be based on scientific support.

78. The Committee agreed not to revise bullet point 4.

Annex 1 - Comparison of GHPs CCP and control measures with examples

Diagram 1 – Logic Sequence for Application of HACCP

Diagram 4 – Example of a HACCP Worksheet

79. The Committee agreed to:

- change the title of Annex I to “Comparison of control measures with examples”; and
- make consequential changes to the texts to be consistent with the main body of the document.

Diagram 2 – Example of Hazard Analysis Worksheet

80. The PWG Chair explained that a number of comments had been received on this diagram; however, as this diagram is widely used and well understood, it was proposed not to make any changes at this stage.

81. The Committee agreed with the PWG Chair's proposal.

Diagram 3 – Example of Decision Tree to Identify CCPs

82. The PWG Chair proposed to delete this diagram for the time-being and in order to avoid delay of adoption of the document, to continue its revision for insertion to the document after its adoption.

83. The Committee agreed with the deletion of the diagram for the time-being noting that further work will continue on the diagram.

Structure of the document

84. Delegations expressed the following views:
- Training and competence were relevant to both GHP and HACCP and was proposed for inclusion in the introduction part after "Management Commitment to Food Safety";
 - "Definitions" should be placed before the "General Principles"; and
 - Paragraphs 4 to 7 in the introduction should be placed in a separate Section e.g. after the definitions and explaining the link between Chapter One (GHP) and Chapter Two (HACCP).

85. The view that the current structure should remain unchanged was also observed.

86. The Committee agreed with the Chairperson's recommendation to retain the current structure.

Others

87. Noting some inconsistencies in translation into French and Spanish, the Committee requested the Codex Secretariat to address this matter.

Conclusion

88. The Committee:

- agreed to forward the proposed draft revision of the *General Principles of Food Hygiene* (CXC1-1969) to CAC43 for adoption at Step 5/8 (Appendix IV); and
- agreed to return the diagram to the decision tree to Step 2 for drafting by Brazil, Honduras, Jamaica, and Thailand, comment at Step 3 and consideration by CCFH52.

PROPOSED DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS AT STEP 4 (Agenda Item 7)¹⁰

89. Denmark, chair of the Electronic Working Group (EWG), speaking also on behalf of the co-Chairs, Chile and the European Union, introduced the report of the EWG and highlighted some of the key discussions and conclusions of the EWG. She informed the Committee that a revised guidance had been prepared based on the comments submitted at Step 3 (CRD6). She noted that most of the comments were of an editorial nature, but that there were also comments with respect to FAO/WHO documents/references throughout the Guidance, to the wording of the paragraphs on rapid risk assessment (RRA) and to the template asking for a rapid risk assessment (Annex III).

90. In view of these comments:

- Annex I (list of FAO/WHO documents and other relevant documents) and references elsewhere in the document were deleted since the information from these references was incorporated directly in the text; and
- the confusion on what a RRA is as compared to an outbreak assessment was addressed by separating the terms and clarifying the differences between them. As a consequence, a new definition of outbreak assessment was developed, Annex II was changed to examples of requests for RRA and relevant texts in some paragraphs were revised; and Annex III was changed to a template for an outbreak assessment.

91. She proposed that the Committee consider CRD6 as the basis for discussion.

Discussion

92. The Committee considered CRD6, agreed with most of the revisions, and in addition to editorial corrections and additional amendments for purposes of clarity and completeness, made the following comments and decisions.

Definitions

93. The Committee agreed to:

- amend the definition for *case-control study* to bring it more in line with the WHO definition; and
- change the definition for *outbreak assessment* to *outbreak analysis* as more appropriate, and deleted the

¹⁰ CX/FH 19/51/7; CX/FH 19/51/7-Add.1 (Argentina, Canada, Colombia, Gambia, Iraq, Japan, Morocco, Nicaragua, Peru, Thailand United States of America, Collagen Casings Trade Association (CCTA)); CX/FH 19/51/7-Add.2(Ecuador, European Union, Ghana, Nigeria, Senegal and Tanzania); CRD6 (Proposed draft guidance on the management of biological foodborne outbreaks (revised)); CRD8 (Guatemala); CRD9 (Republic of Korea); CRD12 (Morocco); CRD13 (Dominican Republic); CRD16 (Philippines); CRD17 (Benin); CRD18 (El Salvador); CRD19 (Senegal); CRD20 (AU); CRD21 (Mali); CRD24 (Egypt)

reference to “larger” outbreaks as this was rather subjective, noting that smaller outbreaks could also have an impact.

94. The Committee noted the concern of a member about the reference to feed in the definition of *surveillance* as surveillance of feed was not helpful for early detection of human foodborne illness. However, it was clarified that there was experience that surveillance of feed had proved helpful in connection with human food safety in some instances, and was merely an example in the definition (and throughout the document). The Committee agreed to retain the definition of surveillance unchanged.

Analytical methods

95. The Committee had a discussion on the need for the inclusion of extensive text relating to whole genome sequencing (WGS) and the impression that the use of WGS could be considered mandatory. However, it was acknowledged that WGS was increasingly being used as a biological typing tool, and that it was important to retain the sections on WGS to future-proof the Guidance.
96. In order to address the concerns that WGS could be interpreted as being mandatory, para. 50 was amended to read, “*When WGS is used, consideration should be given to:...*”.
97. The Committee further agreed to amend para. 51 by deleting the reference to the cost of WGS as the focus was more on the opportunities for collaboration between countries and that this should be strongly encouraged. The example relating to developed countries carrying out WGS at the request of developing countries was also deleted.

Rapid risk assessment and outbreak assessment

98. The Committee agreed with the revised text and amended outbreak assessment to outbreak analysis in line with its earlier decision (see para. 94).

Combining epidemiological and laboratory data

99. The Committee noted the comments that while it was acknowledged that epidemiological evidence even in the absence of positive laboratory results from sampling, could warrant an outbreak response, such evidence was not conclusive, but rather indicative of a foodborne outbreak. The Committee therefore amended para. 80 to read as follows:

“Robust epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response.”

Annexes

100. The Committee had a general discussion on the annexes and noted that there was general agreement for inclusion of the three annexes, that Annex II on examples of requests for rapid risk assessment made it more understandable on what a rapid risk assessment was; and that Annex III was now a template for an outbreak analysis.
101. A view was expressed that INFOSAN should be included as an example of an international network / organisation (Annex I); and that there were some concerns with how the questions were worded in Annex II.
102. The Committee agreed that further consideration should be given to improving the annexes for further discussion at CCFH52.

Conclusion

103. The Committee agreed to:
- forward the proposed draft Guidance to CAC43 for adoption at Step 5 (Appendix III); and
 - establish a PWG, chaired by Denmark and co-chaired by Chile and the European Union, working in English, French and Spanish to be held in conjunction with CCFH52 to consider all comments received and to prepare a revised proposal for consideration by plenary.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) IN BEEF, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, LEAFY GREENS, AND SPROUTS AT STEP 4 (Agenda Item 8)¹¹

104. Chile and the United States of America, Chair and co-Chair of the EWG, introduced the item and highlighted the timeline to develop the guideline in conjunction with expert meetings of JEMRA scheduled up to 2022 as well as provided proposed terminology/definitions for the commodities which are within the scope of the guideline. It was stressed that further scientific advice from JEMRA was needed to progress development of the guideline (and its annexes).
105. The Committee did not discuss the proposed draft Guidelines, but rather focused on giving guidance on the terminology to be used for each of the commodities covered by the Guidelines; and the request for scientific advice to JEMRA.

Terminology

106. The Committee discussed terminology and agreed to use fresh leafy vegetables instead of leafy greens, for consistency with the *Code of Practice for Fresh Fruit and Vegetables* (CXC 53 – 2003), raw beef instead of beef, raw milk and raw milk cheeses instead of raw milk and cheese produced from raw milk. The exact content of the definitions would be further discussed by the EWG.

Request for scientific advice

107. The Committee further agreed to request scientific advice from JEMRA on:
- the most appropriate application point(s) of specific interventions, including decontamination treatments;
 - any other additional interventions for control of STEC in raw beef, raw milk and raw milk cheeses, fresh leafy vegetables, and sprouts;
 - verification, based on the available data, of the efficacy of the interventions in terms of STEC reduction;
 - advice, with some level of confidence, to the extent possible, on the quantifiable level of reduction that interventions achieve; and
 - advice on the practicality and feasibility of proposed interventions to be applied on commercial scale, and therefore reasonably likely to be adopted by FBOs and appropriate to include in the Codex guidelines.
108. The FAO/WHO JEMRA Secretariat confirmed that the work on beef would include a verification of the efficacy of feed additives to control STEC.

Conclusion

109. The Committee agreed to:
- Return the proposed draft document to Step 2/3 for redrafting and circulation for comments; and
 - Establish an EWG, chaired by Chile and co-chaired by France, New Zealand and the United States of America, and working in English, to:
 - i. redraft the General Section, Raw Beef Annex, and Fresh Leafy Vegetables Annex of CX/FH 19/51/8 based on written comments submitted to CCH51;
 - ii. update the Raw Beef Annex in CX/FH 19/51/8 with any additional information on interventions relevant to control of STEC in raw beef and submit to JEMRA prior to June 2020;
 - iii. draft an annex on Raw Milk and Raw Milk Cheeses describing interventions relevant to control of STEC in these foods and submit to JEMRA prior to June 2020;
 - iv. based on JEMRA feedback, revise the Annexes, as necessary.
110. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH52 for circulation for comments at Step 3.

¹¹ CX/FH 19/51/8; CX/FH 19/51/8-Add.1 (Argentina, Brazil, Canada, Chile, Colombia, Gambia, Honduras, India, Iraq, Japan, Morocco, New Zealand, Nicaragua, Panama, Peru, Sri Lanka, Thailand, Uruguay, the United States of America, Collagen Casings Trade Association (CCTA), International Dairy Federation (IDF/FIL)); CX/FH 19/51/8-Add.2 (Ecuador, European Union, Ghana, Nigeria, Senegal, Tanzania and East African Community); CRD9 (Republic of Korea); CRD12 (Morocco); CRD13 (Dominican Republic); CRD14 (Uganda); CRD18 (El Salvador); CRD21 (Mali); CRD24 (Egypt)

DISCUSSION PAPER ON PRINCIPLES FOR THE SAFE USE OF WATER IN FOOD PROCESSING (Agenda Item 9)¹²

111. The item was considered under Agenda item 10.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)¹³**New Work/ Forward Workplan**

112. The United States of America as PWG Chair introduced CRD3 and provided an overview of the discussions and recommendations.
113. The Committee considered the recommendations of the PWG and made the following comments and decisions.

New work*Guidelines for the safe use and reuse of water in food production*

114. Honduras introduced the revised project document (CRD23) and highlighted changes in the title, scope and main aspects to be covered, and timeline.
115. One Member sought clarification whether chemical contaminants were within the scope of the new work. The Committee agreed that the Guideline would only cover biological hazards, but acknowledged the importance of chemicals in the context of safe use and reuse of water in food production. In light of this, the Committee agreed to inform the Codex Committee on Contaminants in Foods (CCCF) of this new work.

Conclusion

116. The Committee agreed to:
- forward the project document to CAC43 for approval as new work (Appendix V); and
 - establish an EWG, chaired by Honduras and co-chaired by Chile, Denmark, EU and India, working in English with the possibility to also work in Spanish, to prepare, subject to approval of the Commission, the proposed draft guidelines for circulation for comments at Step 3 and consideration at CCFH52. The EWG will take into account published and future JEMRA work on water (see agenda item 3).
117. The report of the EWG should be made available to the Codex Secretariat at least three months before CCFH52 for circulation for comments at Step 3.

Forward workplan

118. The Committee reviewed the forward workplan and noted the offers of:
- Japan, with support from New Zealand, to review the forthcoming JEMRA report (2020) on *Vibrio* and prepare a discussion paper on the possible revision of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* (CXG 73-2010); and
 - Canada, with support from The Netherlands, to prepare a discussion paper on the possible revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012).

Other matters

119. The Committee welcomed the planned JEMRA expert meeting on *Listeria Monocytogenes* as this would help to inform possible future revision of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria Monocytogenes in Foods* (CXG 61-2007).

Conclusion

120. The Committee agreed to:
- endorse the revised forward workplan (Appendix VI); and
 - establish a PWG on CCFH Work Priorities, chaired by the United States of America, to be held in conjunction with CCFH52, working in English, French and Spanish.

¹² CX/FH 19/51/9; CRD7 (European Union, Ghana, Nicaragua, Nigeria, Senegal, Tanzania and East African Community) CRD11 (Uruguay); CRD13 (Dominican Republic); CRD14 (Uganda); CRD15 (Revised discussion paper); CRD16 (Philippines); CRD17 (Benin); CRD18 (El Salvador); CRD20 (AU); CRD21 (Mali); CRD23 (Further revised project document)

¹³ CX/FH 19/51/10, CRD3 (report of the PWG on new work/forward workplan)

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

121. The Committee was informed that its 52nd Session would be held from 16 to 20 November 2020 with the final arrangements subject to confirmation by the host Government in consultation with the Codex Secretariat.

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

(at Step 8)

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 consumers suffering from food allergies, those who have people with food allergies in their care, 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, minimize the risk from, and, where possible, prevent unintended allergen presence and that Competent Authorities provide guidance and oversight, 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 harmonized 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 pathogenic microorganisms, such as heating, high pressure processing, etc. generally do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, 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. 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 are¹

¹ The listed foods, with one exception (i.e., deletion of sulphites), are referred to in the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) as the foods and ingredients known to cause hypersensitivity and that must always be declared .

- cereals containing gluten (i.e. wheat, rye, barley, oats², spelt or their hybridized strains)
 - crustaceans;
 - eggs;
 - fish;
 - milk;
 - peanuts;
 - soybeans; and
 - tree nuts
9. 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 disease³, as well as those with specific allergies to those cereals.
10. 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.
11. Poor allergen management 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 individual with an allergy to the food. The doses that provoke reactions vary among individuals and are dependent in part on the type of allergen. The risk of allergic reactions within a larger proportion of the population suffering from food allergies increases with increasing concentration of undeclared allergen.
12. Allergen cross-contact can result from a number of factors in processing, preparing and handling foods, some of which pose a greater potential for allergen cross-contact than others. The control measures implemented to prevent or minimise the likelihood of allergen cross-contact should be based on risk assessment conducted by food business operators.
13. 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

14. A variety of situations may result in the exposure of individuals with a food allergy to undeclared allergens. These include (but are not limited to) 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 including lack of understanding of the serious nature of food allergies.

² While oats do not contain gluten, they are commonly produced in the same location as gluten-containing cereals such as wheat, resulting in allergen cross-contact.

³ 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.

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 allergen 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 or handling 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 of the supplier to provide timely notification of ingredient changes;
- 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
- individuals with a food allergy not making their allergies known to food service personnel.

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

FBO Responsibilities

16. 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 eliminate or 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 consumer with a food allergy from the presence of an unintended allergen.

SECTION I - OBJECTIVES

17. 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 allergen cross-contact that is of risk to the consumer with a food allergy;
 - Prevent or minimize the potential for undeclared allergens being present in a food due to errors arising in the supply chain;
 - ensure the correct allergen label is applied to prepackaged foods; and
 - ensure that accurate information can be provided to consumers at point of sale when the food is not prepackaged.
18. 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.
19. 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 Prepackaged 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

20. 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.
21. This Code covers IgE-mediated, non IgE-mediated food allergies and other 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.
22. 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

23. 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).
24. 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.

25. 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

26. 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 an otherwise 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.

Retail means a food business primarily involved in selling prepackaged 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.

SECTION III – PRIMARY PRODUCTION

PRINCIPLE:

Where the introduction of an allergen may adversely affect the allergen profile of food at later stages of the food chain, primary production should be managed in a way that reduces the likelihood of introducing such allergens.

27. 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).

3.1 Environmental hygiene

28. 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 needed to remove, to the extent practicable, the physical remains of previous crops prior to re-planting.

3.2 Hygienic production of food sources

29. 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

30. 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.

31. 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.

32. 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 allergen 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 allergen cross-contact is managed.

33. 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.
34. FBOs should ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.
35. Transportation of foodstuff 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 single-use 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*

36. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).
37. In addition, FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and allergen 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

38. 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

39. 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. Production sequencing (i.e., 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 allergen cross-contact.
40. 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 allergen cross-contact from one line to another based on the food, the process, and the likelihood of allergen 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

41. 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

42. 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 consumer with a food allergy, 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.

43. 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

44. Manufacturers should consider providing appropriate barriers (e.g. walls, partitions, curtains) or adequate separation (e.g., spacing) between lines, when necessary, to prevent or minimise allergen cross-contact when foods with different allergen profiles are processed at the same time.

45. When necessary, based on an assessment of risk to the consumer with a food allergy, 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 and equipment 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

46. Equipment, tools, utensils and containers (other than single-use containers and packaging) in contact with foods that contain allergens should be designed and constructed to facilitate the effective removal of allergens during cleaning. To prevent or minimise the potential for allergen cross-contact, ideally, equipment, tools and utensils should be designed or selected so that allergens, especially particulate allergens (e.g. peanuts, tree nuts, sesame seeds, crumbs from baked goods), do not 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” in pipework or other areas where pockets of foods containing allergens can accumulate should be eliminated and where elimination is not possible, should be adequately cleaned.

4.3.2 Retail and Food Service

47. 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

48. FBOs, including retail and food service, should place hand wash basins in appropriate areas to prevent or minimise 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 consumers with food allergies, 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*

49. FBOs should control allergens by preventing or minimising the potential for allergen cross-contact, by ensuring that information identifying the allergens present in foods is 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 that may be helpful in assessing the likelihood of allergen cross-contact resulting in a risk to the consumer with a food allergy 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
- the maximum amount of an allergen due to allergen cross-contact (if the information is available).

50. 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.

51. FBOs should:

- identify any steps in their operations that pose the likelihood of allergen cross-contact, assess the level of risk to the consumer with a food allergy at those steps and ascertain the ones that are critical;
- implement effective allergen management procedures to prevent or minimise allergen cross-contact at those steps;
- monitor, and when appropriate document, allergen management procedures to ensure their continuing effectiveness;
- review allergen management 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 management procedures.

5.1.1 Manufacturing

52. Manufacturers should identify steps in the operation that are critical to ensuring allergens are properly declared, including reviewing recipes and labels on compound ingredients, ensuring that the correct ingredients are used, 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.

5.1.2 Retail and food service

53. Retail and food service operators should also manage menus, including in-store and on websites, if they contain allergen information, to assure content is current and matches the food product.

5.2 Key aspects of hygiene control systems

5.2.1 Manufacturing

5.2.1.1 Minimising allergen cross-contact during processing

54. 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.
55. Manufacturers should design traffic flow of allergen-containing ingredients and waste, 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 of transient people such as managers, quality assurance personnel, inspectors, maintenance personnel, and visitors.
56. “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.
57. 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 simultaneously 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.
58. 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 and utensils before use for a food with a different allergen profile. Disposable liners can also be an effective strategy.
59. 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.
60. 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 allergen cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line.
61. When there is a likelihood of allergen cross-contact from the dust of dry ingredients that are, or contain, a food allergen, they 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.

