JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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

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

New Orleans, USA, 12-16 November 2012

NOTE: This report includes Codex Circular Letter CL 2012/37-FH
TO: Codex Contact Points
Interested International Organizations

FROM: The Secretariat
Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy

SUBJECT: Distribution of the report of the Forty-fourth Session of the Codex Committee on Food Hygiene (REP13/FH)

The report of the Forty-fourth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty-sixth Session of the Codex Alimentarius Commission, (Rome, Italy, 1-5 July 2013).

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

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

1. Proposed Draft Principles and Guidelines for the Establishment and Application of Microbiological Criteria (REP13/FH para. 56 and Appendix III); and


Governments and interested international organizations are invited to comment on the above texts and should do so in writing, by e-mail to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy: codex@fao.org, before 15 May 2013.
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SUMMARY AND CONCLUSIONS

The Forty-fourth Session of the Committee on Food Hygiene reached the following conclusions:

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

The Committee agreed to:

- Forward the Proposed Draft Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods; and the Annex on Berries to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) for adoption at Step 5/8 (para. 56 and Appendix III and para. 118 and Appendix IV, respectively).

MATTERS FOR ACTION BY THE COMMISSION (NEW WORK)

The Committee agreed to propose to the Commission to approve new work on:

- Code of Hygienic Practice for Low-Moisture Foods (paras 123 and Appendix V).

MATTERS OF INTEREST TO THE COMMISSION AND FAO/WHO

The Committee agreed to:

- Return the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: Trichinella spp. and Cysticercus bovis; and the renamed Code of Hygienic Practice for Spices and Dried Aromatic Herbs to Step 2 for redrafting, circulation for comments at Step 3 and consideration at its next session (para. 71 and para. 85, respectively);
- Consider two discussion papers, one on occurrence and control of parasites and, the other on the need to revise the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) (paras 125-126); and
- Use the proposed criteria for evaluating and prioritizing new work on an experimental basis and to establish a "forward workplan" for further consideration at its next Session (para. 128).

REQUEST TO FAO/WHO

The Committee requested FAO/WHO to:

- Peer review the practical examples for the establishment and implementation of microbiological criteria for possible posting on the FAO and WHO websites (para. 43);
- Provide assistance on development of an annex on statistical and mathematical considerations for elaboration of microbiological criteria (paras 50 - 51);
- Collect and review existing information on risk-based examples for Trichinella spp. and Cysticercus bovis to illustrate the level of consumer protection likely to be achieved with different post-harvest risk management options (para 66);
- Undertake a risk assessment to determine whether there is a significant public health risk from Salmonella associated with consumption of spices and dried aromatic herbs and to evaluate whether criteria for Salmonella are meaningful to ensure adequate consumer health protection; identify any other foodborne pathogens of concern in spices; and identify the range of spices to be covered in the Code of Hygienic Practice for Spices and Dried Aromatic Herbs (paras 80 - 83); and
- Provide scientific advice on which low moisture foods are considered the highest priority and the associated microbiological hazards; and information relevant to the risk management of microbiological hazards associated with the identified range of low moisture foods (paras 121 – 122).

MATTERS OF INTEREST TO OTHER COMMITTEES

CCNEA

The Committee:

- Endorsed the hygiene provisions with amendments in the Draft Regional Code of Practice for Street-Vended Foods (Near East) (paras 9 - 10, and Appendix II); and
- Requested further clarification on paragraph 6.5 on the scientific basis for the measures prescribed (para. 9).
INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Forty-fourth Session in New Orleans, United States of America, from 12 - 16 November 2012, at the kind invitation of the Government of the United States of America. Dr Emilio Esteban, of the United States of America, chaired the Session. The Session was attended by 207 delegates representing 73 member countries, one member organization and 16 international organizations including FAO and WHO. A complete list of participants, including the Secretariats, is attached as Appendix I.

OPENING OF THE SESSION

2. The Session was opened by Ms Karen Stuck, US Codex Manager.

3. The Committee was addressed by Ms Charlotte Parent, Deputy Director of Health, City of New Orleans. Ms Parent told the delegates that food was very important to New Orleans, noting the city's reputation as a centre of great food and great culture. Ms Parent talked about how Hurricane Katrina provided the catalyst for the transformation of the New Orleans Department of Public Health from one that focused on safety net services to one that focused on the issues that affect health of the community as a whole, such as childhood obesity and physical activity.

4. Mr Brian Ronholm, Deputy Under Secretary, Office of Food Safety, U.S. Department of Agriculture, also addressed the delegates. Mr Ronholm expressed his gratitude for the moral and financial support that New Orleans contributed to the victims of Hurricane Sandy, both in the United States of America and the Caribbean. He mentioned the Panel discussion, "Codex at 50: Past Accomplishment and Future Challenges" that would be held during the session. In his talk, he highlighted the changes in Codex over the past 50 years, but stressed that the goals of Codex have remained the same: to provide member countries with an effective way to protect the health of consumers and to ensure fair practices in the food trade. Mr Ronholm also remarked on the relationship between safe food and the ability to trade. He said that Codex provides a valid way for food safety professionals and regulatory authorities to make good decisions that are in the best interest of producers, distributors and consumers.

Division of Competence

5. The Committee noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)³

6. The Committee adopted the Provisional Agenda as its Agenda for the Session and agreed to:

- Establish in-session working groups on:
  - Endorsement of the hygiene provisions in the Code of Practice for Street-vended Foods (Near East), led by Australia and working in English, French and Spanish, to consider comments submitted and make recommendations for the Plenary; and
  - Proposed draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Cysticercus bovis*, led by the European Union and New Zealand and working in English, French and Spanish, to consider comments submitted and make recommendations for the Plenary.

- Consider the Agenda Items in the following order: 1, 2a, 3a, 3b, 7, 4, 6, 8 (a, b, c), 2b, 5 and 9.

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE (Agenda Item 2a)²

7. The Committee noted the information presented in CX/FH 12/44/2.

DRAFT REGIONAL CODE OF PRACTICE FOR STREET-VENDED FOODS (NEAR EAST) (Agenda Item 2b)³

8. In accordance with its terms of reference, the Committee considered the hygiene provisions in the draft Regional Code or Practice for Street-Vended Foods, developed by the FAO/WHO Coordinating Committee for the Near East (CCNEA), for endorsement.

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³ CL 2012/1-FH, comments of Australia (CX/FH 12/44/3); India, Malaysia and Nicaragua (CX/FH 12/44/3-Add.1); Ghana, Kenya, Senegal and IACFO (CX/FH 12/44/3-Add.2); Uganda (CRD 6); Jamaica (CRD 12); South Africa (CRD 14); Peru (CRD 18); report of in-session working group on endorsement (CRD 26).
9. The Committee considered the report of the in-session Working Group (CRD 26) and agreed to endorse the hygiene provisions with some amendments, aimed at providing more precise text from a scientific and technical point of view and consistency with other Codex texts. The Committee did not endorse the provisions in paragraph 6.5 for the cleaning of utensils and agreed to request further clarification from CCNEA on the scientific basis for the measures prescribed.

10. The Committee agreed to forward the endorsement of the hygiene provisions of draft Regional Code of Practice for Street-Vended Foods to CCNEA for their consideration (Appendix II).

11. The Committee further noted that several comments were received on sections other than on food hygiene and agreed that these would be submitted to CCNEA for their consideration.

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

PROGRESS REPORT ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS (Agenda Item 3a)

12. Referring to the FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products (Rome, Italy, 23-27 July 2012) which addressed the issue of histamine criteria in various fish and fishery products and examined their public health and trade impact, the Representative of WHO, speaking on behalf of FAO and WHO, provided the Committee with an overview of the discussions and conclusions. Specific reference was made to the conclusions on the no-observed-adverse-effect level (NOAEL) for histamine, the link between sensory quality and histamine levels, and the control measures for mitigation of the risk of scombroid fish poisoning (SFP), including the performance of various sampling approaches. The Representative further informed the Committee that FAO and WHO were working to make the mathematical tools that were used in this expert meeting to design and assess different sampling plans available in a user friendly format.

13. The Delegation of Japan noted that the Committee for Fish and Fishery Products (CCFFP) had established an electronic working group to study the meeting report, with the objective of developing recommendations on histamine criteria including proposed sampling plans for consideration by its next session and encouraged all the CCFF delegations to study the Expert Meeting report, especially with regard to sampling plans, and to closely communicate on this matter with the CCFF delegations in their countries. The importance of communicating with other Codex Committees both formally and informally was strongly reiterated by the Chairperson.

14. In response to a question on other biogenic amines, the Representative of WHO noted that the Expert Meeting had considered these and concluded that further data was necessary before an evaluation of the public health risks of these other biogenic amines could be undertaken.

15. The Representative of WHO also referred to a summary report of the pilot project to enhance participation in the development of Codex texts that had been used to support the revision of the Codex principles and guidelines for the establishment of microbiological criteria (Agenda Item 4). In particular the Representative recognized the time and effort contributed by all the working group members who participated in the initiative noting that an evaluation of this initiative would be completed after this Session of the Committee. The Representative noted the willingness of FAO and WHO to post the examples on their respective websites if the Committee decided that was the best location for them. The Chairperson expressed his appreciation to all involved and noted the value of this approach, including its potential value for certain work in the future.

16. The Representative of WHO also noted that FAO and WHO had tentatively planned to address the request from the 43rd Session to provide technical support on the development of the Annex on the statistical and mathematical considerations for elaborating microbiological criteria in 2013 (Agenda Item 4), pending confirmation and further information from the Committee on the need for and scope of this work.

17. With regard to development of a web-based tool to assess the performance of microbiological sampling plans, the Committee was informed that the tool was now available (www.mramodels.org/sampling) and FAO and WHO welcomed any feedback from delegations on the tool.

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4 CX/FH 12/44/4; CX/FH 12/44/5.
The Representative of FAO presented the outcome of the work that had been undertaken by FAO and WHO in response to the request of the 42nd Session to identify the parasite/commodity combinations of greatest concern. Particular reference was made to the approach that had been taken to address this request including holding an expert meeting, and it was noted that the multi-criteria based approach was developed and documented in such a way as to facilitate its application at country or regional level. The outcome of the ranking was considered to represent a “picture” in time and might need to be updated as further information comes available. Furthermore, as the weighting applied to each of the criteria was independent from the scoring along the criteria, alternative weighting schemes reflecting the judgement of risk managers could be used to reflect their priorities in the ranking process. The expert meeting also provided information on food attribution, potential control measures for the top third of the ranked parasites as well as details on the extent of trade in the commodities of concern and existing risk management measures.

The FAO Representative also provided the Committee with an update on the data collection work on *Vibrio* spp in seafoods which had been recommended by the 42nd Session noting the upcoming workshop in South-East Asia and the plans to implement similar workshops in other regions, resources permitting, in order to build a core expertise in *Vibrio* methodology to support data collection at regional level.

Reference was also made to the recently convened Expert Meeting on the Global View of Campylobacteriosis convened by WHO in collaboration with FAO and OIE and in particular the discussions on control of *Campylobacter*. The Representative also extended the appreciation of FAO and WHO to all the experts and data providers who in the course of the year had made the abovementioned work possible.

The Committee expressed their appreciation to FAO and WHO for its work on the provision of scientific advice which was essential for the Committee to undertake numerous aspects of its work.

**Information from the World Organization for Animal Health (OIE) (Agenda Item 3b)**

In addition to information provided in CX/FH 12/44/5, the Observer from OIE informed the Committee of on-going work on the revision of the OIE Terrestrial Animal Health Code Chapter 8.13 on trichinellosis. This revised draft chapter provides recommendations for on-farm prevention of *Trichinella* infection in domestic pigs, and safe trade of meat and meat products derived from suids and equids. The focus is on requirements for establishing a ‘negligible risk compartment’ because there is a clear and objective means of establishing this status in pigs kept under controlled management conditions. The articles dealing with international trade of meat and meat products of suids and equids include a cross reference to the relevant Codex Guidelines.

The Observer from OIE informed the Committee of the latest meeting of the ad hoc Group on zoonotic parasites, which revised the draft chapter taking into account OIE Member comments, and had also included the two co-chairs of the CCFH Working Group on Guidelines for Control of Specific Zoonotic Parasites. She noted that the participation of the co-chairs provided an excellent opportunity for OIE and Codex to work closely together to ensure alignment of risk-based recommendations while avoiding duplication of effort, and overlap and gaps on the development of respective standards on *Trichinella*.

In addition, the Observer noted that OIE encourages its national delegates to collaborate with national Delegates to the Codex, to ensure alignment of respective standards on *Trichinella* under development by the OIE and Codex, and encouraged the delegates to the Codex to collaborate with national Delegates to OIE.

The Observer confirmed OIE’s commitment to continue to explore ways to harmonise OIE and Codex approaches in the development of standards of mutual interest in the food production continuum and their willingness to participate in the electronic working group established by the Committee on General Principles (CCGP) where this will be considered.

The Committee thanked the Observer from OIE for the useful information and their participation in CCFH work and reiterated the importance of collaboration between Codex and OIE.
PROPOSED DRAFT REVISION OF THE PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA (Agenda Item 4)⁶

27. The Committee recalled that at its 43rd Session it had agreed to establish a physical working group, led by Finland and co-chaired by Japan, to review and complete the main document based on the examples developed through electronic means by teams of two or more countries and the comments received before and during the 43rd Session. The Committee further recalled that the development of the examples was part of a pilot initiative funded by the FAO/WHO Codex Trust Fund.

28. The Delegation of Japan introduced the report of the working group (CRD 3), which met immediately before the present session, and recalled that five physical working groups were held since this work had started in 2010. He further recalled the seven examples on the application of microbiological criteria had been developed to help illustrate the various contexts in which microbiological criteria might be used.

29. The Delegation noted that the working group had further revised the proposed draft Principles and Guidelines incorporating many of the comments submitted. He further noted that the working group had not come to a conclusion with regard to some texts highlighting differences between “attributes sampling plan” and “variables sampling plan” in Section 4.5 “Sampling plans”, nor the texts of Sections 4.9 “Moving windows” and 4.10 “Trend analysis” and had put the relevant texts in square brackets.