62. Manufacturers should evaluate the potential for allergen 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 (for example, dedicated cooking media) if it is likely that the risk from allergens cannot be prevented or minimised, e.g. in the case where particles could end up in a food with a different allergen profile.
63. Spills that contain food allergens should be cleaned up as soon as possible, 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*

64. 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.
65. 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*

66. 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.
67. 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.
68. 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*

69. 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.
70. 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. Occasional product testing for undeclared allergens may also be considered as appropriate for verification.

5.2.1.5 *Product development and change*

71. 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.
72. 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 allergen cross-contact with existing products.
73. Procedures for preventing or minimising allergen 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.
74. Product labels should be designed 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 allergen profile, manufacturers should consider indicating this on the packaging and on their websites for an appropriate period, with information such as "new formulation". Consideration could be given to changing packaging features such as colour when a new allergen is included in the formulation.

5.2.2 Retail and Food Service

75. Equipment that is 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.
76. Allergen-containing food that is not in sealed packages, should also be labelled with the allergen and 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 allergen cross-contact during preparation

77. 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. Allergen 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.
78. 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.
79. 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).
80. 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.
81. 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 a new or different 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.
82. 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 or minimise 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.
83. Foods displayed for consumer purchase should be protected from allergen 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.

84. 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*

85. 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. FBOs should implement a policy for rework to only be added back to the same product whenever feasible.

5.2.2.3 *Application of Product Labels*

86. 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*

87. 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*

88. When introducing a new product or recipe with a different allergen profile, procedures for minimising allergen cross-contact should to 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**

89. Manufacturers should indicate requirements for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.
90. Manufacturers should ensure that their suppliers have good allergen management practices to prevent or minimise the likelihood of allergen 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.
91. 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 allergen 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 occasional testing for undeclared allergens when necessary for verification.
92. 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.

93. 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 ingredients used in small amounts 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 where allergen information may be difficult to locate on the package.
94. 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).
95. 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.
96. 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 storage 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

97. 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.
98. 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).
99. Incoming packaged ingredients should be checked to ensure that the correct product was received. 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

100. FBOs should have procedures in place to review and approve all proposed product labels of all foods to ensure the allergens are declared accurately 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*

101. 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 consumers with a food allergy.
102. 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 consumers with a food allergy.

5.6 *Management and supervision*

103. 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 or minimise 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*

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

5.7.1 *Manufacturing*

105. 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 allergen 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);
 - SOPs to minimize/prevent allergen cross-contact;
 - Allergen map; and
 - HACCP documentation.

5.7.2 Retail and Food Service

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

5.8 Recall procedures

107. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).
108. FBOs should have recall procedures which address food allergens in their food recall plan.
109. 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

110. 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.
111. 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.
112. 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

113. Inspect and remove any hand tools and utensils if they are damaged and not easily cleanable. Where feasible and appropriate, consider dedicated tools for specific equipment and/or label or colour code maintenance tools to correspond with specific allergens.
114. 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, if some equipment cannot be disassembled, the allergen management program should take this into account. Dust socks should be removed and cleaned periodically.

115. 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.
116. 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 allergen cross-contact.
117. 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 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 recontamination of surfaces with allergenic food residues.

6.1.2 Retail and Food Service

118. 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

119. 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.
120. 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 product matrix combination. Cleaning processes should be verified through visual observation (checking that equipment is visibly clean) and, where feasible and appropriate, through an analytical testing program (refer to section 6.5 of this Code).
121. 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 allergenic ingredient, such as wheat 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.
122. Manufacturers should develop allergen clean up procedures for the manufacturing line to be followed in the event of spills of allergenic ingredients.
123. 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

124. 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

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

126. 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

127. 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

128. 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.

129. 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).

130. 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 prevent or minimize the potential for food handlers to contribute to allergen cross-contact.

131. FBOs should consider the potential for allergen cross-contact of products with allergenic materials via food handlers. For example, food handlers may become a source for allergen 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.

132. FBOs should ensure that personnel are trained to wash their 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

133. 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).

134. 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

135. 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

136. Foods that are being distributed should be adequately contained or packaged to protect against allergen cross-contact.
137. The FBO assigning the food to be transported should ensure that the transporter/hauler has clear instructions to follow regarding potential allergen cross-contact situations.
138. The transporter/hauler should have procedures in place to ensure the integrity of the items they are transporting.

8.2 Requirements

139. 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/hauler e.g. to not allow mixed transportation of goods, when there is the likelihood of allergen cross-contact.
140. The food transportation unit⁴ 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).
141. The transporter/hauler 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

142. 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.
143. 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.
144. 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.

⁴ 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.

145. 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.
146. 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 allergenic foods and ingredients.

9.1 Lot identification

147. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).
148. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

9.2 Product information

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

9.2.1 Manufacturing

150. 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.
151. 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

152. 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 prepackaged products are correctly labelled.
153. 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 allergen 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.
154. Self-serve areas where consumers handle unpackaged food products may pose a particular risk for consumers with a food allergy due to allergen cross-contact. Provision of information on the likelihood of allergen cross-contact, should be considered in these instances (e.g. allergen alert signage or symbol/icons).

9.3 Labelling

155. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).
156. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.
157. The *General Standard for the Labelling of Prepackaged Foods* lists the foods and ingredients known to cause hypersensitivity that “shall always be declared” on the label.

9.4 Consumer education

158. 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

159. 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

160. 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.

161. 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 or minimise 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 or minimising allergen cross-contact;
- handling of rework materials to prevent or minimise unintended allergens from being incorporated into a food;
- waste management, for example how waste should be handled to prevent or minimise 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

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

10.4 *Refresher training*

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

PROPOSED DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

(At Step 5)

INTRODUCTION

1. Foodborne illnesses encompass a wide spectrum of illnesses and are an important public health problem. They are the result of ingestion of foodstuffs contaminated with biological hazards (biological foodborne illness) or chemicals (chemical foodborne illness). The contamination of food may occur at any stage in the process from food production to consumption and can result from the presence of zoonotic hazards in animal production or from handlers, environmental contamination, via equipment, water, soil or air.
2. Biological food-borne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynecological, immunological and other symptoms. The symptoms can be mild with recovery in days or have severe consequences for the individuals due to long-term sequelae with serious health effects or even death.
3. Biological foodborne outbreaks can have significant socio-economic costs related to hospitalization and medical treatment, lost productivity and effects on tourism. For food businesses, the consequences can be lost markets, loss of consumer confidence, litigation and company closures. Such foodborne outbreaks can cause impediments to domestic production and international trade. Globalization of the food supply has led to the rapid and widespread international distribution of foods, further increasing opportunities for pathogens being inadvertently introduced into many geographical areas.
4. Codex Alimentarius has issued several guidelines for food businesses and competent authorities on hygienic practices to ensure food safety. Those guidelines focus on, prevention, monitoring and corrective actions in case of deviations along the production processes. Despite efforts to ensure a high level of hygiene, foodborne outbreaks still occur.
5. In order to handle biological foodborne outbreaks efficiently, local and national multiagency networks of preparedness should be in place. To facilitate a common understanding and a consistent approach to these situations such networks should use comparable methods and interpretations to the extent possible, as well as transparent exchange of information. Cooperation through international networks is essential and should be a feature of any national network.
6. The principles for risk analysis including risk assessment, risk management and risk communication, as described in the Codex *Working principles for risk analysis for food safety for application by governments* (CXG 62-2007) should form the framework/basis for the establishment of a system for preparedness and management of foodborne outbreaks. The risk management measures chosen will vary according to the situation and the regulatory framework of the competent authorities.
7. Within the available analytical methods, molecular methods best contribute to the detection of clusters of human cases and allow them to be linked to the food source when used in conjunction with epidemiological analysis. They also help to better identify batches/lots of food involved and the root cause; hence reducing the exposure of humans to hazards. In particular, the use of specific genomic methods (e.g. Pulsed-Field Gel Electrophoresis (PFGE), Whole Genome Sequencing (WGS) and Multilocus Sequence Typing (MLST)) can result in improved detection of outbreaks with more associated or linked cases, when the country has the adequate resources to perform it. The increase in the use of this methodology is relevant and will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.
8. The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities. There should be consistency at the local and national level with respect to when an outbreak is declared an incident, emergency or crisis.
9. The following criteria may be used by the competent authorities to categorize biological foodborne outbreaks as an incident, emergency, or crisis and develop and adapt response plans.
 - The number of cases and the geographic spread of the outbreak.
 - The disease severity and its consequences including the number of deaths and treatment options available.
 - The population affected e.g. more vulnerable groups.
 - The pathogenicity (virulence / infectivity) of the microorganism.
 - The distribution pattern, the volumes of the food and national and international trade implications.

- Consumer perception e.g. referring to an outbreak as a “crisis” can affect the consumer confidence in a product or food category clearly not belonging to the consignment implicated.
- Whether or not the outbreak was intentional (e.g. the consequence of fraud or bioterrorism).
- Whether the hazard is known or unknown.
- The capacity of the country to quickly react and limit the extent of the outbreak.

SCOPE

10. These guidelines provide guidance to competent authorities on the preparedness and management of foodborne outbreaks, including the communication with international networks, such as the International Food Safety Authorities Network (INFOSAN) when it is necessary. The guidance addresses preparedness, detection and response with the intent of limiting the extent of such outbreaks. They include recommendations on the appropriate use of new analytical technologies e.g. genetic typing methods in outbreak investigation. The scope is limited to biological hazards, as they are the predominant cause of foodborne outbreaks.

11. These guidelines also describe the role of competent authorities at the local, national and where applicable, the regional level (e.g., groups of countries) and the collaboration between them in formalized network structures. Guidelines are included on collaboration and communication with food business operators and other stakeholders before and during foodborne outbreaks as well as on post outbreak measures and outbreak management review when an outbreak has been declared over. Maintenance of the structures and training methods to strengthen the response by the networks are also addressed.

USE

12. The following Codex Alimentarius documents¹ are relevant for these guidelines:

- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995).
- *Working principles for Risk Analysis for Food Safety for Application by Governments* (CXG 62-2007).
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG-30-1999), as amended).
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CXG 63- 2007), as amended).

13. A number of FAO/WHO documents, describe in more detail some of the issues presented in this guideline.

14. In foodborne outbreaks involving zoonotic agents, the World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stages should also be considered.

DEFINITIONS

For the purpose of this document the following definitions apply:

15. **Biological hazards:** Biological agents including microorganisms that have the capacity to cause harmful effects in humans. These include e.g. bacteria and their toxins, viruses and parasites.

16. **Case-control study:** An observational study in which subjects are enrolled on the basis of presence (cases) or absence (controls) of the foodborne illness of interest. Information is compared between cases and controls.

17. **Case-definition:** A set of criteria for determining whether a person affected by the illness under investigation should be classified as belonging to the outbreak. As such, it is an epidemiological tool for counting cases. It may include clinical and laboratory criteria, a defined period of time, and, as appropriate, limitation/restriction to a place (for example a particular event or restaurant). In some cases criteria could include a limitation based on personal characteristics (for example age).

18. **Cluster:** In epidemiological terms, it describes a group of cases linked by time or place, but with no identified common food or other source. In terms of biological hazards, isolates having the same specific molecular profile or closely related profiles identified by laboratory analyses of specimens from cases.

¹ <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>

19. Cohort study: An observational study in which the occurrence of illness among those who were exposed to a suspected risk factor is compared with the occurrence among those who were not. These studies are feasible for well-defined outbreaks in which all exposed and all non-exposed persons are generally identifiable.

20. Descriptive epidemiology: The aspect of epidemiology concerned with organizing and summarizing health-related data according to the occurrence of disease, in terms of both geographical comparisons and descriptions of temporal trends.

21. 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.

22. Lot: A definite quantity of ingredients or a food that is intended to have uniform character and quality, within specified limits, is produced, packaged and labelled under the same conditions, and is assigned a unique reference identification number by the food business operator. It may also be referred to as a “batch”.

23. Metadata: Data that describe other data. In relation to analytical testing results metadata could be date of sample collection, identification of sample, sample size, product, sampling site etc.

24. Monitoring: The performance of routine analysis aimed at detecting microbiological contamination of e.g. food from which prevalence data may be ascertained.

25. Outbreak analysis: An analysis based on the information available on the foodborne outbreak as well as relevant historical data. It is used to forecast if more cases should be expected under the given circumstances and to finalize tracing information pointing to a source and comparing it with epidemiological outbreak information.

26. Rapid risk assessment: 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 the full development of the four steps of a risk assessment described in the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999).

27. Risk communication: The exchange of information on the biological risk among stakeholders (e.g. government, academia, industry, public, mass media and international organizations) outside the formalized network structures.

28. Surveillance: A systematic and ongoing collection, analysis and interpretation of data from samples from e.g. humans, animals, feed, food or environment for early detection with the purpose of applying appropriate control measures to prevent foodborne illness.

29. Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution. Where “Tracing back” refers to following the path towards its origin/source and “Tracing forward” refers to following the path towards its final distribution/point of consumption.

FOODBORNE OUTBREAKS – PREPAREDNESS SYSTEM

30. To handle foodborne outbreaks in an effective way it is advisable to have and maintain preparedness structures enabling cooperation between competent authorities. In this section, such structures are described in the form of formalized networks at different organizational levels along with some of the good practices and standard tools to include in the system.

A. CREATION OF FORMALIZED NETWORKS BETWEEN HUMAN HEALTH SECTOR AND FOOD AND VETERINARY SECTORS AT LOCAL AND NATIONAL LEVELS

31. In the following paragraphs, the composition and tasks of the networks of competent authorities within a country are described. Competent authorities, other than those at the national/federal level, are referred to as “local” and these may contain sublevels that should also be involved.

32. At the local level defined networks between contact points from the different relevant authorities/agencies covering the same geographical area should be formed e.g. local food control authority, local veterinary authorities, clinical microbiological laboratory, local departments of health/local health authorities, community council and food/veterinary laboratory. The contact points may be either persons or offices as long as they consist of personnel usually participating in the relevant tasks relating to the investigation of foodborne outbreaks at the local level.

33. The tasks of the network contact points are to ensure the exchange of information within the network and coordination of the work with the staff responsible for the various tasks involved in outbreak investigation

and management. To ensure cooperation within the local network one of the contact points should be designated as the local network contact point in charge of the network.

34. The local network contact points should also ensure the timely exchange of information with their respective counterparts in the national network and if relevant with the respective contact points in the other local networks. They should establish channels to engage stakeholders including food business operators, where relevant, in order to exchange information to minimize adverse consequences.

35. At the national level a defined network should be established with personnel experienced in the management of foodborne outbreaks within the competence of their respective authorities/agencies. This national network should be recognized by each of the competent authorities involved, to ensure effective communication and exchange of information. The participants in the national network should be personnel from the equivalent authorities at the national level to the same authorities/agencies that participate in the local networks. In addition, representatives from other relevant institutions, e.g. universities or research institutes, may be included. The authority/agency with the legal responsibility to protect public health in a foodborne outbreak situation should be designated as lead contact point in charge of the national network. The role of the national network should include:

- Ensuring that communication channels between network participants at the local and national levels function effectively and efficiently;
- Ensuring that coordinating efforts to resolve foodborne outbreaks, especially those that are complex, are performed;
- Supporting the local networks where needed;
- Assessing surveillance and monitoring data received from the participating authorities/agencies;
- Assessing information received from the other levels and participants of the network as basis for risk management decisions; and
- Ensuring that communication takes place with regional and international networks e.g. through the INFOSAN emergency contact points, where necessary.

36. The networks should be based on existing structures in the participating authorities and agencies. The network should have an appropriate structure with sufficient capacity and capability. The networks and structures should be described in detail and agreed upon by the participants to ensure cooperation with respect to competences and responsibilities of each participating authority and official agency. They should allow an outbreak to be managed as soon as possible at the lowest possible administrative level i.e. the local network should coordinate the efforts when handling local outbreaks within their area. However, local networks should ask for the support of experts from other local networks or the national network if additional competences are needed to handle a specific outbreak. When several local networks or areas are involved in an outbreak, coordination at a higher level, covering all affected areas should be considered. This could be a task for the national level of the network. A presentation of the structure of the network is provided in Annex I.

37. For the networks to be effective, it is essential that the participants know each other, have familiarity with the system and structures and use them regularly, even in the absence of a foodborne outbreak. It is recommended that participants meet or hold audio-conferences regularly to exchange experiences and best practices, to evaluate the management of past outbreaks and to identify lessons learned.

38. Templates and standard tools should be developed in advance and included in the standard procedures for the network participants to use. Some of them are listed below.

- Template(s) for collecting and maintaining updated information describing the outbreak - descriptive epidemiology;
- standardized questionnaire(s) for hypothesis generation purposes;
- template(s) for cohort and case-control questionnaires. This would allow the networks to adapt them to the specific outbreak situation and to use the questionnaires without delay. Creation of standard questionnaires for this purpose may be performed electronically using one of the Internet-based free software solutions. Data can then be analyzed electronically using a standard statistical software program;
- template(s) for reporting on the outbreak and the outcome of investigations; and
- template for asking a rapid risk assessment addressed in Section E. and Annex II.

39. The national network may also be the forum where new tools and ways to handle outbreaks can be developed and then be made available to local networks.

40. Communication both within a network and between networks is crucial. Communication structures and practices should be included specifically in the documented description of the system and procedures for the network, to ensure that:

- All available information is compiled to form as complete an overview of the situation as possible and kept under review as new information becomes available;
- the appropriate information is distributed to and understood by all necessary and relevant parties in a timely manner;
- there is only one point of contact and a backup in each of the participating authorities/agencies and interested parties for receipt of official information;
- all parties use the established formal information channels, which are tested regularly to demonstrate that they are effective;
- there is a system in place to ensure communication channels remain open (e.g. in the event of infrastructure break down, staff absence, etc.); and
- there is a mechanism in place for the potential use of external experts to reach consensus on and verify the soundness of recommendations given, especially for the national network.

B. INTERNATIONAL ALERT NETWORKS AND EXCHANGE OF INFORMATION WITH THEM

41. Foodborne outbreaks do not respect borders. What initially seems to be a national outbreak at the outset may in fact be or turn into a regional or global foodborne outbreak.

42. The national level network should have a permanent connection with global networks e.g. the INFOSAN and, where applicable, with regional alert networks. These global and/or regional networks have national emergency contact points in most countries. If there is a national contact point (person or institution), it should be actively included in foodborne outbreak investigations at the national level. The contact point at these alert networks may assist in gathering and compiling information and submitting coordinated information concerning ongoing foodborne outbreaks.

43. Information from global networks may be useful for the work of a national network even if the outbreak described does not concern that country, hence it should always be considered if information concerning an outbreak could be useful for other countries and therefore shared.

C. SURVEILLANCE AND MONITORING SYSTEMS (E.G. HUMAN, ANIMAL, FEED, FOOD, ESTABLISHMENT ENVIRONMENT) AND THEIR USE IN FOODBORNE OUTBREAK SITUATIONS

44. Many biological foodborne outbreaks are initially identified through human illness surveillance data. In order to identify the source of a foodborne outbreak there is a need for:

- Surveillance and monitoring of the usual situation of human illnesses from biological foodborne hazards.
- Access to relevant information on cases of illnesses that do not require notification to human health authorities and an assessment of the usual level of illness. This will enable the competent authorities to define when a number of cases exceeds the expected number and may result in the identification of an outbreak.
- Timely centralization and distribution of information through early warning systems; disease notification by medical practitioners to competent authorities should be made mandatory to the extent possible.
- Analysis (e.g. weekly) of the data in order to detect outbreaks in a timely manner.