30. The Delegation added that paragraph 9 of CRD 3 included a proposal for terms of reference for a request to FAO and WHO to provide scientific information to develop an Annex to the main document on the statistical and mathematical considerations for elaborating microbiological criteria, for the Committee’s consideration.

31. With regard to the future use of the examples, the working group had considered the three options proposed in CX/FH 12/44/8 Add.1 and had recommended that FAO and WHO perform a peer review of the examples (Option 1).

32. The Committee deleted footnote 1, which referred to the exclusion of toxins/metabolites such as those addressed by the Committee on Contaminants and Toxins in Foods (CCCF), noting that this section is of general nature and governments and food business operators could develop microbiological criteria for these types of toxins/metabolites and the footnote might limit such possibilities. The Committee further amended the text to indicate that the list provided in the section was not exhaustive.

Introduction

33. In the light of the discussion on the future use of the practical examples on the establishment and application of microbiological criteria (see para. 43), the Committee deleted the last paragraph of the introduction section and agreed to consider in the future the need to add a link to the website where the examples would be posted after the FAO and WHO peer review.

Section 2.1 Scope

34. The Committee deleted footnote 1, which referred to the exclusion of toxins/metabolites such as those addressed by the Committee on Contaminants and Toxins in Foods (CCCF), noting that this section is of general nature and governments and food business operators could develop microbiological criteria for these types of toxins/metabolites and the footnote might limit such possibilities. The Committee further amended the text to indicate that the list provided in the section was not exhaustive.

Section 2.2 Definitions

35. The Committee agreed to remove the definition of “metric” as the current text created confusion and did not add any value to the text. The Committee further noted that a more correct reference, i.e. Guidelines for Food Import Control Systems (CAC/GL 47-2003), had been given to the definition of ALOP.

Section 4.2 Purpose

36. The Committee deleted the bullet point on validation as microbiological criteria were seldom used for the validation of control measures.

⁶ CX/FH 12/44/6; CX/FH 12/44/6-Add.1; comments of Argentina, Brazil, Colombia, Costa Rica, Egypt, Japan, Mauritius, Mexico, New Zealand, Nicaragua, Norway, St. Lucia and USA (CX/FH 12/44/6-Add.2); Ghana, Kenya, Philippines and IACFO (CX/FH 12/44/6-Add.3); report of the physical Working Group on the revision of the Principles for the Establishment and Application of Microbiological Criteria for Foods (CRD 3); Thailand (CRD 4); India (CRD 5); Uganda (CRD 6); ICMSF (CRD 7); Vietnam (CRD 11); Indonesia (CRD 13); South Africa (CRD 14); EU (CRD 15); IDF (CRD 16); Peru (CRD 18); Brazil (CRD 19); Nigeria (CRD 21).
Section 4.3 Relationship between microbiological criteria, other microbiological risk management metrics and ALOP

37. The Committee deleted the last sentence of paragraph 20\(^7\) as it was not clear.

Section 4.4 Components and other considerations

38. The Committee amended the text of the chapeau of paragraph 23 to make it more general and in the sixth bullet point added “when appropriate” prior to “suitable conditions for pooling of samples” for clarity. In paragraph 24, “hazard” was changed to “risks” as the term was more appropriate.

Section 4.5 Sampling plan

39. The Committee agreed to the proposal to revise the text retained in square brackets with new text which more accurately described variables sampling plans. The Committee deleted: paragraph 28, including the three bullet points as their content was already covered in different sections of the document; and the final phrase of the last paragraph as covered elsewhere.

Section 4.6 Microbiological and/or other limits

40. In paragraph 32, the Committee agreed to delete “(often zero)” as unnecessary.

Section 4.7 Analytical methods

41. In paragraph 33, the Committee clarified that when an inter-laboratory study is not available, inter-laboratory validation can be done according to a standardised protocol.

Section 4.9 Moving window

42. The Committee agreed to the proposal, which revised the entire section to better explain the concept, purpose and how to apply the moving windows approach. In view of these changes, the Committee considered that there was no need to further amend Section 10 “Trend analysis”.

Annexes on practical examples

43. The Committee agreed with the recommendation of the working group to ask FAO and WHO to perform a peer review of the practical examples and to give the drafting countries an opportunity to revise and correct the examples prior to sending them to FAO and WHO.

44. Some delegations considered the examples very useful as they had allowed countries to better understand the application of microbiological criteria; however, recognising that difficulties still remained on how they should be developed, they recommended FAO and WHO conduct training to help better understand how to develop and apply microbiological criteria.

45. Some delegations proposed to add a link to the FAO and WHO websites where the examples could be posted after the FAO and WHO peer review. This link should state that these examples are for purposes of illustration only, and do not necessarily represent a microbiological criterion with a universal application.

46. The Delegation of Brazil expressed its concerns that the insertion of any reference to the examples in the proposed draft Principles and Guidelines could be understood as an “extended explanatory material”, and therefore, in their view, contradicting the Guidelines on the Elaboration and/or Revision of Codex of Hygienic Practice for Specific Commodities\(^8\). The Delegation requested FAO and WHO to consider, under the peer review process, the possibility of making the examples more general by eliminating, to the extent possible, any mention to specific products or commodities.

47. Moreover, since the members had chosen Option 1 (CX/FH 12/44/6 Add.1), the Delegation considered it important that the terms of reference for the FAO and WHO clearly state that after the revision and harmonization process, the examples would be published on the FAO and WHO websites and should not be incorporated and/or referenced in the document.

48. One Observer reiterated its concern regarding some of the examples and pointed out a number of errors and inconsistencies with Codex texts and suggested that the examples be corrected and harmonised with Codex texts before being made available to avoid possible misuse and any potential negative impact on international trade. She proposed to exclude the examples that were not practical and feasible.

\(^7\) Paragraph and bullet numbers used in this report correspond to the ones in Appendix III.

\(^8\) Procedural Manual of the Codex Alimentarius Commission.
49. The Committee encouraged delegations who had expressed concerns to contact the lead of the drafting teams so that they could address their concerns. It was further agreed to ask FAO and WHO to: (i) review and harmonise the “Practical examples on the application and establishment of microbiological criteria”, prepared by drafting teams; and (ii) provide an introductory text and background to the examples before making them publicly available.

**Annexes on statistical and mathematical matters**

50. The Committee recalled the recommendation of the working group, held in Grange, Ireland (July 2011), to develop an Annex on statistical and mathematical considerations for the elaboration of microbiological criteria and to request FAO and WHO to assist in the development of the Annex.

51. The Committee considered that the Annex was still necessary and agreed to the recommendation of the working group (CRD 3) to request FAO and WHO assistance with the following terms of reference:

   Address the statistical and mathematical considerations related to establishing the performance characteristics of a sampling plan, including:

   - How to develop and interpret operating characteristics curves;
   - The impact of assumptions about the distribution and standard deviation of microorganisms in a food;
   - How to establish the length of a moving window; and
   - Any other relevant aspects.

52. The FAO Representative, on behalf of FAO and WHO, confirmed the commitment to undertake this work by the next session of the Committee but could not indicate the precise timeframe at this stage. In view of this, both an electronic and a physical working group to meet immediately before the next session of the Committee were proposed. The Committee agreed that it would be premature to establish an electronic working group on the development of the Annex and that the establishment of the physical working group would be difficult in view of the tight schedule. The Committee encouraged FAO and WHO to distribute the report as soon as it became available. If possible the report would be circulated with a request for comments for consideration at its next session.

**Conclusion**

53. The Committee noted that considerable progress had been made on the document and that it was ready for adoption by the Commission. It further noted that the Spanish version needed to be revised to better align with the English version and invited Spanish-speaking delegations to provide the Codex Secretariat with editorial corrections to be included in the final text.

54. The Committee expressed its appreciation to the Codex Trust Fund for supporting the pilot project, which had greatly contributed to the understanding of microbiological criteria and had facilitated the finalisation of this important piece of work. The project had also resulted in a very educational experience for all countries and observers involved.

55. The Committee agreed to take a final decision on the form of the Annex on statistical and mathematical considerations after receiving FAO and WHO advice.

**Status of the Proposed Draft Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods**

56. The Committee agreed to advance to Step 5/8, with the omission of Steps 6 and 7, the proposed draft Principles and Guidelines for adoption by the 36th Session of the Commission (Appendix III).
57. The Delegation of the European Union recalled that: FAO and WHO had reviewed and were updating the risk profiles for *Trichinella spiralis* and *Taenia saginata /Cysticercus bovis*, which would be then made available on the FAO and WHO websites; the electronic working group had revised the proposed draft guidelines on *Trichinella* spp. to take into account the draft revision of Chapter 8.13 “Infection with *Trichinella* spp” of the OIE Terrestrial Animal Health Code; and comments submitted indicated that the scope of the Codex work on *Trichinella* spp. should be limited to meat of suidae. It was noted that the OIE had invited the chairpersons of the Codex electronic working group to participate in the latest meeting of the OIE ad hoc Group who revised Chapter 8.13 “Infection with *Trichinella* spp” of the OIE Terrestrial Animal Health Code, taking into account OIE Member comments, and thus close liaison had been established between the work of OIE and Codex.

58. The Delegation of the European Union introduced the report of the in-session working group (CRD 27) and explained that the meeting had considered three possible options for the completion of the work on *Trichinella* spp.: Option (i) based on the pathway of the current draft of the revised OIE Chapter 8.13, which describes requirements for establishing a “negligible risk compartment”;

Option (ii) based on a proposal for achieving and maintaining a “negligible risk compartment” following an alternative pathway to that described in the current draft OIE Chapter 8.13; and

Option (iii) based on the possibility of achieving a negligible risk status for a country or region for domestic pigs with possible interaction with wildlife, based on an independent pathway to that described in the current draft OIE Chapter 8.13.

59. He explained that Option (ii) required less extensive on-farm auditing to maintain the “negligible risk compartment” than Option (i) because the pathway was linked to a slaughterhouse monitoring plan. It further noted for Option (ii) to become operational, it required including additional provisions in the current draft OIE Chapter 8.13.

60. The Delegation of the European Union noted that Option (iii) was not based on the current draft OIE Chapter on *Trichinella* but on monitoring of “sentinel animals” e.g. wild boars or other wildlife and on the horizontal good veterinary practices of the OIE Terrestrial Animal Health Code.

61. The Delegation of New Zealand explained that to complete the guidelines for the control of *Trichinella* spp. and *Taenia saginata /Cysticercus bovis* the Committee needed to develop risk-based parameters based on slaughterhouse data with the assistance of FAO and WHO. These parameters would guide decisions on post mortem control measures. He further noted that this work would require close collaboration between the electronic working group and FAO and WHO and that some examples of these parameters were available for consideration.

62. The Committee considered the three different options and supported Options (i) and (ii). With regard to Option (ii), the Committee noted that it was necessary that Members supporting this option coordinate their position at country-level with national delegates to OIE. In this regard the Observer of OIE recalled that the draft revised OIE Chapter had been recently circulated with a deadline for comments by 18 January 2013.

63. The Committee did not support Option (iii), which referred to possible monitoring of wildlife, as this was outside the scope of this work at this time.

64. The Committee noted that the official recognition of animal disease status was the remit of OIE and highlighted the importance to continue strengthening the collaboration with OIE without overlapping with each other’s responsibilities. It further noted that strengthened collaboration with OIE would ensure consistency of Codex and OIE texts and allow countries to implement consistently control measures along the entire food chain.

65. The Committee noted that the options described above for the control of *Trichinella* spp. did not apply to the proposed draft guidelines for *Taenia saginata /Cysticercus bovis*.

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9 CX/FH 12/44/7; comments of Argentina, Colombia, Costa Rica, Mexico, Nicaragua, Norway, St. Lucia and USA (CX/FH 12/44/7-Add.1); (CRDs); Kenya (CRD 8); Vietnam (CRD 11); Indonesia (CRD 13); Peru (CRD 18); Republic of Korea (CRD 20); report of in-session working group on control of specific zoonotic parasites in meat (CRD 27).
66. With regard to the development of a surveillance programme based on slaughterhouse data, the Committee refined its earlier request to FAO and WHO to initially focus on the collection and review of existing information and examples and use this to guide further work.

Conclusion

67. The Committee agreed to continue working in parallel on the development of the documents on *Trichinella* spp. and *Taenia saginata / Cysticercus bovis*.

68. The Committee agreed to establish an electronic working group, co-chaired by the European Union and New Zealand and working in English only, to further develop the two proposed draft guidelines taking into account the above discussion and the development of the OIE work on the revision of Chapter 8.13 “Infection with *Trichinella* spp” of the Terrestrial Animal Health Code, where applicable.

69. In order to further progress this work, the Committee agreed to convene a physical working group, subject to OIE adoption of the revision of Chapter 8.13 in May 2013, led by the European Union and New Zealand, to meet immediately prior to its next Session, to review the comments received at Step 3 and facilitate the discussion at the Plenary.

70. The Committee further encouraged Members to collaborate with national Delegates to OIE to ensure alignment of Codex and OIE work on *Trichinella*.

Status of the Proposed Draft Guidelines for Control of Specific Zoonotic Parasites in Meat: *Trichinella* spp. and *Cysticercus bovis*

71. The Committee agreed to return the proposed draft Guidelines to Step 2 for revision by the electronic working group, circulation for comments at Step 3, and consideration by the aforementioned physical working group and next Session of the Committee.

PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR SPICES AND DRIED AROMATIC PLANTS (CAC/RCP 42-1995) (Agenda Item 6)

72. The Committee recalled that the 43rd Session had agreed to begin new work on the revision of the Code of Hygienic Practice for Spices and Dried Aromatic Plants and agreed to establish an electronic working group led by the United States of America to prepare the proposed draft revision for comments and consideration by this session. The Committee also recalled that this document might become an Annex to a general code of hygienic practice on low moisture foods at a later stage (Agenda Item 8).

73. The Delegation of the United States of America introduced the report of the working group and informed the Committee that the draft had been developed with the recognition that a wide diversity of practices are used in spice production, processing and packaging throughout the world. The Delegation highlighted the key issues addressed in the proposed draft: moisture control, pest control, additional practices that limit growth of mycotoxin-producing moulds and contamination by pathogens such as *Salmonella*; supplier control and microbial reduction treatments. The Delegation, however, noted that there were several issues that needed further discussion and proposed that the Committee provide advice on these matters to assist in the further development of the Code.

74. The Committee considered the recommendations (paragraph 8 of CX/FH 12/44/8) and took the following decisions.

Terminology

75. The Committee agreed to refer to “spices” rather than “dried spices” as it was understood that spices were by definition dried.

Scope

76. The Committee agreed that tea and dried vegetables would not be included in the scope as these were considered beverages and ingredients, respectively. In view of this decision, the title was changed to reflect that it would cover spices and dried aromatic herbs.

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10 CX/FH 12/44/8; comments of Colombia, Costa Rica, Japan, Mauritius, Philippines and USA (CX/FH 12/44/8-Add.1); Cuba and Senegal (CX/FH 12/44/8-Add.2); Thailand (CRD 4); India (CRD 5); Uganda (CRD 6); Indonesia (CRD 13); South Africa (CRD 14); European Union (CRD 15); Peru (CRD 18); Brazil (CRD 19); Republic of Korea (CRD 20); Nigeria (CRD 21).
Provisions on protection of source plants, irrigations systems and access to visitors

77. On the need to include provisions for the protection of source plants (section 3.1.2) and recommendations to avoid sprinkler irrigation systems and flood irrigation (section 3.2.1.1), the Committee noted that there were varying views. The Committee therefore recommended these provisions receive further consideration in the development of the Code.

78. In the case of section 3.2.3, paragraph 25, relating to provisions to deter entry of casual visitors and, to the extent possible, children, a delegation proposed its deletion noting that the source plant would be dried later in the process and that the risks posed by casual visitors and children were not the same as for fresh leafy greens or melons. However, the Committee agreed to its retention.

Microbiological specifications

79. The Committee agreed that section 5.2.3, paragraph 71 should be redrafted to provide guidance more appropriate for a code of practice; that paragraph 73 should be retained, but that the reference in paragraph 74 to a microbiological criterion for *Salmonella* should be deleted or retained in square brackets until a decision was taken on the appropriateness of a criterion for *Salmonella*.

80. In order to take a decision on a criterion for *Salmonella*, the Committee agreed to request that FAO and WHO undertake a risk assessment to determine whether there is a significant public health risk from *Salmonella* associated with consumption of spices and dried aromatic herbs and to evaluate whether criteria for *Salmonella* are meaningful to ensure adequate consumer health protection.

81. It was further proposed that FAO and WHO extend their call for data to any microbiological hazard associated with spices and dried aromatic herbs in order to identify any other foodborne pathogens of concern.

82. It was also agreed that FAO and WHO should identify the range of spices to be covered in the Code, and the critical points for control of *Salmonella* and/or other foodborne pathogens.

83. Specific questions that FAO and WHO could address include:

- Is there a significant risk associated with *Salmonella* or other identified foodborne pathogens in spices and dried aromatic herbs? If so, are there particular spices and dried aromatic herbs which present a greater risk than others?

- Is the criterion and the associated sampling plan for *Salmonella* in the draft Annex (CX/FH 12/44/8) meaningful for public health protection?, i.e. what is the performance of the existing microbiological criterion and associated sampling plan given the information on the prevalence and concentration of *Salmonella* in spices and dried aromatic herbs and identify and consider alternative microbiological criteria and associated sampling plans that could be effectively applied to the management of *Salmonella* (or any other identified pathogen) in spices and dried aromatic herbs given the available information on prevalence and levels of contamination.

- What would be the impact on public health of microbial reduction treatments of different levels, e.g., 2 – 5 log reduction of *Salmonella* provided to spices and dried aromatic herbs?

Conclusion

84. The Committee agreed to establish an electronic working group led by the United States of America, working in English only, to redraft the Code taking into account the decisions taken at the Session, and the written comments submitted. The Committee noted the provisional offer of the Delegation of India to co-chair the electronic working group, pending confirmation of their government.

Status of the Proposed Draft Code of Hygienic Practice for Spices and Dried Aromatic Herbs

85. The Committee agreed to return the proposed draft renamed Code to Step 2 for redrafting by the electronic working group, circulation for comments at Step 3 and consideration by the next Session of the Committee.
PROPOSED DRAFT ANNEX ON BERRIES TO THE CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES (CAC/RCP 53-2003) (Agenda Item 7)\(^{11}\)

86. The Committee recalled that the 43\(^{rd}\) Session agreed to request the 35\(^{th}\) Session of the Commission to approve new work on the development of an Annex on berries to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) and to establish an electronic working group, led by Brazil, to develop the proposed draft Annex for comments at Step 3 and consideration by the present Session.

87. The Delegation of Brazil introduced the report of the electronic working group (CX/FH 12/44/9) and highlighted the approach taken in the development of the Annex. He pointed out that special attention should be given to the scope and the definition of berries and recommended that the entire Code and all its annexes be reviewed to ensure consistency and remove duplication (Agenda Item 8). Therefore, he recommended that the Committee should not pay too much attention to the consistency and duplication with the main text and/or other annexes at this time.

88. The Committee considered the proposed draft Annex section by section and, in addition to editorial corrections, made the following comments and amendments.

Introduction

89. In the third paragraph, “manipulation” was replaced by “handling” as more correct.

Scope

90. The Committee agreed to limit the scope to all varieties of edible strawberries, raspberries, blackberries, mulberries, blueberries, currants and gooseberries and groundcherries that would be indicated also by their scientific name to avoid confusion, as common names differed from country to country. In view of this decision, it was agreed that there was no need for a definition for berries in section 2.3.

91. The Committee further agreed to clarify that in the case of wild berries, only the measures for handling and post-harvest activities apply.

3.1.1 Location of the production site

92. The second paragraph was amended to clarify cleaning and disinfection steps and to state that berries that have come into contact with flood waters should not be used because of the high risk of contamination.

93. The Committee agreed to amend the third paragraph to allow flexibility for a drying period before harvesting.

3.1.2 Wild and domestic animals and human activity

94. The Committee agreed to refer to wild and domestic animals and not to list specific examples.

95. In the first bullet point, it was agreed to replace “cultural” by “cultivation” as this was a more understandable and common term, and to refer only to environmental protection regulations, as this would encompass both animal and plant.

3.2 Hygienic primary production of berries

96. The section was amended by the addition of examples to clarify those production practices that could minimize contact with airborne contaminants.

97. The last paragraph was amended to provide examples of biodegradable materials used during growing and harvesting by small farmers.

3.2.1.1 Water for primary production

98. The Committee agreed to delete the second bullet point and to insert guidance on selection of indicators as the selection of indicators should be fit for purpose and not limited to \textit{E. coli} testing.

3.2.1.2 Manure, biosolids and other natural fertilizers

99. The Committee did not agree to a proposal to delete “to the extent possible” in the first sentence as this would prevent the use of manure (untreated and liquid). It was noted that manure was used, in particular for organic agriculture, and that general guidance on the use of manure was provided in the main Code (section 3.2.1.2).

\(^{11}\) CX/FH 12/44/9; comments of Costa Rica, Cuba, Egypt, Japan, Malaysia, Mexico and USA (CX/FH 12/44/9-Add.1); Argentina, Philippines, Senegal and IACFO (CX/FH 12/44/9-Add.2); Thailand (CRD 4); India (CRD 5); EU (CRD 15); Brazil (CRD 18).
3.2.3 Personnel Health, hygiene and sanitary facilities

100. The Committee agreed to also indicate that whenever possible harvesting, packing and inspection processes should be designed to reduce fruit handling.

101. In addition, the Committee agreed to move the last sentence of the first paragraph to the section on training. In view of this deletion, it was agreed to indicate in the second sentence that hand drying was necessary before handling of berries.

3.2.3.1 Personnel hygiene and sanitary facilities

102. The section was replaced by more detailed information for purposes of clarity.

3.2.4 Equipment associated with growing and harvesting

104. The first bullet point was deleted as more appropriate to training and the third bullet point was amended to indicate that containers and liners that were not clean should be disposed of.

3.3 Handling, Storage and Transport

105. The Committee amended the second paragraph to make it less prescriptive by indicating that the period of two hours for cooling was not the only means to achieve precooling, but an example of precooling. Furthermore, it was agreed that growers should use potable water for ice and hydrocoolers when required.

106. The second bullet point was amended by deleting the first sentence on training to section 10 as more appropriate, and to make it more clear that berries that had fallen on the ground should be discarded unless a microbiocidal step was applied.

3.3.1 Prevention of cross-contamination

107. This section was amended by deleting bullet point 3 as it was already covered by the main Code and by moving bullet point 4 to the section on training as more appropriate and bullet point 6 to section 5.2.4.

3.3.3 Field packing

108. For purposes of clarity and noting that it was not possible to disinfect pallets, the Committee agreed to amend the second paragraph to indicate that growers should ensure that clean pallets and containers are used and disinfected where necessary.

4.1.2 Equipment

109. The Committee agreed to replace “organisms” with “foodborne pathogens” as more correct and to apply this change throughout the document. The second sentence on written SOPs and cleaning and disinfection of equipment was moved to a new section 6.1.2 as more appropriate.

4.2.1 Design and Layout

110. The section was amended to clarify the design and layout to keep incoming berries from the field separate from outgoing washed berries and to indicate that the design should allow thorough cleaning and disinfection of food contact surfaces.

5.2.2.1 Post-harvest water use

111. The section was amended to indicate the use of testing for indicator organisms and/or foodborne pathogens for the control and monitoring of the quality of water for washing of berries; the additional controls for water used in pre-washing and washing tanks; that water for final rinses should be potable; and to indicate the correct use of antimicrobial agents in water.

5.2.4 Microbial cross-contamination

112. A new sentence was added to clarify that cross-contamination between raw and washed berries for freezing should be prevented.

Section 8 - Transportation

113. A new section on transportation was inserted with a reference to the Code of Practice for Packaging and Transport of Fresh Fruits and Vegetables (CAC/RCP 44-1995) as relevant.
9.4 Consumer education

114. The Committee agreed to amend the first bullet point to indicate that purchase of trays or cases with damaged or rotten berries should be avoided; and to insert an additional bullet point to indicate that consumer information should also include the need to wash berries with potable water before consuming for consistency with the WHO Five Keys to Safer Food.

10.2 Training programs

115. The Committee agreed: to amend the chapeau to the bullet points to indicate the information to be included in specific employee training programmes; to delete the first bullet point as it related to quality rather than food safety; and to include a sentence at the end of the section to indicate that training records should be kept.

Conclusion

116. The Committee noted that considerable progress had been made on the document and that there were no outstanding issues and, therefore, it could be advanced for adoption.

117. The Committee further supported the recommendation that the Code of Hygienic Practice for Fresh Fruits and Vegetables and all its annexes be reviewed and noted that this matter would be discussed further under Agenda Item 8.


118. The Committee agreed to advance the proposed draft Annex on Berries to Step 5/8, with the omission of Steps 6 and 7, for adoption by the 36th Session of the Commission (Appendix IV).

OTHER BUSINESS AND FUTURE WORK (Agenda Item 8)12

DISCUSSION OF THE REPORT OF THE WORKING GROUP FOR ESTABLISHMENT OF CCFH WORK PRIORITIES

DISCUSSION PAPER ON A CODE OF HYGIENIC PRACTICE FOR LOW-MOISTURE FOOD

DISCUSSION PAPER ON NEW WORK AND PERIODIC REVIEW/REVISION OF CODES OF HYGIENIC PRACTICE

119. The Delegation of the United States of America, the chair of the working group for establishment of CCFH work priorities, which was held immediately before the present Session, introduced this Item and provided an overview of discussions and recommendation of the working group as presented in CRD 2.

120. The Committee considered the recommendations and took the following the decisions.

New Work Proposal

Code of Hygienic Practice for Low Moisture Foods

121. The Committee agreed to the recommendation to start new work on a Code of Hygienic Practice for Low Moisture Foods. The Committee further agreed to request FAO and WHO to undertake work to provide the Committee with scientific advice on the following:

- The low moisture foods, which should be considered as the highest priorities for the Committee and the associated microbiological hazards. The ranking process should include, but not be limited to, dried fruits and dehydrated fruits and vegetables, peanut butter, cereals, dry protein products (e.g. dried dairy products), confections (e.g. cocoa and chocolate), snacks (e.g. spiced chips), tree nuts, desiccated coconut, seeds for consumption, spices and dried aromatic plants.

- Information relevant to the risk management of the microbiological hazards associated with the identified range of low moisture foods, with particular attention to the role of agricultural and handling/manufacturing practices in the introduction and control of hazards and the identification of the critical control points for mitigation of the risks associated with low moisture foods.

122. To assist with this request, FAO and WHO should issue a call for data on microbiological hazards associated with low moisture foods; reported illnesses associated with low moisture foods; the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards; and any other data relevant to prioritizing low moisture foods and managing the associated risks.

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12 CX/FH 12/44/10 (not issued); CX/FH 12/44/11; CX/FH 12/44/12; Report of the CCFH working group for the establishment of CCFH work priorities (CRD 2); comments of Thailand (CRD 4); India (CRD 19); USA (CRD 10); Nigeria (CRD 21)
Conclusion

123. The Committee agreed to submit the project document to the 36th Session of the Commission for approval as new work (Appendix V). The Committee agreed to establish an electronic working group, led by Canada and co-chaired by the United States of America, and working in English only, to develop the proposed draft Code for comments at Step 3 and consideration by its next Session pending approval by the Commission.

124. The Committee also agreed to establish a physical working group with interpretation in English, French and Spanish to meet immediately prior to the next session, but noted that this would be subject to confirmation.

Other matters

Discussion papers

125. The Committee agreed to the recommendation of the working group to develop two discussion papers, one on occurrence and control of parasites in food and, the other on the need to revise the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003), for consideration by the next session.

126. The Committee agreed that:

- An electronic working group led by Australia and working in English only, would prepare the discussion paper on occurrence and control of parasites in food. The discussion paper should (i) consider whether control of parasites should be addressed in a general code of practice or within existing commodity codes; (ii) consider whether additional guidance on criteria for prioritization of parasites for use by governments should be developed; and (iii) include a project document as appropriate.

- Brazil would prepare a discussion paper on the need to revise the Code of Hygienic Practice for Fresh Fruit and Vegetables and its annexes, specifically with regard to eliminating duplication and redundancies and to identify provisions that might be missing from the Code.