45. Information from surveillance and monitoring of e.g. animals, feed, food and environment, including equipment of food businesses, may also indicate a potential risk and may help identify the source of a foodborne outbreak as early as possible. Surveillance and monitoring systems are essential tools for detecting and limiting foodborne outbreaks and may help in the early identification of the source. They should preferably be used as an integrated element in the outbreak investigation.

46. Data from these systems may also be used in conjunction with epidemiological data to inform and if necessary prioritize an investigation, e.g. by checking if the strain found in a human outbreak has been found previously in certain reservoirs (e.g. a specific animal population, species, specific food category or environment).

47. For sharing of surveillance data, it is necessary that data collected are comparable among sectors and that confidentiality of personal information is maintained. Information exchange should occur both routinely and during foodborne outbreaks. There should be regular exchange of information among the human health sector, competent food authorities, and laboratories. It is recommended that the information exchange include where possible:

- New signals (increasing trends or sudden elevated numbers of analytical findings/disease reports) from these sectors and follow-up on ongoing outbreaks.
- The use of preferably harmonized and standardized laboratory methods to allow comparability and sharing of laboratory data among human health, food control and veterinary sectors.
- Tools for sharing surveillance data and epidemiological information such as databases or data sharing sites.
- Tools for comparing and presenting data, such as a phylogenetic tree, (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the laboratory data at hand).
- Epidemiological data to evaluate the relevance of the source and to conduct tracing back.

D. ANALYTICAL METHODS

48. Validated analytical methods should be used to isolate and identify causative agents. Traditional analytical methods (such as pathogen isolation) or Polymerase Chain Reaction (PCR) methods used for surveillance and monitoring are essential as the basis for detecting and investigating any outbreak, but often they do not allow a conclusion on a link between different human cases and between the human cases and the suspected food source. In some cases basic typing information such as the serotype, may be enough to allow such linkage. When further characterization is needed for outbreak investigation purposes, molecular or genetic typing methods can be and are increasingly being used.

49. Molecular typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA) but in recent years, other genetic based methods like WGS have become widespread worldwide as biological typing tools. WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of the outbreak. The method can also be used to identify genetic differences, virulence factors and antimicrobial resistance mechanisms. The implementation and use of WGS and the analysis of the WGS results require additional resources and capacity compared to other methods.

50. When WGS is used, consideration should be given to:

- Laboratory capability, specific equipment (properly maintained and, where applicable, calibrated) and personnel trained in implementation of WGS, analysis and interpretation of WGS results.
- Storage capacity of large amounts of metadata and sequence data and the availability of bioinformatics tools to compare data in either restricted or open international databases for genomics. Fast and stable internet connections are a prerequisite.
- Sharing of WGS sequences in a form that is useful for comparison between the human health authorities and the food and veterinary authorities. Sharing of actual raw whole genome sequences and associated metadata is most useful for comparing results obtained by various analytical methods, including both multilocus sequence typing (MLST)-based and (single-nucleotide polymorphism (SNP)-based approaches.
- Legal requirements for sharing of data. If data are shared in open databases there may be a need for anonymizing the samples to ensure confidentiality of personal or business information, thus only allowing limited metadata to identify the sequences.

51. There are various opportunities for collaboration between public health and food safety laboratories within a single country and across countries that could reduce WGS costs, if the necessary equipment and/or experience is missing. Collaboration between countries to carry out WGS is therefore strongly encouraged.

E. RAPID RISK ASSESSMENT – STRUCTURES FOR ASSESSING RISK

52. A risk assessment during a foodborne outbreak may be useful to provide a sound scientific basis to determine the appropriate risk mitigation actions to be taken. In a number of cases, a risk assessment conducted for same or similar pathogen - food combinations will be available. Adaptations to the specific outbreak circumstances may be required (within a short timeframe) based on the information from investigations and regional/local contexts (climate, consumption patterns, serving size).

53. If a risk assessment conducted for same or similar pathogen - food combinations is not available, there might not be sufficient time to ask for a full assessment of the risk at hand. A simplified version of a risk assessment - a rapid risk assessment - will be more practical.

54. The rapid risk assessment is based on the data readily available at that time from the foodborne outbreak itself and, if possible, data from similar outbreaks. There might be no time for collecting additional evidence/data to fill in data gaps or to conduct larger literature studies. These types of assessments need to be updated regularly during the outbreak investigation as new information (e.g. surveillance data, analytical results, epidemiological information, information on consumption and distribution of suspected food items) becomes available.

55. An essential part of outbreak preparedness is to have a framework and structures in place to allow for a timely rapid risk assessment. They should include but are not limited to:

- Lists of risk assessors and experts for specific hazards available with the identification of their area of competence.
- Instructions clearly outlining what is expected of these risk assessors and subject matter experts, including the scope of any rapid risk assessment, taking into account the short timeline for the assessment to be completed or having a template ready to be used for such rapid risk assessment. Examples of requests are provided in Annex II.
- Structure to ensure the direct and immediate submission of information from the outbreak investigations to the risk assessors and for them to ask for additional clarification when required, from the investigators and/or implicated food business operators.
- Availability of (regional/national/local) data on consumption, consumer habits and serving sizes that is as up to date as possible.
- Procedures for rapid contact of food business operators including maintaining contact information.

F. RISK COMMUNICATION SYSTEM/STRATEGY

56. Effective risk communication is essential to objectively inform on both the known data and uncertainties from an outbreak, to justify actions taken and convince affected parties of the necessity to take appropriate action when required.

57. Risk communication should include exchange of information with all stakeholders. Establishing communication links with food industry experts in advance of foodborne outbreaks is important in order to gather/provide information about food categories that may be linked to/potentially involved in an outbreak with respect to production, manufacturing/processing and/or distribution practices. Established relationships can enhance collaboration during the investigation.

58. In terms of risk communication, the preparedness should aim to;

- Establish a public communication strategy for the network members and, where appropriate, designate official spokespersons from the national network or the government, which includes the means of communication (websites, social media etc.) that is appropriate to the size and nature of an outbreak. Where it is possible, the jurisdiction of each of the competent authorities should be accounted for when setting roles and responsibilities for each organisation in the risk communication strategy.
- Consider a structure to allow for the communication to be handled locally, in case of small and local outbreaks.
- Identify organizations that may be involved and make alliances and partnerships with them to ensure a coordinated message. This will minimize the risk for contradicting public statements to ensure the consumer can correctly identify the food item or cause of the outbreak.
- Draft initial messages for the different situations that could potentially arise while specific details can be filled at the moment the outbreak occurs. Consider that each population group may have its own characteristics that affect how they perceive risks (e.g. religious beliefs, traditions), so understanding the audience and testing messages to ensure they are culturally and demographically appropriate is important.
- Test established communication strategies on a regular basis to evaluate their efficiency.

FOODBORNE OUTBREAK – MANAGEMENT

59. When a foodborne outbreak occurs, the established networks and structures should be used to manage the situation with an integrated approach. Often management of foodborne outbreaks will be carried out

under pressure with time and budgetary constraints. It is therefore important that each sector/participant carry out the tasks within their responsibilities according to the procedures decided upon in the networks. The following sections give information of the basic roles of the participants in the networks.

60. The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills and collaboration in the areas of clinical medicine, epidemiology, laboratory medicine, food microbiology, food safety and food control, and risk communication and management among others. The management of a biological foodborne outbreak includes the establishment and confirmation, if possible, of the likely food source by epidemiological investigations of human cases, of food data (traceability of implicated food data) and laboratory analysis.

61. Evidence from these sources should be combined to find the likely source and can provide input for an outbreak analysis, which serves as the basis for the communication. All aspects of an outbreak investigation, including factors considered when declaring an outbreak over, actions and communication should be documented for post-outbreak evaluation.

A. IDENTIFYING AND INVESTIGATING A FOODBORNE OUTBREAK – HUMAN HEALTH

62. A foodborne outbreak is typically identified by

- a national or regional surveillance system when a cluster of human cases occurs with an identical or closely related type of infection likely to be foodborne, or
- the food control authorities when they are informed about illness related to specific products or food businesses. The information may be obtained either through consumer complaints, information from the public health sector or by the food businesses themselves e.g. a restaurant that received complaints from guests.

63. Careful description and characterization of the foodborne outbreak is an important first step in any epidemiological investigation. The initial descriptive epidemiological investigation provides an overview of the outbreak in terms of the three standard epidemiological parameters – time, place and person.

64. Depending on the information available, the public health authorities should establish a case definition. It should be used in a systematic and uniform way to identify additional cases and determine the magnitude of the outbreak. The case definition may be updated or revised if new or additional information indicate a need to do so. Cases that fall within the definition should be interviewed by trained personnel to obtain as much information as possible on food items consumed prior to illness onset. The information asked should include:

- On the food items consumed: (if known) the place (the commercial name of the establishment and the exact address) and date of purchase and time of consumption, method of preparation, brand name, lot/batch code.
- With regards to the affected person: information on travel, animal and environmental exposures, person-to-person contact, disease onset, symptoms, duration, hospitalization, underlying health concerns, etc.

65. The information should be obtained in a structured way using a standardized questionnaire for hypothesis generation purposes when available. Data collected can be analyzed using a standard statistical software program.

66. Other tools that can be used for hypothesis generation to determine the source of attribution in case of a foodborne outbreak include review of surveillance data, or prior sample matches, source attribution studies, historical outbreak data and mathematical modelling.

67. When a hypothesis is established, it may be appropriate where possible to perform analytical epidemiological investigations such as a retrospective cohort study or a case-control study. This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up control measures. These studies can help determine if an exposure is associated with a cluster of human cases. These investigations should not delay other ongoing investigations but can help to give a direction to them.

B. SUBSTANTIATE HYPOTHESIS AND/OR HANDLING OF A FOODBORNE OUTBREAK – FOOD SAFETY (FROM FARM TO FORK)

68. Initial epidemiological investigations (descriptive epidemiology and interviews with a few of the cases using open-ended interviews for hypothesis generation purposes) pointing to a particular food source or a site (e.g. restaurant, production facility, or farms) as the possible source of the outbreak should be followed by a thorough on site investigation. This onsite investigation should cover all aspects of the production, storage, transport, handling, distribution and consumption to substantiate if it is possible that the food source

or the production conditions are actually the source of the outbreak. If possible, the root cause of contamination should be identified and verification by sampling and analyses should be attempted.

69. When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, in order to allow further investigations including tracing.

70. If the epidemiological investigations do not identify a source, the competent authority could use other information to elaborate their investigation of the cause of an outbreak. For example, historical outbreak data, prevalence of the hazard in food, information from the cases concerning food preferences, trade patterns, knowledge of production, distribution, and consumer preferences, may be helpful to narrow down the possible food sources or sites. Such information should however be used prudently e.g. to target investigations and not for communications on the outbreak source without additional supporting evidence.

71. Tracing a food item both back and forward in the food chain is an essential tool in the investigation. Tracing enables the investigators to see the full distribution of the food item e.g. going back from the lot that caused illness to the place/source of initial contamination and identify from that source on, the distribution of all products made with that lot. The following information should be collected:

- Identification of the affected lot(s) for each food item suspected
- Information to identify the root cause of the contamination (raw material status, processing steps that may influence the presence of the microbiological hazard identified, registrations of process and product controls, identified shortcomings, samples analyzed and results etc.)
- List of suppliers of product or raw materials
- List of operators who received the affected lots of the food item and other distribution paths including to institutions and via internet sales.

72. The data from tracing should be gathered in a standard way using templates and business names and product descriptions curated to ensure links are not lost due to abbreviation or spelling mistakes. The information gathered should be combined with the information from the epidemiological investigations of the outbreak to see if cases are consistent with product distribution. The tracing information, as well as the findings from the on site investigation, can also be used to determine the extent of the problem.

73. If the overall evidence concludes that the source of the foodborne outbreak or the affected lot(s) has been identified, appropriate risk management actions should be put in place. When a recall is identified as the appropriate risk management action, tracing back and tracing forward should be used to remove all lots implicated or suspected to be implicated. The recall should be carried out in the shortest time frame possible by the food business operator to avoid greater impact on public health and the business. The competent authority should monitor the recall to ensure compliance.

74. Consideration should be given to the actions required by consumers in recalls and businesses in recalls and product withdrawals concerning the suspect lots. Consideration should also be given to provide advice to consumers and/or businesses about appropriate disposition of affected foods and should take into account any potentially associated public health risks.

C. COMBINING EPIDEMIOLOGICAL AND LABORATORY DATA

75. Management of outbreaks benefits from the food control and veterinary and agricultural sectors being able to share and combine relevant laboratory surveillance and monitoring data among themselves and with the public health sector in order to identify a match between a clinical human isolate and a food source.

76. Even in case of a match in serotypes, supplementary analysis by molecular methods may be necessary to draw conclusions on the likelihood of a relationship.

77. The decision of the degree of correlation between strains should be made as part of the case definition. The level agreed upon may differ according to the typing method and the biological hazard.

78. For example, with WGS, there are no established standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) at present. In general, when the number of SNP differences, or allele differences in the case of MLST analysis, is fewer, there is the potential that the strains could share a common ancestor. The actual number of SNP or allele differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis.

79. The use of databases containing comparable molecular based testing results from e.g. humans, animals, feed, food and establishment environmental sampling, facilitates the detection and assessment of outbreaks and informs the search for the source of the contamination.

80. Robust epidemiological evidence can be sufficiently indicative of a foodborne outbreak even without positive laboratory results from sampling to warrant an outbreak response. Efforts by sampling and analysis should be made to allow laboratory results to support the epidemiological evidence. Laboratory confirmation can be difficult to achieve for several reasons, e.g.

- biological contaminants in food are not likely to be evenly distributed,
- the level of contamination may be low hence the chance for detection is limited,
- there may not be a standard method available for detecting the biological hazard in a specific food of interest, or
- the affected lot of food was consumed or removed at the end of its shelf life and therefore no longer available for testing. This may happen when a hazard causes illness with a long incubation in humans or the food source has a very limited shelf life (e.g. fresh berries).

81. Analytical evidence on the other hand should always be supported by some epidemiological information such as that obtained from interviewing human cases, as a match between food and human isolates may not necessarily mean that the food is the actual source of the illness.

82. For molecular testing, and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link.

D. RAPID RISK ASSESSMENT AND OUTBREAK ANALYSIS– DURING A FOODBORNE OUTBREAK

83. A rapid risk assessment is useful when answers to specific questions are needed. When possible, a risk assessment or adaptation of an existing risk assessment to the specific outbreak situation should be carried out. Since risk management actions might be needed urgently, a full risk assessment might not be practical, but a simplified rapid risk assessment can be helpful to correctly target risk management activities.

84. Rapid risk assessments can be carried out and updated at any time in the outbreak investigation. Constant communication should be ensured between the risk assessors and the risk managers (from both human health and food safety authorities) in order to:

- ensure that the most recent information is available to the risk assessors;
- formulate targeted questions; and
- identify gaps in information.

85. An outbreak analysis is a prognosis in an outbreak situation and is based on historical data and data generated in the outbreak investigation. It is used to forecast if more cases should be expected in a given scenario and to finalize tracing information pointing to a source. It provides a summary of the information collected during the investigations, thereby identifies gaps to be filled, and provides relevant background information and input for the risk communication. In particular, it includes (see template in Annex III for more details):

- historical information on the prevalence of the hazard in different foods, particularly if the source of the ongoing foodborne outbreak is not confirmed yet;
- results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly);
- laboratory results and results from the epidemiological and food safety (including tracing back) investigations;
- risk identification and characterization linked to the outbreak;
- analyses of hot spots (geographical areas or events with more than usual occurrence within the outbreak) detected, guiding further investigations
- consumer behavior and adherence to intended use and preparation of foods, e.g. use of frozen ready-to-cook vegetables and/or fruit, as a ready-to-eat product, not observing the kill step intended by the manufacturer to achieve food safety;

- where appropriate, recommendations to the consumers and to competent authorities on how to manage the risk; and
- if the potential food source has been traced to a specific food business, information on the overall condition of the facility, such as compliance history, inspection reports, complaint records and company test results.

Parts of the information from the outbreak analysis may be needed for risk assessors to reply to the specific question in the rapid risk assessment.

E. RISK COMMUNICATION

86. Ideally, risk communication will provide stakeholders outside the formalized network structure, including consumers, with the information they need to make informed decisions and take appropriate action. At the beginning of an outbreak, during the period when information is being gathered, there may be confusion and intense public and media interest. Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is still unknown. Such early communication should include information on the ongoing investigations and advice on general food hygiene measures consumers could take.

87. Practices that should be considered when conveying the risk communication message to the public and/ or food industry sector include, but are not limited to;

- Have one official communicator to speak to the public whenever practical. When more than one competent authority communicates with the public the authorities should ensure the messages are consistent.
- Information should be simple and in plain language for key points since the public may have limited familiarity with scientific language. If more languages are used in a specific area (e.g. official national language and official local dialect/language) the information should be available in all the relevant languages.
- Acknowledge any uncertainties and make it clear that the recommendations are based on the best information available at the time. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were based on information known at that time and explain why the recommendations were changed.
- Explain to whom the recommendation applies and to whom it does not apply and why.
- Do not withhold information just because it may be upsetting. If information is lacking or cannot be released, it is important to explain the cause (where known) and what is being done to address the situation. Information gaps that will be addressed in the future should be identified and stakeholders should be informed on the likelihood of additional communication.
- There should be a procedure in place for the consultation of external groups of experts to verify the soundness of the recommendations given.
- Repeat information when appropriate and provide updates in a timely manner.
- Monitor the effectiveness of communications and adjust as necessary.
- A platform that provides the public and other stakeholders with easy access to updated information, e.g. a designated website with contact information. This includes authorities and food business operators in other countries if they may be affected.

88. Foodborne outbreaks may start in one country but can spread rapidly to other countries/regions and require rapid and clear response in terms of communication. INFOSAN or other similar networks can be used as a resource for risk communication messages in such instances to ensure factual information is being shared about an international foodborne outbreak.

F. DOCUMENTATION OF THE OUTBREAK AND LESSONS LEARNED

89. It is important to collect and save sufficient information from the beginning of the outbreak to be able to document all relevant steps in the management of the outbreak, for example by using log books, both when it is ongoing and afterwards. During the investigation a record should be kept that includes relevant tracing information and descriptive epidemiology, hypotheses and status of the situation. The record should be updated as needed while the foodborne outbreak is ongoing and in a way, that protects personal information. When it is over, the record can be finalized to include conclusions and can serve as an outbreak report or as basis for a summary outbreak report.

90. For the documentation to be of future use it should be kept in a structured way and accessible at all times for the personnel involved in the work. This could be in the form of a database or in a shared file system accessible only to the relevant personnel/competent authorities.

91. Information from the shared system should be reviewed regularly by the competent authorities. The information can be valuable for the food control authorities when targeting official control efforts.

92. Outbreaks of special interest should be considered for submission as scientific publications. INFOSAN also facilitates the sharing of experiences and lessons learned in and between countries in order to optimize future interventions to protect the health of consumers.

93. The documentation can be used by the competent authorities and institutions involved in foodborne outbreak management to identify lessons learned and to consider the needs of a review of existing preparedness based on the lessons learned. A special report on lessons learned can be added later on to the documentation. It can also provide input for future training activities.

G. POST OUTBREAK SURVEILLANCE

94. Enhanced surveillance, and rapid centralization and evaluation of data, in particular from human cases, should be continued until the numbers of cases have returned to the baseline level, (or, for new biological hazards, until no further cases are observed). This allows the evaluation of the effectiveness of actions taken and the confidence of consumers and trading partners to be maintained or regained. Possible delays in analyses and reporting and possible seasonal effects should be taken into account before declaring an outbreak over.

MAINTENANCE OF THE NETWORKS

A. REVIEW OF EXISTING PREPAREDNESS

95. Competent authorities at the local and national level should continuously monitor, evaluate, improve and strengthen their existing networks to ensure that they are functioning effectively and efficiently. This should include ongoing strategic planning and review of objectives, priorities, needs, gaps, opportunities and challenges, including both internal processes and interagency/ inter-stakeholder relations. An “after action review system” for foodborne outbreaks should be implemented within the network. The results of such reviews should be documented and areas for improvement addressed to support capability and capacity of the system in place.

96. Evaluation of the local and national network structures and associated procedures can be facilitated by joint training to focus on specific objectives, priorities, needs, gaps, opportunities and challenges.

B. IMPLEMENTATION OF LESSONS LEARNED

97. The evaluation of preparedness systems can include reviews of major, serious or rare foodborne outbreaks. The evaluation should include personnel from various authorities/agencies and if possible also comments from relevant stakeholders such as food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, the timeline of activities, and other essential issues. The review should be used to build a stronger system or network on an international, national or local level.

98. The review could also consider whether changes may be needed to the way a food is processed or whether regulatory oversight or other regulatory change is needed to prevent future outbreaks.

99. The review should be disseminated in order to share the lessons learned broadly within the system. Ideally, dissemination would include information such as:

- What was the most notable success in the management of the outbreak that others may learn from?
- What were some of the most difficult challenges faced and how were they overcome?
- What changes, if any, to the national structure, procedures or analytical methods are recommended?
- What was not done to your satisfaction during the outbreak investigation and what could be the points to be improved next time?

100. The lessons learned should be included in the ongoing development of capacity and capabilities of the international, national, and local system.

C. JOINT TRAINING ON FOODBORNE OUTBREAK PREPAREDNESS AND MANAGEMENT

101. A key part of capability and capacity building is the training of experts and professionals. The training should be extended across different competent authorities and key stakeholders. The purpose should be to

develop a common understanding of the entire system for local, national, and international preparedness. As part of the capability and capacity, building joint simulation exercises should be put in place.

102. The exercises can aim at control/verification or learning/ development.

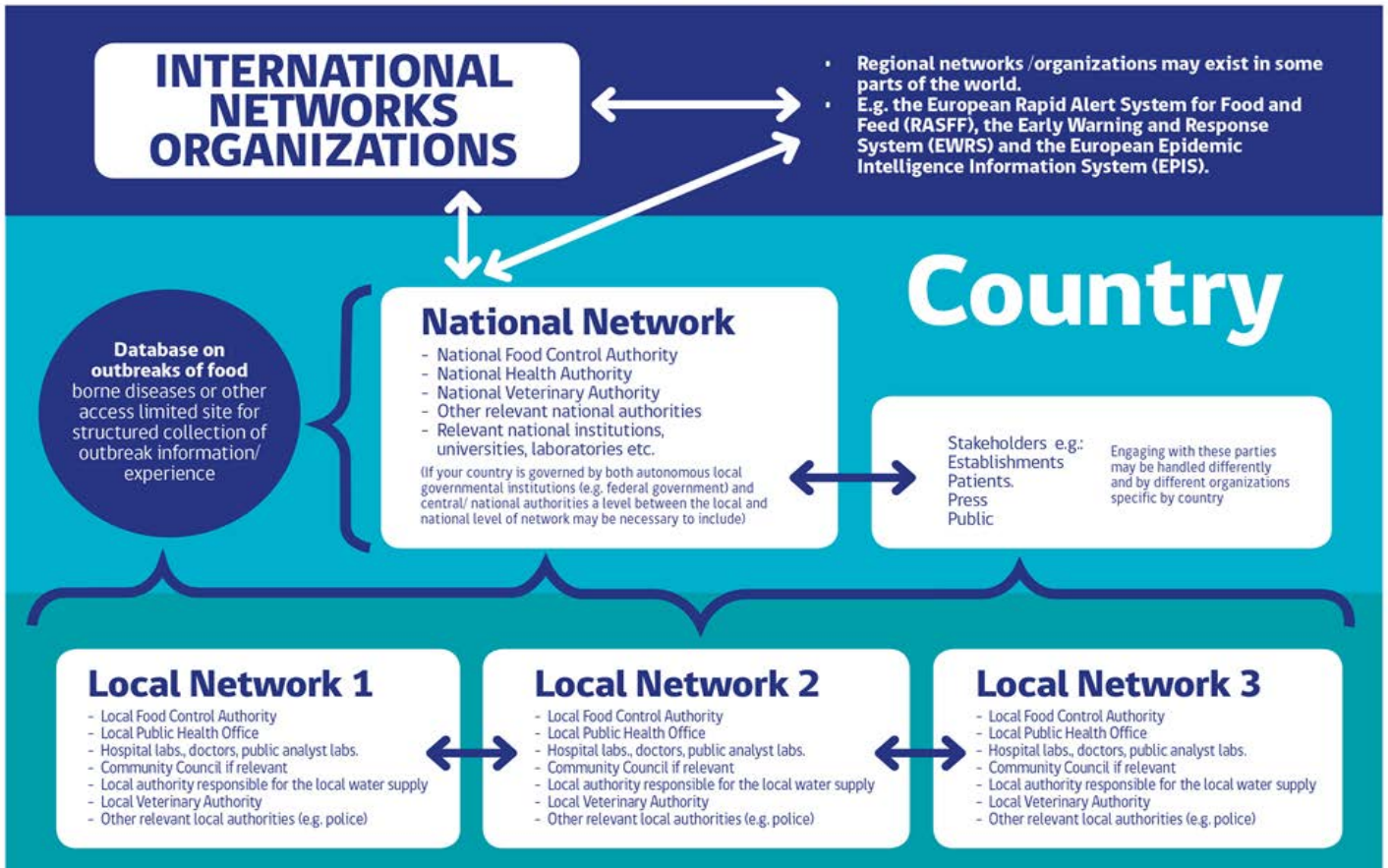
- Control/verification exercises are primarily aimed at testing the performance of the system in place and the participants' ability to carry out their responsibilities effectively, for example an expert or professional handling a particular type of method or a specific procedure. Participants should not be notified in advance of the exercise content. These exercises can vary in both complexity of organization, in number of participants and in length in time and size.
- Learning and development exercises are more organized with the focus on the participants being required to achieve new competences and capabilities. The exercises may involve roles and responsibilities or the development and testing of new procedural concepts and plans. Joint simulation exercises are a proven concept in this setting. Advance notice about learning/development exercises should be given to provide participants with the opportunity to prepare, which can optimize the overall outcome and learning experience.

103. The exercise type should be varied to include exercises concerning the procedures in place (procedural exercises), exercises addressing specific difficult issues/topics and crisis management exercises. The exercises can be done both in a live environment like a laboratory or in a table top form.

104. Regardless of type of joint training or exercise, it is important that the activity is put into a strategic perspective and that lessons learned are captured and put into a structured revision of the system where necessary.

Structure of networks handling foodborne outbreaks

Structure of networks handling foodborne outbreaks.



Examples of requests for rapid risk assessments

Rapid risk assessment - Examples of questions to be clarified / risk to be assessed

The scope of a rapid risk assessment is to answer a specific question or assess a specific risk item in relation to an outbreak.

The topics and listed questions are only examples. The list is not exhaustive.

<p>Related to the suspected food item, a production process etc.</p>	<ol style="list-style-type: none"> 1. Is it possible that the “food item x” produced under the “specific circumstances described” could have caused the outbreak? 2. An unopened sample of the “food item x” acquired in a private household has been tested positive with the outbreak agent. Is it likely that other items of the same food may carry the same risk? – in other words is the production and storage requirements of this food item described sufficient to eliminate the specific risk?)
<p>Related to the agent causing the outbreak</p>	<ol style="list-style-type: none"> 3. A certain strain of “bacteria Y” is causing an outbreak that is suspected of being foodborne. The strain is not previously seen in food items, but a closely related strain has been detected in a feed sample. To be able to conclude whether a reservoir could be in the husbandry sector using the feed in question an assessment on the strain relatedness and stability in the environment could be asked. 4. A certain strain of “bacteria Y” is causing an outbreak that is suspected of being foodborne. The strain is not previously seen in food items. What is the most likely reservoir for this bacteria Y? What may be the most likely production(s) that this bacteria may be found in? 5. “Bacteria Y” is causing an outbreak and is suspected to be caused by products from one or more specific production facilities. However, samples from the facilities turned out negative with standard testing methods. What would be the optimal testing method and number of samples required to be able to determine whether the facilities are the source of the outbreak?
<p>Related to the use of certain food items and consumer eating habits</p>	<ol style="list-style-type: none"> 6. An outbreak caused by <i>Listeria monocytogenes</i> seems to be caused by frozen small meatballs for soup. The meatballs are cooked prior to freezing. Normally they are heat treated when preparing the soup prior to eating. A kitchen added the frozen meatballs to the hot soup prior to chilling and storage. The soup portions are distributed as a chilled product ready to heat and serve. Is this process insufficient to avoid growth of <i>Listeria monocytogenes</i>?

Annex III**Template for an outbreak analysis**

Template for an outbreak analysis - fill in as much information as is available.

Outbreak information/ Descriptive epidemiology	Case definition Number of confirmed cases Number of probable cases not yet verified as part of the outbreak Geographical location (cases per area/jurisdiction) / place of contamination Age and gender distribution Epi-curve (number of cases per day/week or month) Other descriptive information available of the outbreak size and areal distribution.
Analytical information Human cases	Agent involved – characteristics of the agent Overview of human cases reported including hospitalisations and deaths – the severity of the illness.
Outbreak background information	Questions like the following should be answered: How was the outbreak initially detected? Is there any correlation between the distribution of the cases and the distribution of the potentially implicated food? How have the human cases initially been linked to a certain food source? Has outbreak information been reported to the public and how?
Illness background information	Historical data, not related to the ongoing outbreak, on the hazard e.g.; <ul style="list-style-type: none"> • occurrence in humans • outbreaks in the past at local, national or regional level. • occurrence in different types of food <p>The purpose is to indicate if human cases/outbreaks with the involved pathogens are rare or occurring from time to time. Historical data from previous monitoring and isolations in food might target investigations towards the source when not known yet. When possible, these data should be targeted to the pathogen with the same virulence factors/serotypes as the one in the ongoing outbreak.</p> <p>Historical data may also be valuable when determining if / how the agent involved behaves differently than previously seen.</p>
Investigation of human cases	This may include, but not be limited to results of the investigations performed: <ul style="list-style-type: none"> • hypotheses generating interviews • Case-control or cohort investigation
Investigations in food	<ul style="list-style-type: none"> • Information on samples taken – items, places of sampling etc. • Analytical methods used. • Outcome of the laboratory analyses. • Description of production conditions in affected establishments (e.g. hygiene conditions), applicable steps influencing the presence of the hazards (e.g. heat treatments or possibilities for cross-contamination) • Information on tracing of the affected food/food ingredients, e.g. starting from the food/establishment initially linked to the human cases: <ul style="list-style-type: none"> ○ Tracing back the food/ingredients; ○ Tracing forward the distribution; ○ To be repeated for each affected establishment along the chain ○ Data gaps should be identified (e.g. establishments to which the affected food was sent, but where there is no information on investigations carried out in that establishment) • Assessing if the distribution of the suspected food item can explain the outbreak (areal distribution, amount of the food on the market in relation to the distribution and number of cases in the outbreak) • Information on consumer behaviour and eating habits, e.g., not following the manufacturer's instructions for storage (e.g., refrigerate, use-by date) or cooking not intended by the manufacturer to achieve food safety.

Background information concerning the strain in food, feed, animal or environment samples	<p>Has the strain been seen previously? If yes, please describe the time, place etc. further. If isolates are available for comparison, sample identification should be provided.</p> <p>If a specific production or process is suspected to be the source of the outbreak a detailed description of the ingredients, their treatment, production processes etc. need to be described / documented to assess if deviations in the production may be implicated.</p>
Linking epidemiological and laboratory data in humans and food	<p>An attempt should be made to graphically present and link the data from human cases, retailers, distributors, processors until suppliers of raw materials, indicating the link between them when existing and the results of laboratory testing if carried out and available.</p> <p>When available, results from genome sequencing can be added and a single-linkage tree including all human and non-human isolates, should be made, illustrating the core gene allelic differences.</p>
Data not available / not yet available	<p>Uncertainties and data gaps should be indicated.</p> <p>If data /information is necessary for the assessors but not yet available it should be indicated when the data will be available.</p> <p>If data is not available, it should be clearly stated when asking for the assessment as the missing data may be vital for the outcome of the assessment.</p>
Communication	<p>Clear information on the communication strategy towards consumers, affected operators and other stakeholders should be given.</p> <p>It is also a good idea to agree upon a strategy for communication in case the assessors are approached by the press or public – agree on what can be said, by whom and when.</p>
Annexes	References

Prognosis / summary

Summary / prognosis	<p>Overview of involved geographic areas/jurisdictions at local, national or regional level. Overview of human cases reported including hospitalisations and deaths</p> <p>Summary of investigations on food sources and actions taken (e.g. withdrawal) and actions planned.</p> <p>Short and clear communication message to consumers (recommendations on buying and preparing food), affected operators, other stakeholders and trade partners, including possible uncertainties</p> <p>Summary of considerations that resulted in the conclusions including data gaps.</p> <p>Should more cases be expected in near future or can it be assumed that the outbreak is over?</p>
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Appendix IV**PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE*
(CXC 1-1969)*****GENERAL PRINCIPLES OF FOOD HYGIENE: GOOD HYGIENE PRACTICES (GHPs) AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM*****(At Step 5/8)****INTRODUCTION**

1. People have the right to expect the food that they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury can be severe or fatal or have a negative impact on human health over the longer term. Furthermore, outbreaks of foodborne illness can damage trade and tourism. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence.

2. International food trade and the flow of travellers are increasing, bringing important social and economic benefits. However, this also makes the spread of illness around the world easier. Eating habits have undergone major changes in many countries and new food production, preparation, storage, and distribution techniques have developed to reflect this. Effective food hygiene practices, therefore, are vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including primary producers, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to ensure that food is safe and suitable for consumption. Food Business Operators (FBOs) should be aware of and understand the hazards associated with the food they produce, transport, store and sell, and the measures required to control those hazards relevant to their business, so that food reaching consumers is safe and suitable for use.

3. This document outlines the general principles that should be understood and followed by FBOs at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the stage in the food chain, the nature of the product, the relevant contaminants, and whether the relevant contaminants adversely affect safety, suitability or both, these principles will enable food businesses to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities. While it is the FBOs' responsibility to provide safe food, for some FBOs this may be as simple as ensuring that the WHO 5 keys to Safer Food are adequately implemented. The 5 keys are: 'keep clean, separate raw and cooked, cook thoroughly, keep food at safe temperatures and use safe water and raw materials.

4. FBOs need to be aware of 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. Good Hygiene Practices (GHPs) are the foundation of any effective control of hazards associated with their businesses. For some FBOs effective implementation of GHPs will be sufficient to address food safety.

5. The sufficiency of the implemented GHP to address food safety could be determined through conducting a hazard analysis and determining how to control identified hazards. However, not all FBOs have the expertise to do this. If the FBO is not able to conduct a hazard analysis, the FBO may rely on information on appropriate food safety practices from external sources such as that provided by competent authorities, academia or other competent bodies (e.g. trade associations or professional societies) that has been based on the identification of relevant hazards and controls. For example, requirements in regulations for production of safe food are based on hazard analysis often conducted by competent authorities. Similarly, guidance documents from trade associations and other organizations that describe food safety procedures are based on hazard analyses conducted by experts knowledgeable about the hazards and controls needed to ensure the safety of specific types of products. When external generic guidance is used the FBO should make sure that the guidance corresponds with the activities of the establishment and ensure all relevant hazards are controlled.

6. All GHPs are important but some GHPs have a greater impact on food safety. Thus, for some GHPs, based on safety concerns with the food, greater attention may be needed to provide safe food. For example, the cleaning of equipment and surfaces which come into contact with ready-to-eat food should warrant greater attention than other areas such as the cleaning of walls and ceilings, because if food contact surfaces are not properly cleaned, this could lead to direct contamination of food. Greater attention may include a higher frequency of application, of monitoring and of verification.

7. In some circumstances, the implementation of GHPs may not be sufficient to ensure food safety due to the complexity of the food operation and/or specific hazards associated with the product or process, 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 such cases, when there are significant hazards identified through hazard analysis as not being controlled by GHPs, they should be addressed in the HACCP plan.

8. Chapter One of this document describes GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. Chapter Two describes HACCP. HACCP principles can be applied throughout the food chain from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health. The table in Annex 1 provides a comparison of control measures applied as GHPs and those applied at Critical Control Points (CCPs) with examples.

OBJECTIVES

9. The General Principles of Food Hygiene: Good Hygiene Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP) System aim to:

- provide principles and guidance on the application of GHPs applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide guidance on the application of HACCP principles;
- clarify the relationship between GHPs and HACCP; and
- provide the basis on which sector and product-specific codes of practice can be established.

SCOPE

10. This document provides a framework of general principles for producing safe and suitable food for consumption by outlining necessary hygiene and food safety controls to be implemented in production (including primary production), processing, manufacturing, preparation, packaging, storage, distribution, retail, food service operation and transport of food, and where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General

11. The document is intended for use by FBOs (including primary producers, importers, manufacturers/processors, food warehouse/logistics operators, food service operators, retailers and traders) and competent authorities, as appropriate. It provides basic information to meet the needs of food businesses, irrespective of the nature of product and size of food business, in the context of food trade. However, it should be noted that it is not possible for the document to provide specific guidance for all situations and specific types of food businesses and the nature and extent of food safety risks associated with individual circumstances.

12. There will be situations where some of the specific recommendations contained in this document are not applicable. The fundamental question for each food business operator in every case is “what is necessary and appropriate to ensure the safety and suitability of food for consumption?”

13. The text indicates where such questions are likely to arise by using the phrases “where necessary” and “where appropriate”. In deciding whether a measure is necessary or appropriate, an evaluation of the likelihood and severity of the hazard toward establishing the potential harmful effects to consumers should be made, taking into account any relevant knowledge of the operation and hazards, including available scientific information. This approach allows the measures in this document to be flexibly and sensibly applied with a regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food chain operations and practices and varying degrees of risk to public health involved in producing and handling food.