Code of Hygienic Practice for the Storage of Cereals

127. The Committee agreed to include this proposal in the proposed CCFH “forward workplan”; and noted that this work should be considered in relation to the development of the Code of Hygienic Practice for Low Moisture Foods.

Process by which the CCFH undertakes its work and the CCFH “forward workplan”

128. The Committee agreed with the recommendation that the proposed draft revision of the “Process by which CCFH will undertake its work”, which includes the proposed criteria for evaluating and prioritizing new work (Appendix I of CRD 2), be used on an experimental basis by the chair of the next working group on priorities. The Committee further agreed that a “forward workplan” should be established for the Committee in order to prioritize potential future work. It was agreed that the proposed “forward workplan” in Appendix II of CRD 2 would be circulated for comments.

129. The Representative of FAO welcomed the proposed “forward workplan” and requested that the need for scientific advice on the items on the workplan also be included. This would facilitate the future planning, budgeting and preparedness of FAO and WHO to respond to the requests for scientific advice.

Conclusion

130. In accordance with the process by which CCFH undertakes its work, the Committee agreed that the Secretariat would issue a circular letter requesting proposals for new work. In addition, the circular letter would also include a request:

- For comments on the provisional criteria and their weighting values, and on the “forward workplan”;
- To evaluate each workplan item;
- To evaluate the weighting values given to each workplan item;
- To provide weighting values for each criterion for the newly added workplan items, i.e. parasites and cereals.

131. The Committee agreed to re-establish the working group on CCFH work priorities which will meet the day before the next session of the Committee and accepted the offer of the Delegation of Viet Nam to chair this working group with the assistance of the United States of America.
132. Noting the large number of requests for scientific advice from FAO and WHO from this session of the Committee, the Representative of FAO, speaking on behalf of FAO and WHO, expressed appreciation of the Committee’s confidence in the FAO and WHO provision of scientific advice programme. The Representative noted that the advance notice that the Committee had provided on two of the items at its last session, namely the requests for scientific advice in relation to the statistical annex on microbiological criteria and on spices had allowed the organizations to include that work in their programme for 2013. While the Organizations would endeavour to respond to all the requests of the Committee in an expeditious manner the work would however have to be prioritized in terms of the available human and financial resources as well as available data. Recalling the discussions at the 35th Session of the Commission the Representative highlighted the challenges both organizations faced in terms of resources for the provision of scientific advice and while discussions on how to address these challenges were ongoing the support on Members was critical. The Representative of FAO therefore requested the support of Members for the provision of scientific advice noting that that this could be in the form of the direct provision of financial and in-kind (e.g. human) resources as well as high level support for the FAO and WHO food safety programme, including provision of scientific advice, at the governing bodies of each Organization.

DATE AND PLACE OF THE NEXT SESSION (Agenda Item 9)

133. The Committee was informed that the 45th Session of the CCFH, which was tentatively scheduled, from 11 – 15 November 2013, would be co-hosted by Viet Nam. The exact time and venue would be determined by the host Government in consultation with the Codex Secretariat.
## SUMMARY STATUS OF WORK

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### New Work

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### Discussion papers

| Discussion paper on occurrence and control of parasites                        | -     | Electronic Working Group (Australia) 45th CCFH            | Paras 125 - 126               |
| Discussion paper on the need to revise the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) | -     | Brazil 45th CCFH                                         | Paras 125 - 126               |
## APPENDIX I

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2.3 Definitions

For the purposes of the present guidelines, the terms used herein shall have the following definitions:

2.3.1 Appliances

The whole or any part of any utensil, machinery, instrument, apparatus or article used or intended for use, in or for making, preparing, keeping, selling or supplying of food.

2.3.2 Clean water

Water that does not compromise food safety in the circumstance of its use (definition used in The Code of Hygienic Practice for Fresh Fruit and Vegetables) from any natural source where there is no reason to believe the water is contaminated.

2.3.3 Crockery

All tools used for food serving and consumption (whether non-disposable or disposable), such as and they include cups (glasses), plates, trays, mugs, spoons, forks, ladles... etc.

2.3.4 Disposable articles

Any appliance, container, implement, utensil or wrapper that is intended for use only once in the preparation, storage, display, serving consumption or sale of food.

2.3.5 Impermeable

Preventing the passage/absorption of water and/or fluids.

2.3.6 Microorganisms

Any microscopic living organism that can cause disease or food spoilage.

2.3.7 Street food vendor

Individual selling street foods in street food stalls or centres.

2.3.8 Perishables Perishable food

Any food that needs to be kept refrigerated to minimize or prevent growth of food poisoning organisms (and/or food spoilage) (e.g. food that consists wholly or in part of milk, milk products, eggs, meat, poultry, fish or shellfish) Food that is of such a type or is in such a condition that it may spoil.

2.3.9 Potable/Drinking water

Treated water, which shall comply with WHO Guidelines for Drinking Water Quality.

2.3.10 Readily Perishable Food

Perishable food that consists wholly or partly of milk, milk products, eggs, meat, poultry, fish or shellfish, or ingredients that are capable of supporting the progressive growth of microorganisms that can cause food spoilage, food poisoning and other food borne illnesses.
2.3.11 **Ready-to-eat foods**

Any food (including beverages) which is normally consumed in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form in which it is normally consumed without further processing.

2.3.12 **Relevant authority**

Any ministry having competent responsibility and any local or officially recognized authority.

2.3.13 **Sealed containers**

Food grade containers such as:

(a) hermetically sealed containers;
(b) sealed jars, with anchor and crown type closures;
(c) milk bottles sealed with aluminium caps;
(d) glass jars and bottles with screw caps; and
(e) cans and similar containers with seals.

2.3.14 **Street Food Centre**

Any public place or establishment designated by the relevant authority for the preparation, display and sale of street foods by multiple vendors.

2.3.15 **Street Foods**

Wide range of ready-to-eat foods and beverages (included in Codex definition of food) sold and sometimes prepared in public places, notably streets.

2.3.16 **Street Food Stall**

A place where street food is prepared, displayed, served or sold to the public. It includes carts, tables, benches, baskets, chairs, vehicles with or without wheels and any other structure approved by the relevant authority where on it or in it, any street foods are displayed for sale.

2.3.17 **Waste Water**

Waste water means sullage water arising as a result of the activity of vendors (definition in Regional Guidelines for the Design of Control Measures for Street-Vended Foods (Africa)) resulting from the activity of street food vendors.

2.3.18 **Water containers**

Any form of food grade container which is used solely for the purpose of storing and serving water and has not been used previously for any other purposes which could cause contamination of the water stored in it.

**SECTION 3 – GENERAL REQUIREMENTS**

3.5 **Pest and animal control**

3.5.1 Every vendor shall at all times take appropriate measures to keep his/her stall free from animals (e.g. cats and dogs) and pests (e.g. rodents or insects) to prevent contamination of the food.

3.5.2 Every vendor shall, on becoming aware of the presence of any such pest or harbourage, immediately take all practicable measures to get rid of the pest or harbourage and to prevent re-infestation.

3.5.3 Any food found to have become contaminated by pests shall be appropriately disposed of in a hygienic manner.

3.5.4 The direct or indirect contamination of food with pest control materials such as poisons must be prevented.

**SECTION 4 – VENDORS**

4.1 **Health condition of the vendors**
4.1.1 No vendor, assistant or food handler shall be allowed to perform his/her job if showing suffering from any of the following diseases and symptoms: jaundice, diarrhoea, vomiting, fever, sore throat with fever, discharge from ear, eye and nose, visibly infected skin lesions (boils, cuts, etc.). In such cases, he/she shall cease from handling food in any capacity and seek medical treatment.

4.1.2 Any vendor, helper or food handler who has been identified as or is known to be or has previously been a carrier of food borne disease organisms, shall not be involved in any food handling activity until certified by a Medical Officer of Health or any other medical practitioner as a non-carrier.

4.1.3 Any vendor, helper or food handler shall be required to be immunized as required by the relevant authority.

4.2 Personal hygiene and behaviour

Every vendor, helper or food handler, during the conduct of his business, shall observe the following:

4.2.1 Wear an identification tag if issued and required by the relevant authority.

4.2.2 **Wear clean clothing.** Dress in clean and proper attire.

4.2.3 Wash hands thoroughly with soap and **running clean water** before and after handling food, after visiting the toilet, after handling unsanitary articles, touching animals, touching raw food, after handling toxic and dangerous materials as and when necessary. **If running clean water is not available, an acceptable alternative hand washing method should be agreed to by the relevant authority.**

4.2.4 Finger nails should be kept short and clean at all times, and avoid wearing jewellery or ornaments during food preparation.

4.2.5 Hair should be kept clean and tidy and should be covered during operation.

4.2.6 Non-infected cuts shall be completely protected by a waterproof dressing which is firmly secured and routinely changed.

4.2.7 Shall not smoke or chew chewing-gum while preparing or serving food.

4.2.8 Refrain from any unhygienic practices such as spitting and cleaning nose, ears or any other body orifice or touching any body part while handling food.

4.2.9 Shall not sneeze or cough **over or onto** the food.

4.2.10 No vendor is allowed to use the stall as a sleeping or dwelling place, or for any other personal activity.

4.3 Training of vendors

4.3.1 The vendor shall ensure that he/she and all food handlers and helpers have completed basic food hygiene training by the competent authority or other institution recognized or approved by the competent authority. Every vendor, helper or food handler shall undergo a basic food hygiene training prior to licensing and further training as required by the relevant authority. Training is to be conducted by the relevant authority or other institutions recognized or approved by the relevant authorities. Vendors should also be made aware of their responsibility to consumers and be informed of available credit facilities and other sources of finance to assist and improve their businesses.

4.4 Vendors associations

**Vendors are encouraged to be members of their local street food vendor association.** The formation of street food vendor associations or cooperatives should be encouraged to provide a liaison point with the relevant authorities in view of facilitating the implementation of control measures.

SECTION 5 – DESIGN AND STRUCTURE

5.1 Location

5.1.1 The location of street food stall(s) should be suitable for the purpose of avoiding contamination of the food prepared and served or sold at or from the stall. Stalls shall be located in areas designated by the relevant authorities.

5.1.2 The area where the stall is located and immediate surroundings should be easily cleaned and capable of withstanding repeated washing and scrubbing.
5.1.3 The space in and around the **street food stall** vendors' stall shall be free of unnecessary stored goods or articles and discarded articles in order to permit easy access for cleaning.

5.1.4 The stall should have a convenient access to an inlet of a drainage system or any suitable means of disposing waste water in a sanitary manner.

### 5.2 Structures

5.2.1 **Street food stall** Vendors' stalls shall be of a type approved by the competent authority and shall be made of materials that shall be cleaned and disinfected and maintained in a good state of repair, constructed from impervious materials that can be easily cleaned such as stainless steel, aluminium, glazed tiles or any other materials as approved by the relevant authority. It shall be properly constructed as to be readily cleaned and maintained in a good state of repair at all times.

5.2.2 Food preparation areas and **food contact** working surfaces should be made of a smooth and impermeable food grade material.

5.2.3 All cooking ranges, washing equipment, working tables, shelves and cupboards on or in which food is placed should be at least 45 cm above the ground.

5.2.4 There should be adequate provision of artificial light of sufficient intensity to ensure a reasonable standard of illumination for every part of the stall.

### 5.3 Sanitation

5.3.1 **Water supply**

Vendors should ensure sufficient supply of potable water at all times. Where necessary, such as in the case of mobile vendors or where potable water supply is not yet available, potable water should be stored in clean water containers.

5.3.2 **Waste water disposal**

Vendors' stalls should have an efficient waste water disposal system which should be maintained in a good state of repair and working order. The system should be large enough to carry peak loads and be provided with traps to ensure only liquid waste is discharged into the drain/sewer.

5.3.3 **Solid waste disposal**

Solid waste material should be handled in such a manner as to avoid contamination of food and/or potable water. Waste should be removed from the working area of the stall as often as necessary and at least daily. All solid waste should be properly disposed into suitable containers which are secured with tight fitting lids or placed in rubbish bins or central rubbish bins.

**Waste receptacles, equipment which has come into contact with the waste and waste storage areas should be cleaned and disinfected when required by the relevant authority. Only appropriate and suitable sanitizing agents should be used.**

In areas without garbage collection services, solid waste is to be disposed of in a sanitary manner, as recommended, or approved by the relevant authority. Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste should be cleaned using one of the methods described in paragraph (5.6). The waste storage area should also be cleaned daily.

**Waste receptacles, equipment which has come into contact with the waste and waste storage areas should be disinfected when required by the relevant authority. Only appropriate and suitable sanitizing agents should be used.**

**In areas without garbage collection service, solid waste is to be disposed of in a sanitary manner, as recommended or approved by the competent authority.**

5.3.4 **Cleaning**

All **food contact surfaces should be cleaned and disinfected and** working surfaces, table tops, floors and surrounding areas should be thoroughly cleaned at least daily, using one of the methods described in paragraph (6.5-6.6)
Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste should be cleaned using one of the methods described in paragraph (5.66.5). The waste storage area should also be cleaned daily.

5.3.5 Toilets
Every vendor, helper or food handler should have easy access to adequate facilities which are approved by the relevant authorities and kept at all times in a clean and operational condition.

SECTION 6 – APPLIANCES
6.1 The appliances should be kept clean. The equipment, including containers for storing drinking water, should be made of materials which do not transmit toxic substances, odour or taste, are not absorbent (unless its use is intended for that purpose and will not result in food contamination), are resistant to corrosion and capable of withstanding repeated cleaning and disinfection.

6.2 Every cutting surface used in the preparation of food should be free from cracks and crevices, with only reasonable wear and tear, and should be cleaned using one of the methods described in Section 6.5 at least on the following occasions:

(a) before and after daily operations; and

(b) immediately after being used to prepare raw food especially after having put unclean material or food on it if the surface is subsequently to be used to cut street foods or foods to be consumed raw.

6.3 Cooked and uncooked food should be handled with separate utensils.

6.4 Every vendor should ensure that all defective, damaged, cracked, rusted, chipped and unsuitable appliances and crockery are removed from use and discarded.

6.5 All non-disposable utensils should be regularly cleaned by thoroughly washing them in warm water containing adequate amount of soap or other suitable detergents and then either immersing them for one-half (30 seconds) minute in boiling clean water and draining them or, for two (2) minutes in potable water at a temperature of not less than 77°C and draining them.