Roles of Competent Authorities, Food Business Operators, and Consumers

14. Competent authorities are responsible for deciding how these general principles are best applied through legislation, regulation or guidance to:

- protect consumers from illness, injury, or death caused by consumption of food;
 - ensure FBOs implement an effective control system so that food is safe and suitable for consumption;
 - maintain confidence in domestically and internationally traded food; and
 - provide information that effectively communicates the principles of food hygiene to food business operators and consumers.
15. FBOs should apply the hygienic practices and food safety principles set out in this document to:
- develop, implement and verify processes that provide food that is safe and suitable for its intended use;
 - ensure personnel are competent as appropriate to their job activities;
 - build a positive food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food safety practices;
 - contribute to maintaining confidence in domestically and internationally traded food; and
 - ensure that consumers have clear and easily understood information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing food correctly.
16. Consumers should play their role by following relevant guidance and instructions for food handling, preparation, and storage and applying appropriate food hygiene measures.

GENERAL PRINCIPLES

- (i) Food safety and suitability should be controlled using a science-based preventive approach, for example a food hygiene system. GHPs should ensure that food is produced and handled in an environment that minimizes the presence of contaminants.
- (ii) Properly applied prerequisite programmes, which include GHPs, should provide the foundation for an effective HACCP system.
- (iii) Each FBO should be aware of the hazards associated with the raw materials and other ingredients, the production or preparation process, and the environment in which the food is produced and/or handled, as appropriate to the food business.
- (iv) Depending on the nature of the food, food process, and the potential for adverse health effects, to control hazards it may be sufficient to apply GHPs, including, as appropriate, some that require more attention than others, as they have a greater impact on food safety. When the application of GHPs alone is not sufficient, a combination of GHPs and additional control measures at CCPs should be applied.
- (v) Control measures that are essential to achieve an acceptable level of food safety, should be scientifically validated¹.
- (vi) The application of control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate to the nature of the food product and the size of the food business.
- (vii) Food hygiene systems should be reviewed to determine if modifications are needed. This should be done periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment, new scientific knowledge) associated with the food business.
- (viii) Appropriate communication about the food and food process should be maintained among all relevant parties to ensure food safety and suitability across the entire food chain.

Management Commitment to Food Safety

17. Fundamental to the successful functioning of any food hygiene system is the establishment and maintenance of a positive food safety culture acknowledging the importance of human behaviour in providing safe and suitable food. The following elements are important in cultivating a positive food safety culture:
- commitment of the management and all personnel to the production and handling of safe food;

¹ *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008)

- leadership to set the right direction and to engage all personnel in food safety practices;
 - awareness of the importance of food hygiene by all personnel in the food business;
 - open and clear communication among all personnel in the food business, including communication of deviations and expectations; and
 - the availability of sufficient resources to ensure the effective functioning of the food hygiene system.
18. Management should ensure the effectiveness of the food hygiene systems in place by:
- ensuring that roles, responsibilities, and authorities are clearly communicated in the food business;
 - maintaining the integrity of the food hygiene system when changes are planned and implemented;
 - verifying that controls are carried out and working and that documentation is up to date;
 - ensuring that the appropriate training and supervision are in place for personnel;
 - ensuring compliance with relevant regulatory requirements; and
 - encouraging continual improvement, where appropriate, taking into account developments in science, technology and best practice.

DEFINITIONS

For the purposes of this document the following definitions apply:

Acceptable level: A level of hazard in a food at or below which the food is considered to be safe according to its intended use.

Allergen cross-contact: the unintentional incorporation of an allergenic food, or ingredient, into another food that is not intended to contain that allergenic food or ingredient.

Cleaning: The removal of soil, food residues, dirt, grease or other objectionable matter.

Competent Authority: The government authority or official body authorized by the government that is responsible for the setting of regulatory food safety requirements and/or for the organization of official controls including enforcement.

Contaminant: Any biological, chemical or physical agent, foreign matter or other substances not intentionally added to food that may compromise food safety or suitability.

Contamination: The introduction or occurrence of a contaminant in the food or food environment.

Control:

- when used as a noun: The state wherein correct procedures are being followed and any established criteria are being met.
- when used a verb: To take all necessary actions to ensure and maintain compliance with established criteria and procedures.

Control measure: Any action or activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

Corrective action: Any action taken when a deviation occurs in order to re-establish control, segregate and determine the disposition of the affected product if any and prevent or minimize reoccurrence of the deviation.

Critical Control Point (CCP): A step at which a control measure or control measures, essential to control a significant hazard, is/are applied in a HACCP system.

Critical limit: A criterion, observable or measurable, relating to a control measure at a CCP which separates acceptability from unacceptability of the food.

Deviation: Failure to meet a critical limit or to follow a GHP procedure.

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

Flow diagram: A systematic representation of the sequence of steps used in the production or manufacture of food.

Food business operator (FBO): The entity responsible for operating a business at any step in the food

chain.

Food Handler: Any person who directly handles packaged or unpackaged food, equipment and utensils used for food, or surfaces that come into contact with food and that is expected, therefore, to comply with food hygiene requirements.

Food hygiene: All conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Food hygiene system: Prerequisite programmes, supplemented with control measures at CCPs, as appropriate, that when taken as a whole, ensures that food is safe and suitable for its intended use.

Food safety: Assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability: Assurance that food is acceptable for human consumption according to its intended use.

Good Hygiene Practices (GHPs): Fundamental measures and conditions applied at any step within the food chain to provide safe and suitable food.

HACCP Plan: Documentation or set of documents, prepared in accordance with the principles of HACCP to ensure control of significant hazards in the food business.

HACCP System: The development of a HACCP plan and the implementation of the procedures in accordance with that plan.

Hazard: A biological, chemical or physical agent in food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards identified in raw materials and other ingredients, the environment, in the process or in the food, and conditions leading to their presence to decide whether or not these are significant hazards.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.

Primary Production: Those steps in the food chain up to and including storage and, where appropriate, transport of outputs of farming. This would include growing crops, raising fish and animals, and the harvesting of plants, animals or animal products from a farm or their natural habitat.

Prerequisite programme: Programmes including Good Hygiene Practices, Good Agricultural Practices and Good Manufacturing Practices, as well as other practices and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of a HACCP system.

Significant hazard: A hazard identified by a hazard analysis, as reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food.

Step: A point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption.

Validation of control measures: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.

CHAPTER ONE

GOOD HYGIENE PRACTICES

SECTION 1: INTRODUCTION AND CONTROL OF FOOD HAZARDS

19. The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling hazards in food products.

20. Knowledge of the food and its production process is essential for the effective implementation of GHPs. This Chapter provides guidance for effective implementation of GHPs, including appropriate location, layout, design, construction and maintenance of premises and facilities, and should be applied in conjunction with

sector and product-specific codes.

21. GHPs manage many sources of food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing, and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display.

22. As previously noted, all FBOs should be aware of and understand hazards associated with their businesses, and the control measures required to manage these hazards, as appropriate. FBOs should consider (using external resources as needed) whether the application of GHPs alone is sufficient to manage some or all of the hazards associated with the operation through control of their sources, e.g.

- Control of water quality – minimizes the presence of many potential hazards (e.g. biological, chemical, physical);
- Control of faecal contamination – minimizes the potential for contamination with many foodborne pathogens such as *Salmonella*, *Campylobacter*, *Yersinia*, pathogenic strains of *E. coli*;
- Control of food handler practices and hygiene – prevents many potential communicable diseases that could be foodborne; and
- Control of food contact surfaces by cleaning – removes bacterial contaminants, including foodborne pathogens, and allergens.

23. After consideration of the conditions and activities in the business, it may be determined that GHPs alone may be sufficient to manage the hazards. However, it may also be determined that it is necessary to place greater attention on some GHPs that are particularly important for food safety (e.g. increased stringency of cleaning of a mincer for producing minced meat for raw or lightly cooked consumption compared to equipment used for producing meat to be cooked prior to consumption; increased monitoring and/or verification of disinfection of food contact surfaces).

24. Hazards that occur or are present at levels such that GHP procedures are not sufficient to provide safe food should be managed by an appropriate combination of control measures that are capable of preventing occurrence of hazards or eliminating or reducing them to an acceptable level. The control measures can be identified in one or more steps throughout the production process. In the case in which significant hazards are identified that need to be controlled after the implementation of GHPs, it will be necessary to develop and implement a HACCP system (see Chapter 2).

SECTION 2: PRIMARY PRODUCTION

OBJECTIVES :

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- an assessment of the suitability of water used where it may pose a hazard, for example, crop irrigation, rinsing activities, etc.
- avoiding the use of areas where the environment poses a threat to the safety of food (e.g. contaminated sites);
- controlling contaminants, pests and diseases of animals and plants, to the extent practicable, to minimize the threat to food safety (e.g. appropriate use of pesticides and veterinary drugs);
- adopting practices and measures to ensure food is produced under appropriately hygienic conditions (e.g. cleaning and maintaining harvest equipment, rinsing, hygienic milking practices).

RATIONALE:

To reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at all stages of the food chain.

25. The types of activities involved in primary production may make eliminating or reducing some hazards difficult. However, by applying prerequisite programmes such as Good Agricultural Practices (GAPs) and/or GHPs, steps can be taken to minimize the occurrence and levels of hazards in the food chain, e.g. at milking for dairy production, steps taken in the hygienic production of eggs, or the controls on irrigation water used for growing salad crops. Not all provisions apply for all primary production situations and consideration will need to be given by the FBO on the appropriateness of the measures to be taken.

2.1 Environmental control

26. Potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of contaminants would lead to an unacceptable level of such contaminants in food, e.g. using polluted areas², locating near facilities emitting toxic or offensive odours which could taint foodstuffs or near sources of contaminated water such as discharge of waste water from industrial production or runoff from agricultural land with high faecal material or chemical residues, unless there is a measure to reduce or prevent the contamination of food.

2.2 Hygienic Production

27. The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize and, if possible, eliminate that probability.

28. Producers should as far as practicable implement measures to:

- control contamination from soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;
- protect food sources from faecal and other contamination (e.g. zoonotic foodborne agents);
- control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product (e.g. observe the withdrawal period of veterinary drugs and pesticides, keeping records where applicable); and
- manage waste and store harmful substances appropriately.

2.3 Handling, Storage and Transport

29. Procedures should be in place to:

- sort food to remove material which should not be used for human consumption;
- dispose of any rejected material in a hygienic manner; and
- protect food from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling (e.g. sorting, grading, washing), storage and transport. Care should be taken to prevent deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

2.4 Cleaning, Maintenance and Personnel Hygiene

30. Appropriate facilities and procedures should be in place to ensure that:

- cleaning and maintenance are carried out effectively and do not compromise food safety (e.g. ensuring equipment used in harvest is not a source of contamination); and
- an appropriate degree of personal hygiene is maintained to ensure personnel are not a source of contamination (e.g. by human faeces).

² Code of Practice Concerning Source Directed Measures to Reduce Contamination of Food with Chemicals (CXC 49-2001)

SECTION 3: ESTABLISHMENT - DESIGN OF FACILITIES AND EQUIPMENT

OBJECTIVES:

Depending on the nature of the operations and the associated risks, premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination is minimized;
- design and layout permit appropriate maintenance, cleaning and disinfection and minimize airborne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic for their intended use;
- where appropriate, suitable facilities are available for temperature, humidity and other controls;
- there is effective protection against pest access and harbourage; and
- there are sufficient and appropriate washroom facilities for personnel.

RATIONALE:

Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities is necessary to enable contaminants to be effectively controlled.

3.1 LOCATION AND STRUCTURE

3.1.1 Location of establishment

31. Food establishments should not be located where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of an establishment, including temporary/mobile establishments, should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, establishments should normally be located away from:

- environmentally polluted areas and industrial activities which are reasonably likely to contaminate food;
- areas subject to flooding;
- areas prone to infestations of pests; and
- areas where wastes, either solid or liquid, cannot be removed effectively.

3.1.2 Design and layout of food establishment

32. The design and layout of food establishments should permit adequate maintenance and cleaning. The layout of premises and the flow of operations, including the movements of personnel and material within the buildings, should be such that cross-contamination is minimized or prevented.

33. Areas having different levels of hygiene control (e.g. the raw material and finished product areas) should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, or separation in time, with suitable cleaning and disinfection between uses.

3.1.3 Internal structures and fittings

34. Structures within food establishments should be soundly built of durable materials, which are easy to maintain, clean and, where appropriate, easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. In particular, the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials that are easy to clean and, where necessary, disinfect;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;

- ceilings and overhead fixtures (e.g. lighting) should be constructed to be shatterproof where appropriate, and finished to minimize the build-up of dirt and condensation and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build-up of dirt and, where necessary, be fitted with removable and cleanable insect-proof screens; and
- doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect.

35. Work surfaces that come into direct contact with food should be in sound condition, durable, and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and to disinfectants under normal operating conditions.

3.1.4 Temporary/mobile food establishments and vending machines

36. Establishments and structures covered here include market stalls, street vending vehicles, vending machines and temporary premises such as tents and marquees.

37. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of pests. Adequate facilities for toileting and washing hands should be provided, where appropriate.

3.2 FACILITIES

3.2.1 Drainage and waste disposal facilities

38. Adequate drainage and waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the likelihood of contaminating food or the water supply is avoided. For plumbing, steps should be taken to prevent backflow, cross-connections, and backup of sewer gases. It is important that drainage does not flow from highly contaminated areas (such as toilets or raw production areas) to areas where finished food is exposed to the environment.

39. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

40. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent intentional or accidental contamination of food.

3.2.2 Cleaning facilities

41. Adequate, suitably designated facilities should be provided for cleaning utensils and equipment. Such facilities should have an adequate supply of hot and/or cold water, where required. A separate cleaning area should be provided for tools and equipment from highly contaminated areas like toilets, drainage and waste disposal areas. Where appropriate, facilities for washing food should be separate from facilities for cleaning utensils and equipment, and separate sinks should be available for hand washing and food washing.

3.2.3 Personnel hygiene facilities and toilets

42. Adequate washing and toilet facilities should be available so that an appropriate degree of personal hygiene can be maintained and to avoid personnel contaminating food. Such facilities should be suitably located and should not be used for other purposes such as storage of food or items that contact food. They should include:

- adequate means of washing and drying hands, including soap (preferably liquid soap), wash basins and, where appropriate, a supply of hot and cold (or suitably temperature controlled) water;
- hand washing basins of an appropriate hygienic design, ideally with taps not operated by hands; where this is not possible, appropriate measures to minimize contamination from the taps should be in place; and
- suitable changing facilities for personnel, if needed.

43. Handwashing basins should not be used for washing food or utensils.

3.2.4 Temperature

44. Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, and, when necessary, controlling ambient temperatures to ensure the safety and suitability of food.

3.2.5 Air quality and ventilation

45. Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- help control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity to ensure the safety and suitability of food (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

46. Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas; the systems should be easy to maintain and clean.

3.2.6 Lighting

47. Adequate natural or artificial lighting should be provided to enable the food business to operate in a hygienic manner. Lighting should be such that it does not adversely impact the ability to detect defects of, or contaminants in, food or the examination of facilities and equipment for cleanliness. The intensity should be adequate to the nature of the operation. Light fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages of lighting elements.

3.2.7 Storage

48. Adequate and, where necessary, separate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided. Storage should allow for segregation of raw and cooked foods or allergenic and non-allergenic food.

49. Food storage facilities should be designed and constructed to:

- facilitate adequate maintenance and cleaning;
- avoid pest access and harbourage;
- enable food to be effectively protected from contamination, including allergen cross-contact, during storage; and
- where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

50. The type of storage facilities required will depend on the nature of the food. Separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

3.3 EQUIPMENT

3.3.1 General

51. Equipment and containers coming into contact with food should be suitable for food contact; designed, constructed and located to ensure that they can be adequately cleaned (other than containers which are single-use only); disinfected (where necessary); and maintained or discarded as necessary to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

3.3.2 Food control and monitoring equipment

52. Equipment used to cook, heat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and to maintain food temperatures effectively.

53. Such equipment should also be designed to allow temperatures to be monitored, where necessary, and controlled. Where appropriate, monitoring equipment should be calibrated to ensure that temperatures of food processes are accurate.

54. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and any other characteristics likely to have an effect on the safety or suitability of food.

SECTION 4: TRAINING AND COMPETENCE

OBJECTIVE:

All those engaged in food operations who come directly or indirectly into contact with food should have sufficient understanding of food hygiene to ensure they have competence appropriate to the operations they are to perform.

RATIONALE:

Training is fundamentally important to any food hygiene system and the competence of personnel.

Adequate hygiene training, and/or instruction and supervision of all personnel involved in food-related activities contribute to ensuring the safety of food and its suitability for consumption.

4.1 Awareness and Responsibilities

55. Food hygiene training is fundamentally important to the food business. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Personnel should have the knowledge and skills necessary to enable them to handle food hygienically. Those who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in proper use to prevent contamination of food.

4.2 Training Programmes

56. Elements to take into account in determining the extent of training required include:

- the nature of hazards associated with the food, e.g. its ability to sustain growth of pathogenic or spoilage microorganisms, the existence of potential physical contaminants or known allergens;
- the manner in which the food is produced, processed, handled and packed, including the likelihood of contamination;
- the extent and nature of processing or further preparation before consumption of the food;
- the conditions under which the food will be stored;
- the expected length of time before consumption of the food; and
- the use and maintenance of instruments and equipment associated with food.

57. Training programmes should also consider the knowledge and skill levels of the personnel being trained. Topics to be considered for training programmes could include the following as appropriate to a person's duties:

- the principles of food hygiene applicable to the food business;
- the measures relevant to the food business that are used to prevent contaminants in food;
- the importance of good personal hygiene, including proper hand washing and wearing, when needed, appropriate clothing, for food safety;
- the good hygiene practices applicable to the food business.
- appropriate actions to take when food hygiene problems are observed.

58. In addition, for retail and food service operations, whether personnel have direct customer interaction is a factor in training, since it may be necessary to convey certain information about products (such as allergens) to customers.

4.3 Instruction and Supervision

59. The type of instruction and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers, supervisors and/or operators/workers should have sufficient knowledge of food hygiene principles and practices to be able to identify deviations and take necessary action as appropriate to their duties.

60. Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and verification to ensure that procedures are being carried out effectively. Personnel tasked to perform any activities used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks on the safety and suitability of the food.

4.4 Refresher Training

61. Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers and personnel associated with the food business, such as maintenance staff, remain aware of all procedures necessary to maintain the safety and suitability of food. Records should be kept of training activities.

SECTION 5: ESTABLISHMENT MAINTENANCE, CLEANING AND DISINFECTION, AND PEST

OBJECTIVES:

To establish effective systems that:

- ensure appropriate establishment maintenance;
- ensure cleanliness and, when necessary, adequate disinfection;
- ensure pest control;
- ensure waste management; and
- monitor effectiveness of cleaning and disinfection, pest control and waste management procedures.

RATIONALE:

To facilitate the continuing effective control of food contaminants, pests, and other agents likely to compromise food safety and suitability.