In the case where non-disposable crockery is used and water at 77°C or boiling temperatures is unavailable, potable water, wash soap or detergent and running water rinse is allowed. However, this method is not preferred.

6.6 Disposable crockery shall be used only once and properly disposed of. In the case where non-disposable crockery is used, the crockery is to be cleaned after each use using the method described for utensils in paragraph 6.5 5.6.

6.7 All appliances are to be maintained in good state of repair and working order.

6.8 All washed and clean utensils and crockery should be handled, stored or transported separately from unclean and used utensils and crockery and other sources of contamination. They shall be stored in a clean and protected area which is not accessible to animals or pests.

6.9 Only containers made of food grade material, not previously used for non-food use, shall be used.

6.10 Wash basins and sinks for cleaning utensils and washing hands should always be clean and maintained in a good state of repair.

6.11 Towels used for wiping crockery should be clean, handled in a sanitary manner and only be used for that purpose.

6.12 Containers used for table side condiments should be kept clean and maintained in good condition and protected from pests.

6.13 All hand service articles such as napkins, towels and hand wipes should be of the disposable type.

6.14 Hand washing facilities such as hand wash basins, disposable towels and soap should be provided at all times.
SECTION 7 – FOOD PREPARATION

7.1 Requirements for ingredients

Every vendor should ensure the following

7.1.1 Supply of all raw food, other ingredients, including ice, must be from known and reputable reliable sources.

7.1.2 The food handling method employed should be such as to minimize the loss of nutrients.

7.1.3 Freshness and wholesomeness of ingredients to maintain quality and safety of food.

7.1.4 Transportation of ingredients should be made in a manner so as to prevent exposure to the environment, spoilage and contamination.

7.1.5 Only permitted food additives should be used and the amount added should follow the specifications provided.

7.2 Cooking and handling

7.2.1 Thoroughly wash fresh vegetables and fruit whether for cooking or consuming raw, with sufficient running potable water, to remove adhering surface contamination. For any soaking, potable water should be used.

7.2.2 Where appropriate, wash raw food before using in food preparation to reduce the risk of contamination. Never wash perishable raw food with other foods that will be consumed raw or in a semi-cooked state.

7.2.3 There should be an area for handling, storing, cleaning and preparing raw food ingredients, separate and apart from the cooked, street food display, handling and serving areas.

7.2.4 Thawing: Frozen products, especially frozen vegetables, can be cooked without thawing. However, large pieces of meat or large poultry carcasses often need to be thawed before cooking. When thawing is carried out as an operation separated from cooking this should be performed only in:

(a) a refrigerator or purpose-built thawing cabinet maintained at a temperature of 4°C; or
(b) running potable water maintained at a temperature not above 21°C for a period not exceeding 4 hours;
(c) a commercial microwave oven only when the food will be immediately transferred to conventional cooking units as part of a continuous cooking process or when the entire, uninterrupted cooking process takes place in the microwave oven.

NOTE: Hazards associated with thawing include cross-contamination from drip and growth of micro-organisms on the outside before the inside has thawed. Thawed meat and poultry products should be checked frequently to make sure the thawing process is complete before further processing or the processing time should be increased to take into account the temperature of the meat.

7.2.5 The time and temperature of cooking should be sufficient to reduce to safe levels any pathogens that may be present in the food, ensure the destruction of non-spore forming pathogenic micro-organisms.

7.2.6 Water used for the purpose of drinking, preparation of hot or cold drinks and beverages should be potable.

7.2.7 Ice should be made from potable water. Ice should be handled and stored so as to protect it from contamination. Containers used to transport or store ice should meet the requirements for water containers prescribed by Section 2.3.18.

7.2.8 Food should not be re-heated more than once and only the portion of the food to be served should be re-heated. A temperature of at least 75°C should be reached in the centre of the food within one hour of removing the food from refrigeration. Lower temperatures may be used for reheating providing the time/temperature combinations used are equivalent in terms of destruction of microorganisms to heating to a temperature of 75°C. (concerns over food handlers correctly using alternatives)

7.2.9 Utensils used for tasting food should be washed immediately after each use.
7.3 Serving food

Every vendor should observe the following:

7.3.1 All vendors purchasing street foods for the purpose of serving or selling must assure that such food is from licensed and reliable sources.

7.3.2 Cooked street foods should not be handled with bare hands. Clean tongs, forks, spoons or disposable gloves should be used when handling, serving or selling food.

7.3.3 All crockery used should be clean and dry and not handled by touching the food contact surfaces.

7.3.4 Plates filled with food should not be stacked one on top of the other during display, storing or serving.

7.3.5 Food grade packing materials should be used.

7.3.6 Printed material should preferably never be used to serve food. Only food grade aluminium foil, waxed paper, food grade plastic and any other suitable material should be used for packing and serving food.

7.3.7 Never blow into plastic bags, wrappers or packages used for food.

7.3.8 All beverages offered for sale should be dispensed only in their individual original sealed containers or from taps fitted to bulk containers and made of food grade plastic or other suitable material. Bulk containers should be covered with tight fitting lids.

7.3.9 Cut fruit or other foods ordinarily consumed in the state in which they are sold may be set out in an enclosed display case, cabinet or similar type of protective device and should be displayed in a manner to protect the food from contamination, which will not affect the wholesomeness and cleanliness of such foods.

7.3.10 Food handlers should avoid handling money. If this is unavoidable, the food handler should wash his hands before handling food again after handling money.

7.3.11 Ready-to-eat foods intended for continuous serving should be protected from environmental contamination and kept at the following holding temperatures:

(a) for food served hot..... 60°C or above;
(b) for food served cold..... 5°C or below;

Frozen food should be maintained frozen. (c) for food served frozen..... -18°C or below.

7.3.12 A food warmer should be used to maintain continuous holding temperatures (Section 7.3.11 (i)), and should not be used for re-heating purposes (Section 7.2.8).

7.4 Unsold Food

All unsold cooked food and prepared beverages that cannot be properly preserved should be safely disposed of at the end of the day if they cannot be stored in a sanitary manner.

7.5 Transportation of street foods

7.5.1 Street foods which require transportation to the point of sale/stall should be placed in a well protected, covered and clean container to avoid contamination.

7.5.2 Any vehicle used in transporting food should be clean and in good condition, appropriately equipped to accommodate any special requirements of the food being transported and provide protection from environmental contamination.

7.5.3 Perishable food should be transported under temperature control. Milk should be transported to the point of sale in an insulated container maintained at a maximum temperature of 4°C.

7.5.4 Street foods should not be transported together with raw food and ingredients, animals, toxic substances and any other materials which may contaminate the food.

7.6 Food storage

7.6.1 The food should at all times be kept clean and free from contamination, and be adequately protected from pests, environmental contaminants and stored at proper temperatures where appropriate.
7.6.2 Readily perishable food should be placed or stacked so that it is not likely to be contaminated by contact with raw food, pet food, toxic materials or any other materials which may cause contamination. The bulk of readily perishable foods should be stored in clean containers under temperature control, placed in a clean ice box or refrigerator in which the food should not exceed a temperature 10°C. Quantities displayed for continuous serving should be handled according to the requirements listed in Section 7.3.11.

7.6.3 All dry ingredients should be stored and maintained in their original labelled commercial container or subsequent containers and should be properly labelled as to the content and designed to prevent moisture absorption.

7.6.4 All non-perishable food should be stored in a clean, protected and closed container/cupboard to prevent cross contamination by pests.

7.6.5 Once cleaned, following the requirements of Sections 7.2.1 and 7.2.2, the bulk of perishable raw food including wet milled legumes, cereals or pulses should be stored in clean separate containers preferably placed in a clean ice box, a refrigerator or a freezer to prevent spoilage.

7.6.6 Refrigerators and freezers should not be overloaded and their temperatures should be maintained at a maximum of 4°C and -18°C or below, respectively.

7.6.7 All enclosed spaces, cupboards, shelves and racks used for the storage of food should be constructed so as to be easily cleaned and to protect the food from pests.

7.6.8 All food stored in bulk should be stored in an orderly fashion and should be placed so as to facilitate ventilation, inspection and the detection of pests.

7.6.9 All food should be stored and handled separately from toxic, poisonous, deleterious and injurious substances.

7.6.10 The principle "First in, first out" should be applied to stock rotation.

7.6.11 Date marking on all food containers shall be checked before the food is used. Expired food shall not be sold or used for the preparation of food.

SECTION 8 – STREET FOOD CENTRES

8.1 General requirements

All vendors located in a street food centre should comply with all provisions stated in the officially recognized regulations applicable to street food vendors.

8.2 Location, design and construction and facility

8.2.1 The location of any street food centre is to be approved beforehand by the relevant authority, having taken into consideration the provisions stated in Section 5.1 - Location, of these Guidelines.

8.2.2 The design of the street food centre shall:

(a) be reviewed and approved beforehand by the relevant authority;
(b) provide sufficient and adequate space and orderly placement of vendor stalls, carts, display cases, food preparation, handling, storing, serving and selling areas;
(c) allow for the orderly flow of materials and goods, in and out of the centres, which will prevent possible routes of food contamination;
(d) allow for the proper placement of client facilities, such as toilets, hand washing and eating facilities and be located or arranged in a manner that prevents routes of food contamination;
(e) provide suitable, sufficient and properly placed areas for solid waste storage and crockery and appliance cleaning, washing and sanitizing;
(f) be adequately ventilated to remove hazardous obnoxious gases and odours, cooking fuel fumes and other offensive airborne materials and provide a continuous and sufficient supply of fresh air to support the activities within the centre;
(g) be provided with sufficient and adequate electrical power supply to support the vendors in the centre to operate appliances, equipment and other implements used in the preparation, handling, storage, serving and selling of food; and

(h) have available an ample supply of potable water, under adequate pressure and of suitable temperature, with adequate facilities for its storage, where necessary, and distribution, and with adequate protection against contamination.

**NOTE:** Samples should be taken regularly, but the frequency should depend upon the origin and the usage of the water, e.g. more frequent from private supplies that from public supplies. Chlorine or other suitable disinfectants may be used. If chlorination has been employed checks should be made daily by chemical tests for available chlorine. The point of sampling should preferably be at the point of usage, but occasionally it would be useful to sample at the point of entry of the water to the establishment.

8.2.3 Street food centres shall be properly constructed in a manner using materials approved by the relevant authority, taking into consideration the provisions stated in the paragraph on “Structure, of these Guidelines. In addition to these provisions, street food centres should:

(a) have smooth cement, glazed tile or tarmac paved floors, equipped with properly placed floor drains for the purpose of removing surface water and to facilitate cleaning and sanitizing;

(b) have, where applicable, smooth non-permeable surface walls or partitions, such as glazed tile, to facilitate cleaning and sanitizing;

(c) have, if applicable, a smooth non-absorbent ceiling to facilitate cleaning;

(d) provide sufficient artificial lighting, properly placed to facilitate food preparation, handling, storage, serving and selling for each vendor located at the centre;

(e) provide for smoke hoods and flues above cooking ranges to enable the removal of fuel and cooking gases, smoke and fumes from the centre into the open air.

(f) provide centralized or individualized appliance, crockery, utensil and other implement washing facilities, equipped with hot and cold running potable water, wash basins or sinks with appropriate drains to an approved sewer or drain system, detergent and sanitizing agents to satisfy the proper sanitary and complete cleaning needs of the vendors in the centre; and

(g) comply with any other requirement of the relevant authority related to the structure of street food centres.

8.3 Liquid and solid waste

8.3.1 Pertaining to liquid waste disposal, street food centres are to:

(a) be equipped with an efficient centralized or individual (for each vendor in the centre) liquid waste disposal system(s) approved by the relevant authority and of suitable size and design to exceed the level of demand for liquid waste disposal at peak levels of activity by the vendors in the centre;

(b) maintain the liquid sewage disposal system in good working condition;

(c) ensure that the liquid waste disposal system exits to a relevant authority approved sewage drain system capable of efficiently carrying away the liquid waste from the centre; and

(d) comply with any other relevant authority requirements related to liquid waste disposal.

8.3.2 Regarding solid waste disposal, street food centres are to have an efficient system for disposal of solid waste complying with all solid waste disposal requirements of the relevant authority, to include:

(a) the allocation of an appropriate and separate amount of space for solid waste storage, located at a convenient but suitably distant location from food preparation, storage, handling, serving or selling areas to prevent contamination;

(b) sufficient number of suitably designed and constructed waterproof solid waste containers with tight fitting lids to adequately contain the volume of accumulated solid waste produced by vendor activity in one day. Containers should be lined with suitable disposable liners or inner containers for securing waste and which are easy to handle at time of disposal;
(c) the daily, and more often if necessary, disposal of solid waste from the street food centre to:
   (i) rubbish bins approved, designed and intended for the centralized collection of solid waste by garbage service agencies;
   (ii) approved sanitary land fill; or
   (iii) other disposal methods authorized and approved by the relevant authority.
(d) routine inspection of solid waste disposal areas for the presence or harbourage of pests, taking any and all practical measures to eliminate and further prevent any infestation; and
(e) compliance with any other requirement of the relevant authority related to solid waste disposal.

8.4 Customer hygiene facilities
Street food centres should have sufficient toilet facilities for each gender to accommodate the vendors, their employees and the clientele, conveniently located but separate and apart from food preparation, handling, storage, serving and selling areas, in order to prevent contamination of the food. The toilet facilities should be approved and subject to all requirements for such facilities by the relevant authority. Among other requirements the facilities should:
   (a) have smooth walls of glazed tile to a height of at least two (2) meters;
   (b) should be clean, free of bad odours and provided with a flushing system;
   (c) be well lit, ventilated, and routinely cleaned and sanitized and maintained in good working condition;
   (d) include hand washing and drying facilities and properly supplied with soap and other needed supplies;
   (e) contain posters instructing vendors and employees to wash hands thoroughly after each use of the toilet facilities before returning to work; and
   (f) have doors which are equipped with self-closing devices.
APPENDIX III

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION
OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS
(at Step 5/8)

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1. INTRODUCTION

1. Diseases caused by foodborne pathogens constitute a major burden to consumers, food business operators and national governments. Therefore, the prevention and control of these diseases are international public health goals. These goals have traditionally been pursued, in part, through the establishment of metrics such as the microbiological criterion, reflecting knowledge and experience of Good Hygienic Practice (GHP) and the impact of potential hazards on consumer health. Microbiological criteria have been used for many years and have contributed to improving food hygiene in general, even when established based on empirical observation of what is achieved under existing measures without any explicit linkage to specific levels of public health protection. Advances in microbiological risk assessment (MRA), and the use of the risk management framework are increasingly making a more quantifiable estimation of the public health risk and a determination of the effect of interventions possible. This has led to a series of additional food safety risk management metrics: Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC) (see Annex II of the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)). Where MRA models are available or these metrics have been elaborated, they can allow the establishment of a more direct relationship between microbiological criteria and public health outcomes.