CONTROL

5.1 Maintenance and Cleaning

5.1.1 General

62. Establishments and equipment should be maintained in an appropriate condition to:

- facilitate all cleaning and disinfection procedures;
- function as intended; and
- prevent contamination of food, such as from pests, metal shards, flaking plaster, debris, chemicals, wood, plastic, glass, paper.

63. Cleaning should remove food residues and dirt which may be a source of contamination, including allergens. The cleaning methods and materials necessary will depend on the nature of the food business, the food type and the surface to be cleaned. Disinfection may be necessary after cleaning, especially for food contact surfaces.

64. Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety and suitability. Cleaning products suitable for food contact surfaces should be used

in food preparation and storage areas.

65. Cleaning and disinfection chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions and contact times, and stored, where necessary, separated from food, in clearly identified containers to avoid contamination of food.

66. Separate cleaning equipment and utensils, suitably designated, should be used for different hygiene zones e.g. food and non-food contact surfaces.

67. Cleaning equipment should be stored in an appropriate place and in such a manner to prevent contamination. Cleaning equipment should be kept clean, maintained and replaced periodically so as not to become a source for cross-contamination of surfaces or food.

5.1.2 Cleaning and disinfection methods and procedures

68. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, and vacuum cleaning (or other methods that avoid the use of water), and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water increases the likelihood of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food, e.g. spray from pressure washing can spread contamination from dirty areas, such as floors and drains, over a wide area and contaminate food contact surfaces or exposed food.

69. Wet cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying an appropriate detergent solution to loosen soil; and
- rinsing with water (hot water where appropriate) to remove loosened material and residues of detergent.

70. Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate that, on a scientific basis, rinsing is not required. Concentrations and application time of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions for optimal effectiveness. If cleaning is not done effectively to remove soil to permit the disinfectant to contact microorganisms or if sub-lethal concentrations of the disinfectant are used, the microorganisms may persist.

71. Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean. Where appropriate, programmes should be drawn up in consultation with relevant experts.

72. Written cleaning and disinfection procedures should be used, where appropriate. They should specify:

- areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected;
- responsibility for particular tasks;
- method and frequency of cleaning and, where appropriate, disinfection; and
- monitoring and verification activities.

5.1.3 Monitoring of Effectiveness

73. Application of cleaning and disinfection procedures should be monitored for effectiveness and periodically verified by means such as visual inspections and audits to ensure the procedures have been applied properly. The type of monitoring will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensure the cleaning and disinfection programme is being implemented as designed and verify its effectiveness.

74. Microorganisms can sometimes become tolerant to disinfecting agents over time. Cleaning and disinfection procedures should follow the manufacturers' instructions. Periodic review with disinfectant

manufacturers/suppliers, where feasible, should be conducted to help ensure the disinfectants used are effective and appropriate. Rotation of the disinfectants could be considered to ensure inactivation of different types of microorganisms (e.g. bacteria and fungi).

75. While effectiveness of cleaning and disinfecting agents and instructions for use are validated by their manufacturers, measures should be taken for sampling and testing the environment and food contact surfaces (e.g. protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning and disinfection procedures, including the correct disinfectant concentration, to achieve the necessary results and to make sure protocols are being followed. Cleaning and disinfection and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

5.2 PEST CONTROL SYSTEMS

5.2.1 General

76. Pests (e.g. birds, rodents, insects etc.) pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. GHPs should be employed to avoid creating an environment conducive to pests. Good building design, layout, maintenance, and location, along with cleaning, inspection of incoming materials and effective monitoring, can minimize the likelihood of infestation and thereby limit the need for pesticides.

5.2.2 Prevention

77. Establishments should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be covered. Roll up doors should close tightly against the floor. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of food processing establishments.

5.2.3 Harboursage and infestation

78. The availability of food and water encourages pest harboursage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and preferably away from walls. Areas both inside and outside food premises should be kept clean and free of waste. Where appropriate, refuse should be stored in covered, pest-proof containers. Any potential harboursage, such as old and unused equipment, should be removed.

79. Landscaping surrounding a food establishment should be designed to minimize attracting and harbouring pests.

5.2.4 Monitoring and detection

80. Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps (e.g. insect light traps, bait stations) should be designed and located so as to prevent potential contamination of raw materials, products or facilities. Even if monitoring and detection are outsourced, FBOs should review monitoring reports and, if necessary, ensure they or their designated pest control operators take corrective action (e.g. eradication of pests, elimination of harboursage sites or invasion routes).

5.2.5 Control of pest infestation

81. Pest infestations should be addressed immediately by a qualified person or company and appropriate corrective action taken. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. The cause of infestation should be identified, and corrective action taken to prevent a problem from reoccurring. Records should be kept of infestation, monitoring and eradication.

5.3 WASTE MANAGEMENT

5.3.1 General

82. Suitable provision should be made for the removal and storage of waste. Waste should, as far as possible, be collected and stored in covered containers and should not be allowed to accumulate and overflow in food handling, food storage, and other working areas or the adjoining environment in a manner that compromises food safety and suitability. Personnel responsible for waste removal (including hazardous waste) should be properly trained so they do not become a source of cross-contamination.

83. Waste storage areas should be easily identifiable, be kept appropriately clean, and be resistant to pest infestation. They should also be located away from processing areas.

SECTION 6: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:

- maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

RATIONALE:

Personnel who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers through food.

84. Food businesses should establish policies and procedures for personal hygiene. FBOs should ensure all personnel are aware of the importance of good personal hygiene and understand and comply with practices that ensure food safety and suitability.

6.1 Health Status

85. Personnel known or suspected to be ill or carrying a disease likely to be transmitted through food should not enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

86. It may be appropriate for personnel to be excluded for a specific time after symptoms resolve or, for some illnesses, to get medical clearance before returning to work.

6.2 Illness and Injuries

87. Some symptoms of illnesses that should be reported to management so that the need for possible exclusion from food handling and/or medical examination can be considered include:

- jaundice;
- diarrhoea;
- vomiting;
- fever;
- sore throat with fever;
- visibly infected skin lesions (boils, cuts, etc.); and
- discharges from the ear, eye or nose.

88. Personnel with cuts and wounds should, where necessary, be assigned to work in areas where they will have no direct contact with food. Where personnel are permitted to continue working, cuts and wounds should be covered by suitable waterproof plasters and, where appropriate, gloves. Appropriate measures should be applied to ensure plasters do not become a source of contamination (e.g. plasters of contrasting colour compared to the food and/or detectable using a metal detector or x-ray detector).

6.3 Personal Cleanliness

89. Personnel should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by personnel through adequate hand washing and, where necessary, the wearing of gloves. If gloves are worn, appropriate measures should be applied to ensure the gloves do not become a source of contamination.

90. Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety. In particular they should wash hands:

- at the start of food handling activities;
- when returning to work after breaks;
- immediately after using the toilet; and
- after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items.

91. In order not to contaminate food, personnel should wash hands with soap and water and rinse and dry them in a manner that does not recontaminate the hands. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

6.4 Personal Behaviour

92. When engaged in food handling activities personnel should refrain from behaviour which could result in contamination of food, for example:

- smoking or vaping;
- spitting;
- chewing, eating, or drinking;
- touching the mouth, nose or other places of possible contamination; and
- sneezing or coughing over unprotected food.

93. Personal effects such as jewellery, watches, pins or other items such as false nails/eye lashes should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

6.5 Visitors and other persons from outside the establishment

94. Visitors to food businesses, including maintenance workers, in particular to food manufacturing, processing or handling areas, should, where appropriate, be instructed and supervised, wear protective clothing and adhere to the other personal hygiene provisions for personnel. Visitors should be guided through a hygiene policy of the business prior to visits and encouraged to report any type of illness/injury that may pose cross-contamination issues.

SECTION 7: CONTROL OF OPERATION

OBJECTIVES:

To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, production, processing, distribution, and consumer use to be met as appropriate to the food business;
- designing, implementing, monitoring and reviewing effective control systems as appropriate to the food business.

RATIONALE:

If operations are not controlled appropriately, food may become unsafe or unsuitable for consumption.

95. Control of operation is achieved by having an appropriate food hygiene system in place. The following

section describes practices that can assist in the identification and application of appropriate controls, as well as activities that should take place to ensure the operation is under control.

7.1 Description of products and processes

96. After consideration of the conditions and activities of the food business it may be necessary to pay greater attention to some GHPs that are particularly important for food safety. In this case, the following provisions could be considered.

7.1.1 Product description

97. An FBO that is producing, storing or otherwise handling food should have a description of the food. Products may be described individually or in groups in a manner that does not compromise the awareness of hazards or other factors such as suitability of the products for the purpose intended. Any grouping of food products should be based on them having similar inputs and ingredients, product characteristics (such as pH, water activity (a_w)), process steps and/or intended purpose.

98. The description could include, as appropriate:

- the intended use of the food, e.g. whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example raw seafood to be cooked;
- products intended for specific vulnerable consumer groups e.g. infant formula or food for special medical purposes;
- any relevant specifications e.g. ingredient composition, a_w , pH, type of preservation method used (if any), or important characteristics associated with the food, such as any allergens present;
- any relevant limits established for the food by the competent authority or, in the absence thereof, set by the FBO;
- instructions provided for further use, for example keep frozen until cooking, cook to a specified temperature for a specified length of time, product shelf-life (use-by date);
- storage of product (e.g. refrigerated/frozen/shelf stable) and transport conditions required; and
- food packaging material used.

7.1.2 Process description

99. The FBO should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram, which shows the sequence and interaction of all processing steps in the operation, including where raw materials, ingredients and intermediate products enter the flow and where intermediate products, by-products and waste are released or removed. The flow diagram could be used for a number of similar food products that are produced using similar production or processing steps, to ensure all steps are captured. The steps should be confirmed as accurate by an on-site review of the operation or process. For example, for restaurants the flow diagram could be based on the general activities from the receipt of ingredients/raw material, storage (refrigerated, frozen, room temperature), preparation before use (washing, defrosting), and cooking or preparation of food.

7.1.3 Consideration of the effectiveness of GHPs

100. Having considered the product and process descriptions, an FBO should determine (using information relevant to hazards and controls from various sources as appropriate) whether the GHPs and other programmes they have in place are sufficient to address food safety and suitability or if some GHPs need greater attention. For example, a cooked meat slicer may require specific and more frequent cleaning to prevent the build-up of *Listeria* spp. on its meat contact surfaces, or a conveyor belt used in direct contact with the food, such as in sandwich production, may require an increased frequency of cleaning or a specific cleaning programme. When such increased attention on GHPs is insufficient to ensure food safety, it will be necessary to implement a HACCP system (Chapter 2).

7.1.4 Monitoring and corrective action

101. The FBO should monitor the hygienic procedures and practices as relevant to the business and as applicable to the hazard being controlled. Procedures could include defining methods of monitoring (including

defining responsible personnel, frequency and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control.

102. When monitoring results indicate a deviation, the FBO should undertake corrective action. Corrective action should consist of the following actions, as appropriate:

- bringing the process back into control by, for example, altering temperature or timing, or concentration of disinfectant;
- isolating any affected product and evaluating its safety and/or suitability;
- determining proper disposition of affected product that is not acceptable to market;
- identifying the cause that resulted in the deviation; and
- taking steps to prevent reoccurrence.

103. Records of corrective actions should be retained.

7.1.5 Verification

104. The FBO should undertake verification activities as relevant to the business, to check that GHP procedures have been implemented effectively, monitoring is occurring, where planned, and that appropriate corrective actions are taken when requirements are not met. Examples of verification activities could include the following, as appropriate:

- review of GHP procedures, monitoring, corrective actions and records;
- review when any changes occur to the product, process and other operations associated with the business; and
- assessment of the efficacy of cleaning.

105. Records of GHP verification activities should be kept, where appropriate.

7.2 KEY ASPECTS OF GHPS

106. Some key aspects of GHPs such as those described in Sections 7.2.1. and 7.2.2, could be considered as control measures applied at CCPs in the HACCP system.

7.2.1 Time and temperature control

107. Inadequate time and temperature control, e.g. during cooking, cooling, processing and storage, are among the most common failures of operational control. These allow survival or growth of microorganisms that may cause foodborne illness or food spoilage. Systems should be in place to ensure that temperature is controlled effectively where it impacts the safety and suitability of food.

108. Time and temperature control systems should take into account:

- the nature of the food, e.g. its a_w , pH, and likely initial level and types of microorganisms, such as pathogenic and spoilage microflora;
- the impact on the microorganisms, e.g. time in growth/dangerous temperature zone;
- the intended shelf-life of the product;
- the method of packaging and processing; and
- how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

109. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be validated, and as appropriate, monitored and recorded. Temperature monitoring and recording devices should be checked for accuracy and calibrated at regular intervals or as needed.

7.2.2 Specific process steps

110. There are many individual processing steps for specific foods which contribute to the production of

safe and suitable food products. These vary depending on the product and can include key steps such as cooking, chilling, freezing, drying and packaging.

111. The composition of a food can be important in preventing microbial growth and toxin production, e.g. in its formulation by adding preservatives, including acids, salts, food additives or other compounds. When formulation is used to control foodborne pathogens (e.g. adjusting the pH or a_w to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly and that the controlling parameters are monitored.

7.2.3 Microbiological³, physical, chemical and allergen specifications

112. Where microbiological, physical, chemical and allergen specifications are used for food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, sampling parameters, analytical methods, acceptable limits and monitoring procedures. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized.

7.2.4 Microbiological contamination

113. Systems should be in place to prevent or minimize contamination of foods by microorganisms. Microbiological contamination occurs through a number of mechanisms, including the transfer of microorganisms from one food to another, e.g.:

- by direct contact or indirectly by food handlers;
- by contact with surfaces;
- from cleaning equipment;
- by splashing; or
- by airborne particles.

114. Raw, unprocessed food, where not considered ready-to-eat, which could be a source of contamination, should be separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and, where appropriate, effective disinfection.

115. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a potentially high microbiological load such as meat, poultry, and fish have been handled or processed.

116. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. For example, where the likelihood of product contamination is high, access to processing areas should be via a properly designed changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from that worn in other parts of the facility), including head and beard covering, footwear, and to wash their hands and where necessary sanitize them.

7.2.5 Physical contamination

117. Systems should be in place throughout the food chain to prevent contamination of foods by extraneous materials, such as personnel belongings, especially any hard or sharp object(s), e.g. jewellery, glass, metal shards, bone(s), plastic, wood fragments, that could cause injury or present a choking hazard. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection of equipment, should be undertaken. Detection or screening devices which are appropriately calibrated should be used where necessary (e.g. metal detectors, x-ray detectors). Procedures should be in place for personnel to follow in the case of breakages (e.g. breakage of glass or plastic containers).

7.2.6 Chemical contamination

118. Systems should be in place to prevent or minimize contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, chemical residues from pesticides and veterinary drugs such

³ Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21- 1997).

as antibiotics. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, safely stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives and food processing aids that may be harmful if used improperly should be controlled so they are only used as intended.

7.2.7 Allergen Management⁴

119. Systems should be in place to take into account the allergenic nature of some foods, as appropriate to the food business. Presence of allergens, e.g. tree nuts, milk, eggs, crustacea, fish, peanuts, soybeans and wheat and other cereals containing gluten and their derivatives (not an inclusive list; allergens of concern differ among countries and populations), should be identified in raw materials, other ingredients and products. A system of allergen management should be in place at receipt, during processing and storage to address the known allergens. This management system should include controls put in place to prevent the presence of allergens in foods where they are not labelled. Controls to prevent cross-contact from foods containing allergens to other foods should be implemented, e.g. separation either physically or by time (with effective cleaning between foods with different allergen profiles). Food should be protected from unintended allergen cross-contact by cleaning and line change-over practice and/or product sequencing. Where cross-contact cannot be prevented despite well-implemented controls, consumers should be informed. Where necessary food handlers should receive specific training on allergen awareness and associated food manufacturing/processing practices and preventive measures to reduce the risk to allergic consumers.

7.2.8 Incoming Materials

120. Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to specifications, and their compliance with food safety and suitability specifications should be verified where necessary. Supplier quality assurance activities, such as audits, may be appropriate for some ingredients. Raw materials or other ingredients should, where appropriate, be inspected (e.g. visual examination for packages damaged during transportation, use-by-date and declared allergens, or temperature measurement for refrigerated and frozen foods) for appropriate action before processing. Where appropriate, laboratory tests could be conducted to check food safety and suitability of raw materials or ingredients. These tests may be conducted by a supplier that provides a Certificate of Analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or processing where appropriate. Stocks of raw materials and other ingredients should be subject to effective stock rotation. Documentation of key information for incoming materials (e.g. supplier details, date of receipt, quantity etc.) should be maintained.

7.2.9 Packaging

121. Packaging design and materials should be safe and suitable for food use, provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used should not contain toxic contaminants and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Any reusable packaging should be suitably durable, easy to clean and, where necessary, to disinfect.

7.3 Water

122. Water, as well as ice and steam made from water, should be fit for its intended purpose based on a risk-based approach.⁵ They should not cause contamination of food. Water and ice should be stored and handled in a manner that does not result in their becoming contaminated, and the generation of steam that will contact food should not result in its contamination. Water that is not fit for use in contact with food (e.g. some water used for fire control and for steam that will not directly contact food) should have a separate system that does not connect with or allow reflux into the system for water that will contact food. Water recirculated for reuse and water recovered from e.g. food processing operations, by evaporation and/or filtration should be treated where necessary to ensure that the water does not compromise the safety and suitability of food.

⁴ See the *Code of Practice on Allergen Management for Food Business Operators*.

⁵ Microbiological Risk Assessment Series 33: Safety and Quality of Water Used in Food Production and Processing

7.4 Documentation and Records

123. Appropriate records for the food business operation should be retained for a period that exceeds the shelf-life of the product or as determined by the competent authority.

7.5 Recall Procedures - removal from the market of unsafe food

124. FBOs should ensure effective procedures are in place to respond to failures in the food hygiene system. Deviations should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective identification, and removal from the market by the involved FBO(s) and/or return to the FBO by the consumers of any food that may pose a risk to public health. Where a product has been recalled because of the likely presence of hazards that may represent an immediate health risk, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. Reporting to the relevant competent authority should be required and public warnings considered where product may have reached consumers and when return of product to the FBO or removal from the market is appropriate. Recall procedures should be documented, maintained, and modified where necessary based on the findings of periodic field trials.

125. Provision should be made for removed or returned products to be held under secure conditions until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to reduce the hazard to acceptable levels, where permitted by the competent authority. The cause and extent of a recall and the corrective actions taken should be retained by the FBO as documented information.

SECTION 8: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Appropriate information about food should ensure that:

- adequate and accessible information is available to the next FBO in the food chain or the consumer to enable them to handle, store, process, prepare and display the product safely and correctly;
- consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and removed/returned if necessary.

Consumers should be given enough information on food hygiene to enable them to:

- be aware of the importance of reading and understanding the label;
- make informed choices appropriate to the individual, including about allergens; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using food correctly.

RATIONALE:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been implemented earlier in the food chain. Insufficient product information about the allergens in food can also result in illness or potentially death for allergic consumers.