2. The establishment and application of microbiological criteria should comply with the principles outlined in this document and should be based on scientific information and analysis. When sufficient data are available, a risk assessment may be conducted on foodstuffs and their use.

3. The microbiological safety of foods is managed by the effective implementation of control measures that have been validated, where appropriate, throughout the food chain to minimise contamination and improve food safety. This preventative approach offers more advantages than sole reliance on microbiological testing through acceptance sampling of individual lots of the final product to be placed on the market. However, the establishment of microbiological criteria may be appropriate for verifying that food safety control systems are implemented correctly.
4. Criteria for monitoring of the food-processing environment are often considered important parts of the food safety control system. Since they cannot be defined as specifically as microbiological criteria for food they generally are not used in defining the acceptability of food, and therefore they are not in the scope of the document, despite their utility in managing food safety.

5. The required stringency of food safety control systems, including the microbiological criteria used, should be appropriate to protect the health of the consumer and ensure fair practices in food trade. Microbiological criteria used should be capable of verifying that the appropriate level of control is achieved.

6. Codex Alimentarius has a role in recommending microbiological criteria at the international level. National governments may choose to adopt Codex microbiological criteria into their national systems or use them as a starting point for addressing their intended public health goals. National governments also may establish and apply their own microbiological criteria. Food business operators may establish and apply microbiological criteria within the context of their food safety control systems.

7. This document should be read in conjunction with the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007), the General Guidelines on Sampling (CAC/GL 50-2004) and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999).

2. SCOPE AND DEFINITIONS

2.1 Scope

8. These Principles and Guidelines are intended to provide a framework for national governments and food business operators on the establishment and application of microbiological criteria that can be applied for food safety and other aspects of food hygiene. Microbiological criteria established for the monitoring of the food processing environment are not in the scope of this document. Microbiological criteria can be applied, but are not limited to, to the following:

- Bacteria, viruses, moulds, yeasts, and algae;
- Protozoa and helminths;
- Their toxins/metabolites; and
- Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. anti-microbial resistance genes) where/when linked to the presence of viable cells where appropriate.

2.2 Definitions

9. A microbiological criterion is a risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain.

10. Other definitions relevant to these guidelines include:

- Appropriate Level of Protection (ALOP)\(^1\)
- Food Safety Objective (FSO)\(^2\)
- Performance Objective (PO)\(^2\)
- Performance Criterion (PC)\(^2\)
- Lot\(^3\)
- Sample\(^3\)
- Food safety control system\(^4\)
- Validation\(^4\)
- Verification\(^4\)
- Attributes sampling plans\(^3\)
- Variables sampling plans\(^3\)

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\(^1\) Guidelines for Food Import Control Systems (CAC/GL 47-2003)
\(^2\) Codex Alimentarius Commission, Procedural Manual
\(^3\) General Guidelines on Sampling (CAC/GL 50-2004)
\(^4\) Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008)
3. GENERAL PRINCIPLES

- A microbiological criterion should be appropriate to protect the health of the consumer and where appropriate, also ensure fair practices in food trade.
- A microbiological criterion should be practical and feasible and established only when necessary.
- The purpose of establishing and applying a microbiological criterion should be clearly articulated.
- The establishment of microbiological criteria should be based on scientific information and analysis and follow a structured and transparent approach.
- Microbiological criteria should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.
- The intended as well as the actual use of the final product by consumers needs to be considered when setting a microbiological criterion.
- The required stringency of a microbiological criterion used should be appropriate to its intended purpose.
- Periodic reviews of microbiological criteria should be conducted, as appropriate, in order to ensure that microbiological criteria continue to be relevant to the stated purpose under current conditions and practices.

4. ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA

4.1 General considerations

11. When considering the establishment of microbiological criteria, a variety of approaches can be used depending on the risk management objectives and the available level of knowledge and data. These approaches can range from developing microbiological criteria based on empirical knowledge related to GHPs, to using scientific knowledge of food safety control systems such as through HACCP, or by conducting a risk assessment. The choice of the approach should be aligned with the risk management objectives and decisions relating to food safety and suitability.

12. Since the levels/prevalence of a microorganism can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological criterion is established at a specified point in the food chain.

13. The need for a microbiological criterion should be demonstrated, e.g. by epidemiological evidence that the food under consideration may represent a significant public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment.

4.2 Purpose

14. There may be multiple reasons for establishing and applying microbiological criteria. The purposes of microbiological criteria include, but are not limited to, the following:
   i) Evaluating a specific lot of food to determine its acceptance or rejection, in particular if its history is unknown.
   ii) Verifying the performance of a food safety control system or its elements along the food chain, e.g. prerequisite programs and/or HACCP systems.
   iii) Verifying the microbiological status of foods in relation to acceptance criteria specified between food business operators.
   iv) Verifying that the selected control measures are meeting POs and/or FSOs.
   v) Providing information to food business operators on microbiological levels, which should be achieved when applying best practices.

15. In addition, a microbiological criterion is a valuable risk management metric when applied to detect potential unforeseen problems in the design and/or operation of a food safety control system and for obtaining safety and suitability information that is not otherwise available.

4.3 Relationship between Microbiological Criteria, other Microbiological Risk Management Metrics and ALOP

16. Microbiological criteria may be used by competent authorities and food business operators to operationalize the ALOP either directly or through other microbiological risk management metrics (e.g. PO, FSO). This requires the use of quantitative risk assessment. The risk estimation should include a
combination of several factors such as the prevalence and concentration distribution of target microorganisms, as well as any changes in these after the step for which the microbiological criterion has been set. The risk assessment should include a characterization of the variability inherent to the food production system and express the uncertainty in the risk estimate. Ongoing efforts to reduce the complexity of risk assessment should help facilitate the development and use of risk-based microbiological criteria.

17. A microbiological criterion can be linked directly to the ALOP, without explicit articulation of an FSO or a PO. One approach involves testing the acceptability of individual lots and evaluating the relative risk to public health of the lot as compared to the ALOP. Another approach is to link a microbiological criterion directly to an ALOP, using a risk assessment model to estimate the reduction in public health risk as a result of applying corrective actions to lots or processes that do not conform to the microbiological criterion.

18. Statistical models can be used to translate a PO or FSO to a microbiological criterion. The link between the PO or the FSO and the ALOP should also be demonstrated. To establish such a microbiological criterion for a food, an assumption needs to be made regarding the distribution of the target microorganism in the food. A log-normal distribution is often assumed and a default value for the standard deviation applied. Furthermore, the maximum frequency and/or concentration of the hazard needs to be defined in the FSO or PO. If a concentration is used as a limit, also the proportion (e.g. 95%, 99%) of the distribution of possible concentrations that satisfies this limit should be defined.

4.4 Components and other considerations

19. A microbiological criterion consists of the following components:
   - The purpose of the microbiological criterion;
   - The food, process or food safety control system to which the microbiological criterion applies;
   - The specified point in the food chain where the microbiological criterion applies;
   - The microorganism(s) and the reason for its selection;
   - The microbiological limits ($m$, $M$; see Section 4.6) or other limits (e.g. a level of risk);
   - A sampling plan defining the number of sample units to be taken ($n$), the size of the analytical unit and where appropriate, the acceptance number ($c$);
   - Depending on its purpose, an indication of the statistical performance of the sampling plan; and
   - Analytical methods and their performance parameters.

20. Consideration should be given to the action to be taken when the microbiological criterion is not met and the action should be specified (see Section 4.11).

21. Other considerations could include, but are not limited to, the following:
   - Type of sample (e.g. type of food matrix, raw materials, finished product);
   - Sampling tools and techniques;
   - Prevalence and concentration data for the organism of concern (e.g. baseline data)
   - Frequency and timing of sampling;
   - Type of sampling (randomized, stratified etc.);
   - Methodology used and, when appropriate, suitable conditions for pooling of samples;
   - Economic and administrative feasibility, in particular in the choice of sampling plan;
   - Interpretation of results;
   - Record keeping;
   - The intended and actual use of the food;
   - The microbiological status of the raw material(s);
   - The effect of processing on the microbiological status of the food;
   - The likelihood and consequences of microbial contamination and/or growth and inactivation during subsequent handling, packaging, storage, preparation and use; and
   - The likelihood of detection.

22. In addition, for a microbiological criterion targeting a foodborne pathogen, consideration should be given to:
   - The evidence of actual or potential risks to health; and
• The population at risk and consumption habits.

4.5 Sampling plan

23. In the development and selection of sampling plans consideration should be given to the principles in the General Guidelines on Sampling (CAC/GL 50-2004).

24. The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. Variables sampling plans for inspection evaluate quantitative data without grouping it into classes. Variables sampling plans require information about the distribution of microorganisms and typically assume that the inspected variables follow a normal or log-normal distribution. Variables sampling plans are seldom used, in part because they are not applicable to presence/absence testing. For microbiological criteria based on quantitative levels, where information is available on within lot and between lot variability, variables sampling plans can be tailored for the specific condition of a particular production process, resulting in a more informative interpretation of results.

25. In practice, most microbiological sampling plans designed for lot acceptance are attributes sampling plans. For these, to assess the probability of acceptance as a function of the percentage of non-conforming units, no knowledge or assumption about the underlying distribution of the microorganism is required. For attributes sampling plans to be valid, all that is required is that some probability based sampling technique (e.g. simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. For these plans, to assess the probability of acceptance as a function of the level of the target microorganism, it is necessary to know or estimate the distribution of microorganisms.

26. The number and size of analytical units should be those stated in the sampling plan and should not be modified where the microbiological criterion has been established for regulatory compliance. In unusual circumstances (e.g. during a foodborne outbreak situation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market) a sampling plan with increased stringency may become appropriate and it may become necessary to adopt an alternative microbiological criterion. The rules and procedures for switching from one sampling plan to another should be clearly stated in the sampling approach. Unless the sampling plan specifies otherwise, a lot should not be subjected to repeat testing.

4.6 Microbiological and/or other limits

27. Microbiological limits separate conforming from non-conforming analytical units.

28. Where the microbiological limits $m$ and $M$ are part of an attributes sampling plan further defined through $n$, $c$, and the size of the analytical unit, they are expressed as presence/absence or concentration of the microorganism in one analytical unit.

29. In the establishment of microbiological limits in the context of microbiological criteria, any changes (e.g. decrease or increase in numbers) in the levels of the target microorganism likely to occur after the point for which the microbiological criterion has been set should be taken into account, where appropriate. It should also be clearly stated in the microbiological criterion whether the limits apply to every analytical unit, to the average, or to another specific method of calculation.

30. In the case of a two-class attributes sampling plan, there is one upper microbiological limit on the acceptable concentration in the analytical unit, denoted by $m$, and the acceptance number $c$ is the maximum tolerable number of analytical units above the limit.

31. For a three-class attributes sampling plan the microbiological limit $m$ separates conforming from marginally acceptable, and a limit $M$ defines non-conforming analytical units. In this case, the acceptance number $c$ refers to the maximum allowable number of marginally acceptable analytical units.

32. Alternatives to microbiological limits $m$ and $M$ may be used in applying microbiological criteria to other risk management metrics or the ALOP.

4.7 Analytical methods

33. Depending on the microbiological limit (e.g. presence/absence of a specific foodborne pathogen), an appropriate analytical method should be selected. The methods used should be fit for purpose, meaning the method has been validated for relevant performance characteristics (e.g. limit of detection, repeatability, reproducibility, inclusivity, exclusivity). The validation study should be based on internationally accepted protocols and include an interlaboratory study. If not available, a validation should be done by the laboratory applying the method, according to a standardised protocol.

34. The analytical methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.
35. The results of testing may be impacted by compositing (i.e. pooling) of sample units prior to analysis. Compositing will affect the final concentration in the tested sample and is not appropriate for enumeration methods of analysis or within three-class sampling plans. Compositing may be considered in the case of presence/absence testing within a two-class sampling plan, as long as it is ensured that the result of testing will not be affected when compared to testing of individual analytical units.

4.8 Statistical performance

36. The statistical performance of a sampling plan is usually illustrated by its operating characteristic (OC) curve, which describes the probability of acceptance as a function of the actual proportion of non-conforming analytical units or concentration of the microorganisms in the food. An OC curve can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan.

37. Web-based tools for evaluation of sampling plans developed by FAO and WHO through JEMRA\(^5\) or by others can be utilised to evaluate sampling plans under consideration.

4.9 Moving Window

38. In a moving window approach a sufficient number of sample units \((n)\) is collected for a defined period of time (the “window”). The results of the latest \(n\) sample units are compared with the microbiological limit(s) \((m, M)\) using the acceptance number \(c\). Each time a new result from the sampling period is available, it is added to the window while the oldest result is removed, creating the “moving window”. This approach can also be applied to a set of results, e.g. results obtained during a week. The window, always consisting of \(n\) results, moves one result or set of results forward in time. In determining the size of the moving window consideration should be given to the combination of the production frequency and sample frequency necessary to obtain a sufficient number of results that enables appropriate verification of performance of a process or a food safety control system.

39. The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system. As in the traditional point-in-time approach commonly used in connection with microbiological criteria, the moving window determines the acceptability of the performance so that appropriate interventions can be made in case of unacceptable shifts in control.

40. The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner. If more than \(c\) out of \(n\) results is above the limit \(m\), or the limit \(M\) is exceeded, then corrective action is required.

41. The moving window approach should not be confused with trend analysis, which is described in the following section.

4.10 Trend Analysis

42. Trend analysis is a procedure to detect a change in the patterns of observations over a period of time (usually over a relatively long period of time, often not predefined). It can be applied to many types of information including results of microbiological testing against a microbiological criterion. Trend analysis can detect a gradual loss of control that might not be detected by a moving window approach, as well as a more sudden loss of control.

43. Trend analysis may show changes or patterns in the data that are a result of unwanted changes in the manufacturing process enabling the food business operator to take corrective actions before the food safety control system is out of control. The trends (or patterns) can be visualized, e.g. by displaying the test results graphically.

4.11 Action to be taken when the microbiological criterion is not met

44. In situations of non-conformance with the microbiological criterion (unsatisfactory results), actions to be applied should include corrective actions related to the purpose of the testing. These actions should be based on an assessment of the risk to the consumer where relevant; the point in the food chain, and the food specified and may consider history of conformance. Food business operators should re-evaluate their food safety control systems, including GHP and operational procedures, and/or further investigation to determine appropriate preventative actions to be taken.

45. In the event of a non-conformance with a microbiological criterion for a foodborne pathogen, actions should include appropriate product containment and disposition. This may include further processing, diversion to an alternate use, withdrawal and/or recall, rework, rejection or destruction of product, and/or

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\(^5\) [http://www.mramodels.org/sampling/](http://www.mramodels.org/sampling/)
further investigation to determine appropriate actions to be taken. Other actions taken may include more frequent sampling, inspection and audits, fines or official suspension of operations.

4.12 Documentation and Record Keeping

46. Documentation and records are essential to support the microbiological criterion, e.g. documentation on scientific evidence underpinning the microbiological criterion, records on application/performance of the microbiological criterion. Records such as test reports should give the information needed for complete identification of the sample, the sampling plan, the analytical method, the results and, if appropriate, their interpretation. Reporting against the microbiological criterion may be required by some national governments. See also Section 5.7 of the General Principles of Food Hygiene (CAC/RCP 1-1969) and Section 2.3.7 of the General Guidelines on Sampling (CAC/GL 50-2004).

47. Records should be maintained documenting all instances of non-conformance with the microbiological criterion, together with records of the corrective actions taken, both to manage food safety risks and to prevent further instances of non-conformance.

5. REVIEW OF MICROBIOLOGICAL CRITERIA FOR FOODS

48. As establishing and implementing microbiological criteria is a part of Microbiological Risk Management (MRM) activities, refer to the Section 8.2 of the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007). In addition, revision of microbiological criteria should be considered in response to revision of other MRM Metrics and also in response to emerging issues or changes in the following, but not limited to:

- Taxonomy, prevalence or distribution for selected microorganisms;
- The incidence of disease including attribution to specific foods;
- Traits of microorganisms (e.g. anti-microbial resistance, virulence);
- The suitability of an indicator organism;
- Available analytical methods/tests/appropriateness of test;
- Food/ingredients/technology/process of food production;
- Food safety control system;
- Population(s) at risk;
- Consumer behaviour or dietary intake pattern of the food concerned;
- Understanding/knowledge of risk;
- Trend analysis results; and
- Required level of assurance.

49. A review of the microbiological criterion may be initiated and carried out by national governments and/or food business operators. Codex members may propose review of microbiological criteria in Codex texts.

50. A review will result in retention, adjustment or revocation of a microbiological criterion, as appropriate.

51. The risk management framework should be used to continuously improve, refine and adjust the relevant components of the microbiological criterion in relation to their effectiveness, to improved scientific knowledge and the increasing knowledge of public health risk and related food safety risk management metrics (FSO, PO and PC). The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria, other metrics and public health outcomes.

52. When microbiological criteria have been developed to address specific risk outcomes they should be reviewed against those outcomes and, if shown not to be effective, they should be adjusted or revoked.
INTRODUCTION

Berry crops are geographically diverse and represent a wide range of phenotypically unique fruits. Not only are they diverse in the size, shape and colours of their fruits, they are also diverse horticulturally, from low growing berries (e.g. strawberries), to small bushes (e.g. blackberries, blueberries, raspberries) and tall shrubs (e.g. blackcurrant and gooseberry). All are perennial but some are cultivated as annuals (e.g. strawberry); most are cultivated while others are collected from the wild (e.g. wild blueberries).

These fruits are relevant to international trade due to increasing consumption of fresh produce and globalization as a result of changes and/or optimization in production and distribution. There is increasing awareness on the risk factors associated with berry consumption on the part of public health officials. Berries have been associated with several foodborne illness outbreaks caused by a broad range of etiological agents, from viruses (Hepatitis A, Norovirus)\(^1\), to bacteria (\(E.\ coli\) O26, O157:H7)\(^2,3\) and protozoa (\(Cyclospora\ cayetanensis, Cryptosporidium\ parvum\))\(^1\).

Most berries are conveniently marketed as ready to eat fruits. The handling of berries during production and harvesting and the broad range of etiological agents that have been associated with berry consumption suggest that the safety of those fruits that are consumed raw is highly dependent on maintaining good hygienic practices along the food chain, including up to the point of consumption.

SECTION 1 - OBJECTIVES

Hygienic recommendations for the primary production of fresh fruits are covered in general under the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003). The primary purpose of this Annex is to provide specific guidance to minimize microbiological hazards during primary production through packing and distribution of fresh berries, as well as fresh berries that are processed without a microbiocidal step (e.g. frozen berries eaten raw and ready-to-eat berries) and consumer use.

SECTION 2 - SCOPE, USE AND DEFINITION

2.1 Scope

This Annex covers specific guidance related to all areas, from primary production to consumption, of berries that are intended to be consumed raw (e.g., fresh berries) and/or are processed without a microbiocidal step.

This Annex encompasses all edible varieties of strawberries (i.e. *Fragaria grandiflora* L. and *Fragaria vesca* L.), raspberries (i.e. *Rubus idaeus* L.), blackberries (i.e. *Rubus* spp.), mulberries (i.e. *Morus* L.), blueberries (i.e. *Vaccinium* spp.), currants and gooseberries (i.e. *Ribes* L.) and groundcherries (i.e. *Physalis peruviana* L.).

For wild berries only the measures for handling and post harvest activities (i.e. from Section 3.3.3 onwards) apply.

2.2 Use

This Annex follows the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and should be used in conjunction with it and other applicable codes such as the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003), Annex I, the *Annex for Ready-to-Eat Fresh Pre-cut Fruits and Vegetables*, Annex II of the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CAC/GL 79-2012), the *Code of Practice for Packaging and Transport of Fresh Fruits and Vegetables* (CAC/RCP 44-1995) and the *Code of Practice for the Processing and Handling of Quick Frozen Foods* (CAC/RCP 8-1976).

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\(^1\) Report - Microbiological hazards in fresh fruits and vegetables of reference for an FAO/WHO Expert Consultation to support the development of commodity-specific annexes for the Codex Alimentarius

\(^2\) Non-O157 Shiga toxin-producing E. coli (STEC) outbreaks, United States. CDC Foodborne Outbreak Online Database (2006)

\(^3\) Fresh Strawberries From Washington County Farm Implicated In E. coli O157 Outbreak In NW Oregon. At [http://oregon.gov/ODA/FSD/strawberries.shtml](http://oregon.gov/ODA/FSD/strawberries.shtml) (2011)
2.3 Definitions
Refer to definitions in the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

SECTION 3 - PRIMARY PRODUCTION

Berries are grown in production sites indoors (e.g. greenhouses) and outdoors, harvested, and may be field packed or transported to a packing establishment.

3.1 Environmental hygiene

3.1.1 Location of the production site
Consideration of production site location should include an evaluation of the slope and the potential for runoff from nearby fields, flood risk as well as hydrological features of nearby sites in relation to the production fields. Growers should take measures to mitigate the risks associated with runoff and flooding, e.g. mapping the production field, terracing, construction of a shallow ditch to prevent runoff from entering the fields, etc.

The effects of some environmental events, such as heavy rains, cannot be controlled. For example, heavy rains may increase the exposure of berries to pathogens if soil contaminated with pathogens splashes onto fruit surfaces. Where appropriate, growers should take into consideration natural uncontrolled events, such as heavy rains and evaluate postponing harvesting berries for direct consumption berries and/or to subject the berries to a treatment that will minimise the risk from pathogens. The risk of contamination is greatest when heavy rains cause flooding and flood waters come in direct contact with berries; berries that have been contacted with flood waters should not be used.

Wet berries are very susceptible to spoilage and often resemble overripe berries leaking juice. Growers should allow a drying period, if possible, before harvesting berries to reduce the risk of contamination with foodborne pathogen.

The proximity of high risk production sites, such as animal production facilities, hazardous waste sites and waste treatment facilities, should be evaluated for the potential to contaminate production fields or the water sources used with microbial or other environmental hazards via, for example, runoff, faecal material, aerosols or organic waste. When the risks are high these production sites should not be used for berry production unless adequate measures can be taken to mitigate the risks.

3.1.2 Wild and domestic animals and human activity

Many wild and domestic animal species and humans that may be present in the production environment are known to be potential carriers of foodborne pathogens. Domestic and wild animals and human activity can present a risk both from direct contamination of the crop and soil as well as from contamination of surface water sources and other inputs. The following should be considered:

- Domestic and wild animals should be excluded from the production area, to the extent possible, using appropriate biological, cultivation, physical and chemical pest control methods. Methods selected should comply with local, regional, and national environmental protection regulations.

- Berry production areas should be properly maintained to reduce the likelihood of vector attraction. Activities to consider include efforts to minimize standing water in fields, restrict access by animals to water sources (may be based on local ordinances for public irrigation systems), and keep production sites and handling areas free of waste and clutter.

- Berry production areas should be evaluated for evidence of the presence of wildlife or domestic animal activity (e.g. presence of animal faeces, bird nests, hairs/furs, large areas of animal tracks, burrowing, or decomposing remains). Where such evidence exists, growers should evaluate the risks and whether the affected parcel of the berry production site should not be harvested for direct consumption.

3.2 Hygienic primary production of berries

Berries are pulpy fruits with high moisture content and a soft skin, which makes them susceptible to physical damage that accelerates deterioration of berries by increasing water loss and provide conditions for contamination during production, harvest and transport. Physical damage to the berries may occur during harvesting from the use of sharp edged storage containers, improper field packing or through careless and poor handling. Rodents, insects and birds may also damage berries, leading to increased microbial spoilage and the potential transmission of foodborne pathogens. Growers should take measures to reduce the extent of damaged fruits during production.
Some berries frequently contact soil directly during growth and/or harvesting. Bird droppings and airborne contaminants (birds nesting around the packing area, nearby livestock, poultry areas or manure storage or treatment facilities, etc.) may also pose a risk of contamination to berries. Growers should use production practices (e.g. site selection, wind breaks) to minimize the contact of berries with airborne contaminants and limit contact with the soil, animal droppings, soil amendments (including natural fertilizers) or direct contact with irrigation water.

Where materials are used under the berries during growing, to minimize contact with the soil, e.g. mulch or biodegradable materials (e.g. straw) or during harvest, e.g. plastic or biodegradable materials (e.g. leaves or papers as liners of biodegradable baskets), to collect harvested fruits, it is recommended that:

- Plastic should be clean and sanitary.
- If biodegradable materials and/or mulch are used, they should be applied only once and not reused in order to prevent cross contamination.

3.2.1.1 Water for primary production

Only clean water should be used for berry production. Growers should identify the sources of water used on the farm (municipality, re-used, irrigation water, reclaimed wastewater, discharge water from aquaculture, well, open canal, reservoir, rivers, lakes, farm ponds, etc.). Growers should assess and manage the risk posed by water as follows:

- Assessing the microbial quality of the sources of water used on the farm for the presence of pathogens should include a documented check detailing the potential for microbial contamination from all possible human and/or animal faecal sources of contamination (e.g. from animals, human habitation, leaks from sanitary facilities on field, sewage treatment, manure and composting operations) and the water’s suitability for its intended use. In the case of identified contamination sources of the water used on the farm, corrective actions should be taken to minimize the risk of contamination. The effectiveness of corrective actions should be verified.
- Identifying and implementing corrective actions is a means to prevent or minimize contamination of water for primary production (e.g. settling or holding ponds that are used for subsequent irrigation and/or harvesting may attract animals or in other ways increase the microbial risks associated with water for irrigation). Possible corrective actions may include fencing to prevent large animal contact, proper maintenance of wells, filtering water, not stirring the sediment when drawing water, building settling or holding ponds, and water treatment facilities. If water treatment is needed, consult with water safety experts.
- Determine if microbial and chemical testing should be done to evaluate the suitability of water for each intended use. Analytical testing may be necessary after a change in irrigation water source, flooding or a heavy rainfall when water is at a higher risk of contamination. If testing, determine and document.
- Frequency of testing should depend on the source of the irrigation water (less for adequately maintained deep wells, more for surface waters) and the risks of environmental contamination, including intermittent or temporary contamination (e.g. heavy rain, flooding, etc.).
- If water testing is limited to non-pathogenic indicators, frequent water tests may be useful to establish the baseline water quality so that subsequent changes in the levels of contamination can be identified.
- If the water source is found to have unacceptable levels of indicator organisms or is contaminated with foodborne pathogens, corrective actions should be taken to ensure that the water is suitable for its intended use. Testing frequency should be increased until consecutive results are within the acceptable range.
Reassessment of the potential for microbial contamination is necessary when events or other conditions indicate that water quality may have changed.

### 3.2.1.2 Manure, biosolids and other natural fertilizers

The use of untreated manure and liquid manure should be avoided to the extent possible. Foodborne pathogens can persist in soil for long periods of time and as some berries have a short production cycle, they could become contaminated by pathogens in the manure.

Growers who are purchasing manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants should obtain documentation from the supplier that identifies the origin, treatment used, tests performed and the results thereof. Growers may also evaluate the need to verify the information provided by the supplier on testing for contamination of natural fertilizer samples or auditing the composting process.

### 3.2.3 Personnel health, hygiene and sanitary facilities

Personal hygiene is critical with manual harvesting due to the amount of human handling that could lead to contamination of berries. Whenever possible, harvesting, packing and inspection processes should be designed to reduce fruit handling. All agricultural workers should properly wash their hands using soap and clean running water and dry their hands before handling berries, particularly during harvesting and post-harvest handling.