8.1 Lot Identification and Traceability

126. Lot identification or other identification strategies are essential in product recall and also help effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) applies.

127. A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System* (CXG 60-2006), especially to enable the recall of the products, where necessary.

8.2 Product Information

128. All food products should be accompanied by or bear adequate information to enable the next FBO in the food chain or the consumer to handle, prepare, display, store, and/or use the product safely and correctly.

8.3 Product Labelling

129. Prepackaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1989) applies.

8.4 Consumer Education

130. Consumer education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product label information and following any instructions accompanying products, and to make informed choices. In particular, consumers should be informed of the relationship between time/temperature control, cross contamination and foodborne illness, and of the presence of allergens. Consumers should also be informed of the *WHO 5 Keys to Safer Food* and educated to apply appropriate food hygiene measures (e.g. proper hand washing, adequate storage and cooking and avoiding cross contamination) to ensure that their food is safe and suitable for consumption.

SECTION 9: TRANSPORTATION

OBJECTIVES:

During transportation, measures should be taken where necessary to:

- protect food from potential sources of contamination, including allergen cross- contact;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

RATIONALE:

Food may become contaminated or may not reach its destination in a suitable condition for consumption, unless effective hygiene practices are taken prior to and during transport, even where adequate hygiene practices have been taken earlier in the food chain.

9.1 General

131. Food should be adequately protected during transport⁶. The type of conveyances or containers required depends on the nature of the food and the most appropriate conditions under which it should be transported.

9.2 Requirements

132. Where necessary, conveyances and bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected and dried;
- permit effective separation of different foods or foods from non-food items that could cause contamination where necessary during transport;
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsafe or unsuitable for consumption; and

⁶ *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001)

- allow any necessary temperature, humidity and other environmental conditions to be checked.

9.3 Use and Maintenance

133. Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Containers and conveyances for bulk food transport should be designated and marked for food use and used only for that purpose, unless controls are taken to ensure that the safety and suitability of the food are not compromised.

134. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection, and drying should take place between loads.

CHAPTER TWO

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

INTRODUCTION

135. The first section of this Chapter sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second section provides general guidance for the application of the HACCP system and the third section describes its application in 12 successive steps (Diagram 1), while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food business operation. The HACCP system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on control measures for significant hazards along the food chain, rather than relying mainly on end-product testing. Development of a HACCP system may identify the need for changes in processing parameters, in processing steps, in manufacturing technology, in end product characteristics, in method of distribution, in the intended use or in the GHPs applied. Any HACCP system should be capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

136. HACCP principles can be considered throughout the food chain from primary production to final consumption, and their implementation should be guided by scientific evidence of risks to human health. Although it is not always feasible to apply HACCP at primary production, some of the principles can be applied and may be incorporated into good practices programmes (e.g. Good Agricultural Practices (GAPs), etc.). It is recognised that implementation of HACCP may be challenging for some businesses. However, HACCP principles can be applied flexibly in individual operations, and businesses may use external resources (e.g. consultants) or adapt a generic HACCP plan provided by the competent authority, academia or other competent bodies (e.g. trade or industry associations) to the specific site circumstances. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid review by competent authorities and promote international trade by increasing confidence in food safety.

137. The successful application of HACCP requires the commitment and involvement of management and personnel and the knowledge and/or training in its application for the particular type of food business. A multi-disciplinary approach is strongly recommended; this multi-disciplinary approach should be appropriate to the food business operation and may include, for example, expertise in primary production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application.

SECTION 1: PRINCIPLES OF THE HACCP SYSTEM

The HACCP system is designed, validated and implemented in accordance with the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis and identify control measures.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish validated critical limits.

PRINCIPLE 4

Establish a system to monitor control of CCPs.

PRINCIPLE 5

Establish the corrective actions to be taken when monitoring indicates a deviation from a critical limit at a CCP has occurred.

PRINCIPLE 6

Validate the HACCP plan and then establish procedures for verification to confirm that the HACCP system is working as intended.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

SECTION 2: GENERAL GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

2.1 Introduction

138. Prior to application of a HACCP system by any FBO in the food chain, that FBO should have in place prerequisite programmes, including GHPs established in accordance with Chapter One of this document, the appropriate product and sector-specific Codex Codes of Practice, and in accordance with relevant food safety requirements set by competent authorities. Prerequisite programmes should be well-established, fully operational and verified, where possible, in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of prerequisite programmes including GHPs.

139. For all types of food businesses, management awareness and commitment to food safety are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and personnel having the appropriate HACCP training and competency. Therefore, ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

140. A HACCP system identifies and enhances control of significant hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). By specifying critical limits for control measures at CCPs and corrective actions when limits are not met, and by producing records that are reviewed before product release, HACCP provides consistent and verifiable control beyond that achieved by GHPs.

141. A HACCP approach should be customized to each food business. Hazards, control measures at CCPs and their critical limits, CCP monitoring, CCP corrective actions and verification activities can be distinctive for a particular situation and those identified in a Codex Code of Practice or other appropriate guidelines might not be the only ones identified for a specific application or might be of a different nature.

142. The HACCP system should be reviewed periodically and whenever there is a significant change that could impact the potential hazards and/or the control measures (e.g. new process, new ingredient, new product, new equipment) associated with the food business. Periodic review should also be conducted when the application of the HACCP principles has resulted in a determination that no CCPs are needed, in order to assess whether the need for CCPs has changed.

2.2 Flexibility for small and/or less developed food businesses⁷

143. The application of the HACCP principles to develop an effective HACCP system should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual food businesses. This is particularly relevant in small and/or less developed food businesses. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses are available and encouraged. Some approaches may provide ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this chapter. While it is recognized that flexibility appropriate to the business is important when applying HACCP, all seven principles should be considered in developing the HACCP system. This flexibility should take into account the nature of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food. Applying such flexibility e.g. recording only monitoring results when there is a deviation instead of every monitoring result to reduce unnecessary burden of record keeping for certain types of FBOs, is not intended to impact negatively on the efficacy of the HACCP system and should not endanger food safety.

⁷ *FAO/WHO Guidance to governments on the application of HACCP in small and/or less-developed food businesses.*

144. Small and/or less developed food businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP system. In such situations, expert advice should be obtained from other sources, which may include trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. A comprehensive explanation of the basis for the HACCP plan should be provided to the FBO. The FBO is ultimately responsible for elaboration and implementation of the HACCP system and the production of safe food.

145. The efficacy of any HACCP system will nevertheless rely on management and personnel having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of personnel, including managers, as appropriate to the food business.

SECTION 3: APPLICATION

3.1 Assemble HACCP Team and Identify Scope (Step 1)

146. The FBO should ensure that the appropriate knowledge and expertise are available for the development of an effective HACCP system. This may be achieved by assembling a multidisciplinary team responsible for different activities within the operation, e.g. production, maintenance, quality control, cleaning and disinfection. The HACCP team is responsible for developing the HACCP plan.

147. Where relevant expertise is not available in house, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement a HACCP System in house. A generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

148. The HACCP team should identify the scope of the HACCP system and applicable prerequisite programmes. The scope should describe which food products and processes are covered.

3.2 Describe product (Step 2)

149. A full description of the product should be developed, including relevant safety information such as composition (i.e. ingredients), physical/chemical characteristics (e.g. a_w , pH, preservatives, allergens), processing methods/technologies (heat-treatment, freezing, drying, brining, smoking, etc.), packaging, durability/shelf life, storage conditions and method of distribution. Within businesses with multiple products, it may be effective to group products with similar characteristics and processing steps for the purpose of development of the HACCP plan. Any limits relevant to the food product already established for hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues, and times and temperatures for heat treatments prescribed by competent authorities.

3.3 Identify intended use and users (Step 3)

150. Describe the use intended by the FBO and the expected uses of the product by the next FBO in the food chain or the consumer; the description may be influenced by external information, e.g. from the competent authority or other sources on ways in which consumers are known to use the product other than those intended by the FBO. In specific cases (e.g. hospitals), vulnerable groups of the population may have to be considered. Where foods are being produced specifically for a vulnerable population, it may be necessary to enhance process controls, monitor control measures more frequently, verify controls are effective by testing products, or conduct other activities to provide a high level of assurance that the food is safe for the vulnerable population.

3.4 Construct flow diagram (Step 4)

151. A flow diagram that covers all steps in the production of a specific product, including any applicable rework, should be constructed. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. The flow diagram should indicate all inputs, including those of

ingredients and food contact materials, water and air if relevant. Complex manufacturing operations can be broken down into smaller, more manageable modules and multiple flow diagrams that link together can be developed. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of hazards. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not be limited to the following:

- the sequence and interaction of the steps in the operation;
- where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;
- any outsourced processes;
- where applicable reworking and recycling take place;
- where end products, intermediate products, waste and by-products are released or removed.

3.5 On-site confirmation of flow diagram (Step 5)

152. Steps should be taken to confirm the processing activities against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

3.6 List all potential hazards that are likely to occur and associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6/ Principle 1)

153. Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which of them are significant for the specific food business operation. An example of a hazard analysis worksheet is provided in Diagram 2. The HACCP team should list all potential hazards. The HACCP team should then identify where these hazards are reasonably likely to occur at each step (including all inputs into that step) according to the scope of the food business operation. Hazards should be specific, e.g. metal fragments, and the source or reason for presence should be described, e.g. metal from broken blades after chopping. The hazard analysis can be simplified by breaking down complex manufacturing operations and analysing steps in the multiple flow diagrams described in step 4.

154. The HACCP team should next evaluate the hazards to identify which of these hazards are such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that have to be addressed in the HACCP plan).

155. In conducting the hazard analysis to determine whether there are significant hazards, wherever possible the following should be considered:

- hazards associated with producing or processing the type of food, including its ingredients and process steps (e.g. from surveys or sampling and testing of hazards in the food chain, from recalls, from information in the scientific literature or from epidemiological data);
- the likelihood of occurrence of hazards, taking into consideration prerequisite programs, in the absence of additional control;
- the likelihood and severity of adverse health effects associated with the hazards in the food in the absence of control⁸;
- identified acceptable levels of the hazards in the food e.g. based on regulation, intended use, and scientific information;
- the nature of the facility and the equipment used in making the food product;
- survival or multiplication of pathogenic microorganisms;
- production or persistence in foods of toxins (e.g. mycotoxins), chemicals (e.g. pesticides, drug residues, allergens) or physical agents (e.g. glass, metal);

⁸ FBOs may take advantage of risk assessments and risk management matrices established by a competent authority or by international expert groups such as JEMRA.

- the intended use and/or probability of product mishandling by potential consumers that could render the food unsafe; and,
- conditions leading to the above.

156. The hazard analysis should consider not only the intended use, but also any known unintended use (e.g. a soup mix intended to be mixed with water and cooked but known to commonly be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan. (See Diagram 2 for an example of a hazard analysis worksheet.)

157. In some cases, it may be acceptable for a simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (biological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the specific hazards of concern. There can be drawbacks to such an approach, as the controls can differ for hazards within a group, e.g., controls for pathogenic spore-formers versus vegetative cells of microbial pathogens. Generic HACCP-based tools and guidance documents provided by external sources, for example, by industry or competent authorities, are designed to assist with this step and mitigate concerns about different controls needed for hazards within a group.

158. Hazards which are such that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control and reasonably likely to cause illness or injury if present) should be identified and controlled by measures designed to prevent or eliminate these hazards or reduce them to an acceptable level. In some cases, this may be achieved with the application of good hygiene practices, some of which may target a specific hazard (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes* or to prevent food allergens being transferred from one food to another food that does not contain that allergen). In other instances, control measures will need to be applied within the process, e.g. at critical control points.

159. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment. More than one hazard may be controlled by a specified control measure. For example, a heat treatment can control both *Salmonella* and *E. coli* O157:H7 when they are present as hazards in the food.

3.7 Determine the Critical Control Points (Step 7/ Principle 2)

160. The FBO should consider which among the available control measures listed during step 6, Principle 1 should be applied at a CCP. Critical Control points are to be determined only for hazards identified as significant as of the result of a hazard analysis. CCPs are established at steps where control is essential and where a deviation could result in the production of a potentially unsafe food. The control measures at CCPs should result in an acceptable level of the hazard being controlled. There may be more than one CCP in a process at which control is applied to address the same hazard (e.g. the cook step may be the CCP for killing the vegetative cells of a pathogenic spore-former, but the cooling step may be a CCP to prevent germination and growth of the spores). Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be helped by using a decision tree. A decision tree should be flexible, given whether it is for use in production, slaughter, processing, storage, distribution or other processes. Other approaches such as expert consultation may be used.

161. To identify a CCP, whether using a decision tree or other approach, the following should be considered:

- Assess whether the control measure can be used at the process step being analysed:
 - If the control measure cannot be used at this step, then this step should not be considered as a CCP for the significant hazard.
 - If the control measure can be used at the step being analysed, but can also be used later in the process, or there is another control measure for the hazard at another step, the step being analysed should not be considered as a CCP.
- Determine whether a control measure at a step is used in combination with a control measure at another step to control the same hazard; if so, both steps should be considered as CCPs.

162. The CCPs identified could be summarized in tabular format e.g. the HACCP worksheet presented in diagram 3, as well as highlighted at the appropriate step on the flow diagram.

163. If no control measures exist at any step for an identified significant hazard, then the product or process should be modified.

Establish validated critical limits for each CCP (Step 8/ Principle 3)

164. Critical limits establish whether a CCP is in control, and in doing so they can be used to separate acceptable products from unacceptable ones. These critical limits should be measurable or observable. In some cases, more than one parameter could have a critical limit designated at a particular step (e.g. heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum and/or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, a_w , available chlorine, contact time, conveyor belt speed, viscosity, conductance, flow rate, or, where appropriate, parameters that can be observed, such as a pump setting. A deviation from the critical limit indicates that it is likely that unsafe food has been produced.

165. Critical limits for control measures at each CCP should be specified and scientifically validated to obtain evidence that they are capable of controlling hazards to an acceptable level if properly implemented⁹. Validation of critical limits may include conducting studies (e.g. microbiological inactivation studies). FBOs may not always need to conduct or commission studies themselves to validate critical limits. Critical limits could be based on existing literature, regulations or guidance from competent authorities, or studies carried out by a third party e.g. studies conducted by an equipment manufacturer to determine the appropriate time, temperature and bed depth for dry roasting tree nuts. Validation of control measures is further described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008).

3.9 Establish a Monitoring System for Each CCP (Step 9/ Principle 4)

166. Monitoring of CCPs is the scheduled measurement or observation at a CCP relative to its critical limits. The monitoring procedures should be able to detect a deviation at the CCP. Further, the monitoring method and frequency should be capable of timely detection of any failure to remain within critical limits, to allow timely isolation and evaluation of the product. Where possible, process adjustments should be made when monitoring results indicate a trend towards a deviation at a CCP. The adjustments should be taken before a deviation occurs.

167. Monitoring procedures for CCPs should be capable of timely detection of a deviation from the critical limit to allow isolation of the affected products. The method and frequency of monitoring should take into account the nature of the deviation (e.g., a drop in temperature or a broken sieve, rapid drop in temperature during pasteurization, or a gradual increase in temperature in cold storage). Where possible, monitoring of CCPs should be continuous. Monitoring of measurable critical limits such as processing time and temperature can often be monitored continuously. Other measurable critical limits such as moisture level and preservative concentration cannot be monitored continuously. Critical limits that are observable, such as a pump setting or applying the correct label with appropriate allergen information are rarely monitored continuously. If monitoring is not continuous, then the frequency of monitoring should be sufficient to ensure to the extent possible the critical limit has been met and limit the amount of product impacted by a deviation. Physical and chemical measurements are usually preferred to microbiological testing because physical and chemical tests can be done rapidly and can often indicate the control of microbial hazards associated with the product and/or the process.

168. The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

169. All records and documents associated with monitoring CCPs should be signed or initialled by the person performing the monitoring and should also report the results and timing of the performed activity.

3.10 ESTABLISH CORRECTIVE ACTIONS (STEP 10/ PRINCIPLE 5)

170. Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively respond to deviations when they occur. When critical limits at CCPs are monitored continuously

⁹ *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

and a deviation occurs, any product being produced at the time the deviation occurs is potentially unsafe. When a deviation in meeting a critical limit occurs and monitoring was not continuous, then the FBO should determine what product may have been impacted by the deviation.

171. The corrective actions taken when a deviation occurs should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers. Actions taken should include segregating the affected product and analysing its safety to ensure proper disposition.

172. External experts may be needed to conduct evaluations regarding the safe use of products when a deviation occurs. It may be determined that the product could be reprocessed (e.g. pasteurized) or the product could be diverted to another use. In other situations, the product may need to be destroyed (e.g. contamination with *Staphylococcus enterotoxin*). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. A root cause analysis could identify a reason for the deviation that limits or expands the amount of product impacted by a deviation.

173. Details of the corrective actions, including the cause of the deviation and product disposition procedures, should be documented in the HACCP records. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

3.11. Validation of the HACCP Plan and Verification Procedures (Step 11/ Principle 6)

3.11.1 Validation of the HACCP Plan

174. Before the HACCP plan can be implemented, its validation is needed; this consists of making sure that the following elements together are capable of ensuring control of the significant hazards relevant to the food business: identifying the hazards, critical control points, critical limits, control measures, frequency and type of monitoring of CCPs, corrective actions, frequency and type of verification and the type of information to be recorded.

175. Validation of control measures and their critical limits is performed during the development of the HACCP plan. Validation could include a review of scientific literature, using mathematical models, conducting validation studies, and/or using guidance developed by authoritative sources¹⁰.

176. Where HACCP guidance developed by external experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration.

177. During the initial implementation of the HACCP system and after verification procedures have been established, evidence should be obtained in operation to demonstrate that control can be achieved consistently under production conditions.

178. Any changes having a potential impact on food safety should require a review of the HACCP system, and when necessary a revalidation of the HACCP plan.

3.11.2. Verification Procedures

179. After the HACCP system has been implemented, procedures should be established to confirm that the HACCP system is working effectively. These include procedures to verify that the HACCP plan is being followed and controlling hazards on an ongoing basis, as well as procedures that show the control measures are effectively controlling the hazards as intended. Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

180. Verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing (internal and external), calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly and as planned. Examples of verification activities include:

- reviewing monitoring records to confirm that CCPs are kept under control;

¹⁰ *Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).*

- reviewing corrective action records, including specific deviations, product disposition and any analysis to determine the root cause of the deviation;
- calibrating or checking the accuracy of instruments used for monitoring and/or verification;
- observing that control measures are being conducted in accordance with the HACCP plan;
- sampling and testing, e.g. for microorganisms¹¹ (pathogens or their indicators), chemical hazards such as mycotoxins, or physical hazards such as metal fragments, to verify product safety;
- sampling and testing the environment for microbial contaminants and their indicators, such as *Listeria*; and
- reviewing the HACCP system, including the hazard analysis and the HACCP plan (e.g. internal and/or third-party audits).

181. Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

182. The frequency of verification activities should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

183. Verification should include a comprehensive review (e.g. reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur, to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate significant hazards have been identified, that control measures and critical limits are adequate to control the hazards, that monitoring, and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts. The review should include confirmation that various verification activities have been executed as intended.

3.12 Establish Documentation and Record Keeping (Step 12/ Principle 7)

184. Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilized as part of the documentation, provided that those materials reflect the specific food operations of the business.

185. Examples of documentation include:

- HACCP team composition;
- hazard analysis and the scientific support for the hazards included or excluded from the plan;
- CCP determination;
- critical limit determination and the scientific support for the limits set;
- validation of control measures; and
- modifications made to the HACCP plan.

186. Examples of records include:

- CCP monitoring activities;
- deviations and associated corrective actions; and
- verification procedures performed.

187. A simple record-keeping system can be effective and easily communicated to personnel. It may be

¹¹ *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Food* (CXG 21-1997).

integrated into existing operations and may use existing paperwork, such as delivery invoices, and checklists to record, for example, product temperatures. Where appropriate, records can also be maintained electronically.

3.13 Training

188. Training of personnel in food businesses, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel in charge of each Critical Control Point. Training programmes should be designed to address the concepts at a level appropriate for the knowledge and skill level of the personnel being trained. Training programmes should be reviewed periodically and updated where necessary. Re-training may be needed as part of corrective actions for some deviations.

189. Cooperation between food business operations, trade groups, consumer organisations, and competent authorities is vitally important. Opportunities should be provided for the joint training of food business operators and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

Annex 1 - Comparison of control measures with examples.

	Control measures applied as GHPs	Control measures applied at CCPs
Scope	<p>General conditions and activities for maintaining hygiene, including creating the environment (inside and outside the food business) so as to ensure production of safe and suitable food.</p> <p>Generally, not specific to any hazard but results in reduction of likelihood of hazards occurring. Occasionally a GHP activity may target a specific hazard and this may be a GHP that requires greater attention (e.g. cleaning and disinfection of food contact surfaces for control of <i>Listeria monocytogenes</i> in a ready-to-eat food processing environment).</p>	<p>Specific to production process steps and a product or group of products and necessary to prevent eliminate or reduce to acceptable level a hazard determined as significant by the hazard analysis.</p>
When identified?	<p>After consideration of the conditions and activities necessary to support the production of safe and suitable food.</p>	<p>After a hazard analysis has been completed, for each hazard identified as significant, control measures are established at steps (CCPs) where a deviation would result in the production of a potentially unsafe food.</p>
Validation of the control measures	<p>Where necessary, and generally not carried out by FBOs themselves (<i>Guidelines for the Validation of Food Safety Control Measures CXG 69-2008</i>). Validation data provided by competent authorities, published scientific literature, information provided by manufacturers of equipment/ food processing technology etc. is adequate e.g. cleaning compounds/products/equipment should be validated by the manufacturer and it is generally sufficient for the FBO to use cleaning compounds/products/equipment according to manufacturers' instructions. The FBO should be able to demonstrate it can follow manufacturers' instructions.</p>	<p>Validation should be carried out (<i>Guidelines for the Validation of Food Safety Control Measures CXG 69-2008</i>).</p>

<p>Criteria</p>	<p>GHPs may be observable (e.g. visual checks, appearance) or measurable (e.g. ATP tests of equipment cleaning, concentration of disinfectant), and deviations may require an evaluation of the impact on safety of the product (e.g. whether the cleaning of complex equipment such as meat slicers is adequate).</p>	<p>Critical limits at CCPs which separate acceptability from unacceptability of the food:</p> <ul style="list-style-type: none"> • measurable (e.g. time, temperature, pH, a_w), or • observable (e.g. visual checks of conveyor belt speed or pump settings, ice covering product).
<p>Monitoring</p>	<p>When appropriate and necessary, to ensure procedures and practices are applied properly.</p> <p>Frequency dependent on the impact on the product's safety and suitability.</p>	<p>Necessary to ensure critical limit is met:</p> <ul style="list-style-type: none"> • Continuously during production or • if not continuous, at appropriate frequency that ensures to the extent possible the critical limit has been met.
<p>Corrective actions when deviation has occurred</p>	<ul style="list-style-type: none"> • For procedures and practices: Necessary • For products: Usually not necessary. Corrective action should be considered on a case- by-case basis, as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting (where needed) or post maintenance equipment checks indicating missing machinery parts, may result in action on product. 	<ul style="list-style-type: none"> • For products: Necessary pre-determined actions. • For procedures and practices: Necessary corrective actions to restore control and prevent reoccurrence. • Specific written corrective actions should be developed for each CCP in the HACCP plan in order to effectively respond to deviations when they occur. • The corrective actions should ensure that the CCP has been brought under control and food that is potentially unsafe is handled appropriately and does not reach consumers.
<p>Verification</p>	<p>When appropriate and necessary, usually scheduled (e.g. visual observation that equipment is clean before use).</p>	<p>Necessary: Scheduled verification of implementation of control measures, e.g. through record review, sampling and testing, calibration of measuring equipment, internal audit.</p>
<p>Record keeping (e.g. monitoring records)</p>	<p>When appropriate and necessary, to allow the FBO to assess whether GHPs are operating as intended.</p>	<p>Necessary to allow the FBO to demonstrate ongoing control of significant hazards.</p>
<p>Documentation (e.g. documented procedures)</p>	<p>When appropriate and necessary to ensure GHPs are properly implemented.</p>	<p>Necessary to ensure the HACCP system is properly implemented.</p>

Diagram 1 – Logic Sequence for Application of HACCP

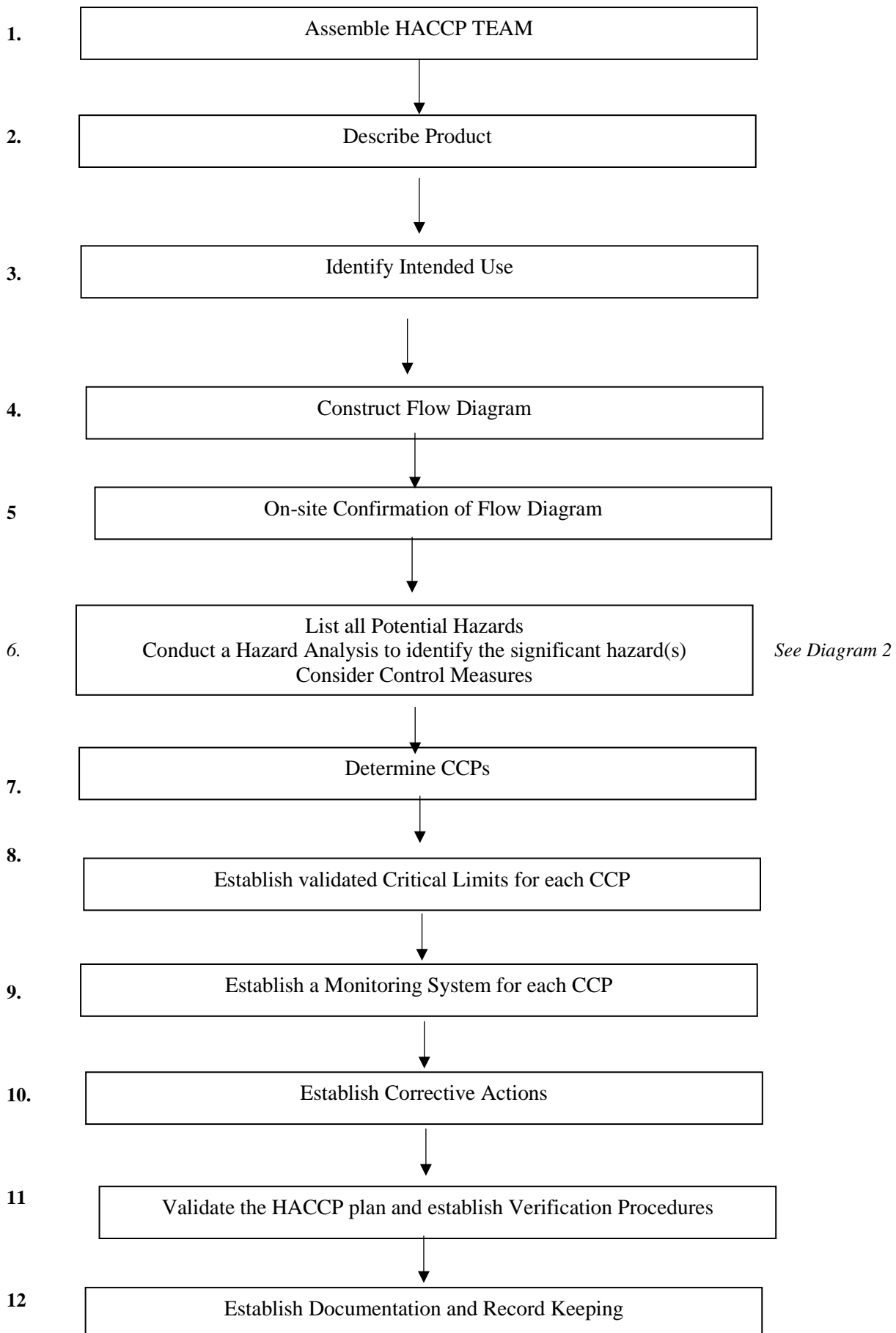


Diagram 2 – Example of Hazard Analysis Worksheet

(1) Step*	(2) Identify <u>potential</u> hazards introduced, controlled or enhanced at this step B = biological C = chemical P = physical		(3) Does this potential hazard need to be addressed in the HACCP plan?		(4) Justify your decision for column 3	(5) What measure(s) can be applied to prevent or eliminate the hazard or reduce it to an acceptable level?
			Yes	No		
	B					
	C					
	P					
	B					
	C					
	P					
	B					
	C					
	P					

*A hazard analysis should be conducted on each ingredient used in the food; this is often done at a “receiving” step for the ingredient. Another approach is to do a separate hazard analysis on ingredients and one on the processing steps.

PROJECT DOCUMENT**Guidelines for the Safe Use and Reuse of Water in Food Production****1. The purposes and scope of the Standard**

The purpose and scope of this document is to elaborate Guidelines for the safe sourcing, use and reuse of water in direct and indirect contact with food across the food chain (primary production and processing) by applying the principle of fit-for-purpose using a risk-based approach.

2. Its relevance and timeliness

In a food business operation, water can be used as an ingredient, to wash food or clean food at contact surfaces, and in many other applications where there is potential for contact between the water and the food. In addition, there are many other applications where there is no intended or expected contact of the water with food (e.g. in personal water use applications and fire control). In all situations, water use should be part of an operation's prerequisite hygiene and HACCP systems.

The requirements for water quality use along the food chain must be considered in context, taking into account the purpose of the water use, hazards that may be present in the water and the need to be controlled to minimize the potential for contamination of food, when used as intended.

Water can be a vector to transmit pathogens or other contaminants from a single food product specimen to a large number of products, thus increasing the number of people exposed and its potential health impact. Therefore, the safest option in food production might be the use of water of potable or drinking water quality. However, this is often not a sustainable, feasible, practical or responsible solution and other types of water could be fit for some purposes or can be made fit for use, provided its intended use does not compromise the safety of the food for the consumer.

The Codex Committee on Food Hygiene (CCFH) has discussed the issue of water since its 30th session (ALINORM 99/13)¹ where a working paper with guidelines for the hygienic recycling of processing water in food plants was circulated to members. Although a proposed draft Guidelines were elaborated for comment at Step 3, CCFH36 (ALINORM 04/27/13)² agreed to discontinue this work due to the heavy workload in the agenda of the Committee at that time. The issue was again discussed at CCFH46 (REP15/FH)³, as an important topic on the Revision of the General Principles of Food Hygiene (CXC 1-1969) and its HACCP annex. CCFH47 then agreed that water was an important issue to be addressed (REP16/FH)⁴ and therefore requested the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), to provide scientific advice to help clarify the use of clean, potable and other types of water in the General Principles of Food Hygiene and other hygiene texts.

The Joint FAO/WHO Expert Meeting on the Safety and Quality of Water Used in Food Production and Processing took place in May 2018. At CCFH 48 (REP17/FH)⁵, the representative of FAO reported the preliminary findings of the meeting, highlighting that the use of water is diverse and complex and that "fit-for-purpose" water should be determined by a risk-based approach.

There is a need in Codex documents for a risk-based approach to safe water and reuse. Rather than focusing of the use of potable water or other quality types (e.g. clean water), a risk-based approach and assessment of the fitness of the water for the purpose intended should be articulated.

Risk management plans addressing food safety and water use or reuse have to consider many factors in their development and implementation. Water reuse is considered a priority as this is becoming an emerging

¹ Report of the 30th Session of the CCFH available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-30%252Fal99_13e.pdf

² Report of the 36th Session of the CCFH available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-36%252Fal04_13e.pdf

³ Report of the 46th Session of the CCFH available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-46%252FREP15_FHe.pdf

⁴ Report of the 47th Session of the CCFH available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-47%252FReport%252FREP16_FHe.pdf

⁵ Report of the 48th Session of the CCFH available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-48%252FReport%252FFinal%252FREP17_FHe.pdf

issue in industry due to increasing requirements for and costs of water discharge and the acceptability of the products produced for global trade.

Although current Codex documents provide guidance on the safe use of water, there is a need to develop practical guidance and tools to help Food Business Operators (FBOs) understand the risks and potential interventions that are available as well as identifying other overarching issues that are required for defining fit-for-purpose water.

3. The main aspects to be covered

The projected format will follow the *General Principles of Food Hygiene* (CXC 1-1969). The proposed structure is as follows:

- General guidance document on key elements, including guidance for determining appropriate and fit-for-purpose microbiological criteria for pathogens (bacteria, viruses, parasites) and definitions, relevant for safe water sourcing, use and reuse as part of a food safety management program in food production;
- Annex 1: Risk-based sector-specific potential intervention strategies for water sourcing, use and reuse in the food chain (e.g. from primary production to retail), examples and/or practical case studies for determining appropriate and fit-for-purpose microbiological criteria (bacteria, viruses, parasites) and examples of the decision support system (DSS) tools such as decision trees (DT) to determine the water quality needed for the specific intended purpose in fresh produce;
- Annex 2: Risk based sector-specific potential intervention strategies for water sourcing, use and reuse in the food chain (e.g. primary production to retail), examples and/or practical case studies for determining appropriate and fit for purpose microbiological criteria (bacteria, viruses, parasites) and examples of the decision support system (DSS) tools such as decision trees (DT) to determine the water quality needed for the specific intended purpose in the fishery sector;
- Annex 3: Risk based sector-specific potential intervention strategies for water sourcing, use and reuse in the food chain (e.g. harvesting to manufacturing and processing), examples and/or practical case studies for determining appropriate and fit for purpose microbiological criteria (bacteria, viruses, parasites) and examples of the decision support system (DSS) tools such as decision trees (DT) to determine the water quality needed for the specific intended purpose in the dairy sector.

4. An assessment against the *Criteria for establishment of work priorities*

The Guidelines need to be developed in order to meet the general criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed work is directed primarily at establishing Guidelines for safe use and reuse of water in direct or indirect contact with food across the food chain including its sourcing, by applying the principle of 'fit-for-purpose' under a risk-based approach.

The proposed work directly relates to several Codex strategic goals from the Codex Strategic Plan: 2020-2025.

- Strategic Goal 1: Address current, emerging and critical issues in a timely manner

These Guidelines would establish a new Codex standard in response to needs identified by Members and in response to current factors that affect food safety and fair practices in the food trade. It will provide practical guidance on fit-for-purpose approach based on risk analysis for sourcing, use and reuse of water in the food chain.

- Strategic Goal 2: Develop standards based on science and Codex risk analysis principles

The development of the Guidelines will be consistent with the use of scientific advice and risk analysis principles in the articulation of the control measures. Scientific advice from the FAO/WHO expert bodies, particularly the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA), and scientific input from all countries will be solicited.

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

The proposed Guidelines will follow the example of the overarching Codex *General Principles of Food Hygiene* (CXC 1-1969), *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and *Code of Practice for Fish and Fishery Products* (CXC 52-2003), *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) all of which provide current guidance on the safety requirements for use of water when

handling food, particularly on the use of potable water or clean water for agriculture, food handling and processing, water reuse and for the elaboration of ice. It is expected that reference to the proposed guidelines will also be made in the aforementioned texts.

6. Identification of any requirement for and availability of expert scientific advice

There may be a need for additional scientific advice from FAO/WHO's expert body JEMRA to establish the general guidance for determining appropriate and fit-for-purpose microbiological criteria (bacteria, viruses, parasites) in water sourcing, use and reuse on food production.

JEMRA's advice would also be needed for the three prioritized sectors:

- Sector-specific examples and case studies for determining appropriate and fit-for-purpose microbiological criteria (bacteria, viruses, parasites) in water sourcing, use and reuse in fresh produce from primary production to retail.
- Sector-specific examples and case studies for determining appropriate and fit-for-purpose microbiological criteria (bacteria, viruses, parasites) in water sourcing, use and reuse in fish and fishery products (e.g. crustaceans, molluscs and cephalopods) from primary production to retail.
- Sector-specific examples and case studies for determining appropriate and fit-for-purpose microbiological criteria (bacteria, viruses, parasites) in water sourcing, use and reuse in dairy sector from harvest to manufacturing and processing.

Finally, the Committee may choose to ask JEMRA to provide practical guidance and revise the examples when using the decision tools described in the review.

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

None identified so far.

8. The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission

A five-year timeline is proposed for the completion of the Guidelines with adoption at Step 5 by CAC45 in 2022 and final adoption in 2023 by CAC46 as regards the main document and Annexes 1 and 2, and with adoption at Step 5 by CAC46 in 2023 and final adoption in 2024 by CAC47 as regards the Annex 3.

CCFH FORWARD WORKPLAN

Title of Work	Last Revision	Information to Update (Yes/No) ¹	Impact to Public Health (20/14/8)	Trade Impact (10/5/4/2/0)	Project document/discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Guidelines for the Safe Use and Re-use of Water in Food Production	N/A	Yes	20	5	Yes	Yes JEMRA has already provided recommendations which will serve as basis for the Guidelines, but it is anticipated that additional advice might be needed	See CX/FH 19/5/9	25
Code of Practice on Food Allergen Management for Food Business Operators	2019	No						
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood (CXG 73-2010)</i>	2010	Yes						
Guidelines for Developing Performance Based Criteria for Microbiological Methods	N/A	Yes						
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG 79-2012)</i>	2012	Yes						

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

Title of Work	Last Revision	Information to Update (Yes/No) ¹	Impact to Public Health (20/14/8)	Trade Impact (10/5/4/2/0)	Project document/discussion paper (Yes/No)	FAO/WHO assistance needed? (Yes/No)	Comments	Total
Code of Hygienic Practice for the Storage of Cereals	N/A	Yes	8	5	Yes ²			13
<i>Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria Monocytogenes in Foods (CXG 61-2007)</i>	2009	No						
<i>Code of Hygienic Practice for Meat (CXC 58-2005)</i>	2005	No						
<i>Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)</i>	2009	No						
<i>Code of Hygienic Practice for Eggs and Egg Products (CXC 5-1976)</i>	2007	No						
<i>Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CXC 39-1993)</i>	1993	No						
<i>Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food (CXC 47-2001)</i>	2001	No						

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

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