If gloves are used, a procedure for glove use in the field should be documented and followed. If the gloves are reusable, they should be made of materials that are easily cleaned and disinfected, and they should be cleaned regularly and stored in a clean area. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated. Glove use alone is not a suitable substitute for good hand washing practices.

Where appropriate, each business operating primary production should have written Standard Operating Procedures (SOPs) that relate to health, hygiene and sanitary facilities. The SOPs should address worker training, facilities and supplies to enable agricultural workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting.

Non-essential persons, casual visitors and, to the extent possible, children, should not be allowed in the harvest area as they may present an increased risk of contamination.

#### 3.2.3.1 Personnel hygiene and sanitary facilities

Growers should consider providing areas away from the field and packing lines for agricultural workers to take breaks and eat. For worker convenience, these areas should provide access to toilet and hand-washing facilities so that agricultural workers can practice proper hygiene.

As far as possible, sanitary facilities should be located close to the field and readily accessible to the work area.

- Sanitary facilities should be located in a manner to encourage their use and reduce the likelihood that agricultural workers will relieve themselves in the field. Facilities should be present in sufficient number to accommodate all personnel.
- Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should identify the areas where it is safe to put portable facilities.
- Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.
- If clean running water is not available, an acceptable alternative hand washing method should be recommended by the relevant competent authority.

#### 3.2.3.2 Health Status

The following should be considered:

- Growers should be encouraged to recognise symptoms of diarrhoeal or food-transmissible communicable diseases, and reassign agricultural workers as appropriate.
- Agricultural workers should be encouraged and, where feasible, be motivated with appropriate incentives to report symptoms of diarrhoeal or food-transmissible communicable diseases.
• Medical examination of agricultural workers should be carried out if clinically or epidemiologically indicated.

3.2.3.3 Personal cleanliness

When personnel are permitted to continue working with cuts and wounds covered by waterproof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the berries they handle or, otherwise they should be reassigned to another working area where they do not handle berries directly.

3.2.4 Equipment associated with growing and harvesting

Standard operating practices should be developed for the maintenance, cleaning and disinfecting operations of growing and harvesting equipment, which include the following:

• Containers used repeatedly during harvest should be cleaned after each load.

• Containers (including liners of containers made from biodegradable materials) that are no longer cleanable should be disposed of since they may increase the risk of microbial contamination of berries.

• Harvesting containers should not be placed directly on the ground.

• If the containers are stored outside, they should be cleaned and disinfected before being used to transport berries.

3.3 Handling, Storage and Transport

Some berries may have high respiration rates making them more perishable. Enzymes and biochemical reactions play an important role in the ripening process but also accelerate spoilage of damaged fruits and increase susceptibility of berries to microbial contamination.

Growers should implement safe handling, transport and storage practices and immediately cool berries after harvesting. Precooling (i.e., rapid removal of field heat) berries after harvesting (e.g. within the first 2 hours) is important to maintain freshness and quality and contributes to the control of foodborne pathogens. When required, growers should use potable water for ice and hydrocooler when precooling to minimize risks of contamination.

• Manual harvest considerations:
  o Appearance and firmness of berries are commonly associated with fruit quality and freshness. Over handling the berries may damage and affect fruit quality. Moreover, adverse temperatures during harvesting in hot and/or humid weather also decreases quality and may affect food safety due to fruit damage and juice leakage, which may spread contamination over healthy fruits.
  o Growers should have a responsible person to supervise harvesting at all times to assure harvesters use proper hand washing and follow procedures not to harvest wet, bruised and/or damaged fruits. Additionally, berries that have fallen on the ground should be discarded unless they are processed with a microbiocidal step.
  o Growers should take measures to train agricultural workers on safe handling, transport and storage practices to ensure that berries are immediately cooled after harvesting.

• Mechanical harvest considerations:
  o Mechanical harvest is a common practice for some berries and may create food safety hazards if the equipment breaks down during the harvest, if it has received poor maintenance and cleaning or if it damages the fruit.
  o Growers should avoid moving harvesting equipment across fields where manure or compost was applied.
  o Before and after harvesting growers should perform proper cleaning and disinfection of all surfaces of equipments that have been in contact with berries. Moreover harvesting equipment should be cleaned and disinfected seasonally or as needed (e.g. if the equipment runs over an area with heavy animal intrusion and faecal deposits).
3.3.1 Prevention of cross-contamination

Specific control methods should be implemented to minimize the risk of cross-contamination from microorganisms associated with harvesting methods. The following should be considered:

- The extent of soil and extraneous matter debris on the fruit during and after harvesting may pose a risk of foodborne contamination. Growers should take measures to improve sorting and selection of berries.
- Harvest workers should not handle culled fruit in the field in order to prevent cross-contaminating healthy berries during harvest. It is recommended that culled be removed from the field by a worker who is not harvesting healthy fruit.
- Poor hygienic practices of agricultural workers in the field can significantly increase the risk of contaminating berries. In order to prevent microbial cross-contamination of berries, growers should continually reinforce the importance of good hygienic practices during pre-harvest, harvest and post-harvest activities.

3.3.3 Field packing

Preference should be given to the field packing into consumer ready containers of berries that will not be washed after harvest (e.g. strawberries), to minimize the possibility of microbial contamination through additional handling steps.

Growers should ensure that clean pallets and containers (disinfected where necessary) are used and take measures to ensure that the containers do not come into contact with soil and manure during field packing operations.

SECTION 4 – PACKING ESTABLISHMENT: DESIGN AND FACILITIES

Refer to the General Principles of Food Hygiene (CAC/RCP 1-1969) in conjunction with the Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods (CAC/GL 61-2007).

4.1 Location

4.1.2 Equipment

Whenever possible, equipment should be designed and placed to facilitate cleaning and disinfection, and to prevent build-up of biofilms that may contain foodborne pathogens of concern.

4.2 Premises and Rooms

4.2.1 Design and Layout

Premises and rooms should be designed to separate the area for incoming berries from the field (areas for incoming soiled and outgoing washed berries) from the area for handling. This can be accomplished in a number of ways, including linear product flow.

Where feasible, raw material handling areas should be separated from processing/packing areas. Within each of these areas, cleaning operations should be conducted separately to avoid cross-contamination between equipment and utensils used in each operation.

For products that are not immediately wrapped or packed (i.e. the berries are exposed to contaminants from the environment), the rooms where final products are packaged and stored should be designed and maintained to be as dry as possible. The use of water or having a wet environment enhances the growth and spread of foodborne pathogens.

Berry packing and/or processing establishments may be seasonal, and used for only a few months per year. The facilities may be dormant for many months, leaving them susceptible to pest infestations. Measures to minimize pest infestations should be put in place. The design should allow thorough cleaning and disinfection of food contact surfaces.

SECTION 5 - CONTROL OF OPERATION

Refer to the General Principles of Food Hygiene (CAC/RCP 1-1969) in conjunction with the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CAC/GL 79-2012) and the Code of Practice for the Processing and Handling of Quick Frozen Foods (CAC/RCP 8-1976).
5.1 Control of food hazards

Prevention of contamination is a key control point for berries and packing establishments should pay special attention to product flow and segregation of incoming soiled and/or damaged and outgoing product to avoid cross-contamination.

Care should be taken to ensure that berries are not damaged and do not become cross-contaminated during transport and handling. Prior to packing, berries that are soiled, come with debris (e.g., insects), or that are damaged, should be inspected and culled.

Culled berries should be removed from the field or packing facility and disposed of to prevent contamination of other fruit. Culled fruit should be hygienically disposed of to avoid it from attracting pests.

5.2 Key aspects of hygiene control systems

5.2.2 Specific process steps

5.2.2.1 Post-harvest water use

Most berries intended for direct consumption are generally not washed after harvest.

For berries that are washed, clean or preferably potable water should be used. It is recommended that the quality of the water used in packing establishments be controlled and monitored, i.e. recording testing for indicator organisms and/or foodborne pathogens.

If water is used in pre-washing and washing tanks, additional controls (e.g. changing water whenever necessary and controlling of product throughput capacity) and monitoring (e.g. recording the pH and temperature, turbidity, and water hardness) should be adopted.

Water used for final rinses should be of potable quality.

Any antimicrobial agents used in the water should be maintained at sufficient levels to ensure that water used in pre-washing and washing tanks does not act as a source of contamination for the fruit, and to prevent antimicrobial agents from damaging fruit skin structure.

If antimicrobials and/or disinfectants are used to control foodborne pathogens in post-harvest water, the efficacy of the treatment should be demonstrated/validated against a target organism under appropriate conditions (see Section 5.2.3).

5.2.3 Microbiological and other specifications

Microbiological testing can be a useful tool to evaluate and verify safety and the effectiveness of cleaning practices and to provide information about an environment, a process, and even a specific product lot, when sampling plans and methodology are properly designed and performed. The intended use of information obtained (e.g. evaluating the effectiveness of a sanitation practice, evaluating the risk posed by a particular hazard, etc.) can aid in determining what microorganisms are most appropriate to test for. Test methods should be selected that are validated for the intended use. Consideration should be given to ensure proper design of a microbiological testing program. Trend analysis of testing data should be undertaken to evaluate the effectiveness of food safety control systems.

5.2.4 Microbial cross-contamination

Berries that have undergone cleaning and/or chemical treatment should be effectively separated, either physically or by time, from raw material and environmental contaminants.

Prevent cross-contamination between raw and washed berries, which will be frozen, from sources such as wash water, rinse water, equipment, utensils and vehicles.

Only workers who have been trained on hygienic handling should be assigned to pack berries.

5.3 Incoming material requirements

The following are recommended:

- For berries that are intended to be consumed raw as well as to be frozen, sorting and selection should be implemented to avoid using fruits that have visible signs of decay or damage due to the increased risk of microbial contamination.

- Berries should be cooled and stored as soon as possible under temperature controls within the processes.
5.7 Documentation and records

Where practicable, a written food safety control plan that includes a written description of each of the hazards identified in assessing environmental hygiene, as well as the steps that will be implemented to address each hazard, should be prepared by the business operating the primary production. The description should include, but is not limited to, the following: an evaluation of the production site, water and distribution system, manure use and composting procedures, personnel illness reporting policy, sanitation procedures and training programs.

The following are examples of the types of records that should be retained:

- Microbiological test results and trend analyses
- Water monitoring and test results
- Storage room temperature levels
- Employee training records
- Pest control records
- Cleaning and disinfection reports
- Equipment monitoring and maintenance records
- Inspection/audit records

5.8 Recall procedures

In the event of a foodborne illness outbreak associated with berries, maintaining appropriate records of production, processing, packaging and distribution may help to identify the source of contamination in the berry food chain and facilitate product recalls. Growers/packers/processors/distributors should consider developing and maintaining a traceability/product tracing system. The 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 (CAC/GL 60-2006), especially to enable the withdrawal of the products, where necessary.

Detailed records should be kept that link each supplier of the product with the immediate subsequent recipient of the berries throughout the food chain. The information needed to link each supplier should include, if available, the packer name, address, and phone number, date packed, date released, type of berry (e.g. strawberry, blueberry, etc.) including brand name, lot identification and number of lots, and transporter.

SECTION 6 – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 Maintenance and Cleaning

6.1.1 General

Food contact surfaces should be cleaned and disinfected before the start and throughout the season of the specific fruit to ensure microbial pathogens do not become established in the facility or on the equipment.

6.1.2 Cleaning procedures and methods

Written SOPs should be developed and implemented for the cleaning and disinfection of equipment used for post-harvest treatment.

SECTION 8 – TRANSPORTATION

Refer to the Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables (CAC/RCP 44-1995).
SECTION 9 – PRODUCT INFORMATION AND CONSUMER AWARENESS

9.4 Consumer education

The following should be considered:

- All stakeholders – government, industry, consumer organizations and the media – should work together to communicate clear consistent messages on handling berries safely to avoid giving contradictory advice and causing confusion.

Consumer information on handling berries safely should cover:

- Avoiding the purchase of trays or cases with damaged or rotten berries.
- Transporting to home. Increase in product temperature during transportation can be considerable.
- Storage/refrigeration of berries. Berries should preferably be stored in a cool environment. All prepackaged berries should be refrigerated as soon as possible.
- Once removed from the refrigerator, berries should be consumed as soon as possible.
- Correct hand washing methods.
- Cross-contamination. Consumers need to handle, prepare, and store berries safely to avoid cross-contamination with foodborne pathogens from various sources (e.g. hands, sinks, cutting boards, utensils, raw meats).
- The need to wash berries with potable water before consuming.

SECTION 10 – TRAINING

10.2 Training programs

Since producing berries for direct consumption is labor intensive, which increases the risk of contamination from manipulation, special attention is needed to properly select and train all personnel involved in primary production, packing, processing or transport operations of berries that are intended to be consumed.

Growers should train personnel to ensure that only experienced pickers harvest berries that are intended for direct consumption.

All agricultural workers should receive training appropriate to their tasks and should be periodically assessed while performing their duties to ensure tasks are being completed correctly.

Specific employee training programmes should include the following:

- The importance of sorting out berries with visible defects, such as broken skin, decay, mold, soiled and insect and/or bird damaged fruit.
- Agricultural workers should be trained to follow the SOPs.
- Training and supervision of the agricultural workers is essential to the success of any harvesting operation.
- Training should be provided and reinforce for agricultural workers on good hygienic practices relevant to the growing, harvesting and post harvesting activities of berries. Poor hygienic practices can significantly increase the risk of the microbial contamination.
- The importance to minimize post harvest handling, thereby increasing the shelf life and safety of the berries.
- The importance of recognizing and recording field contamination indicators (e.g. broken fences, animal droppings, high incidence of insects) and taking appropriate measures to mitigate the risks.

• The importance of proper berry handling techniques to minimize or prevent damage to the fruit and microbial contamination.

• The importance of proper use of hygienic facilities. Training could include, for example, toilet use, proper disposal of toilet paper or equivalent, and proper hand washing and drying procedures.

• Training in cold chain logistics and management, in line with advancing knowledge and technologies for both refrigeration and temperature monitoring and expanding international trade.

Training should be delivered in a language and manner to facilitate understanding of what is expected of them and why, and should emphasize the importance of using hygienic practices. A well-designed training program considers the barriers to learning of the trainees and develops training methods and materials to overcome those barriers.

Training programs should be repeated periodically, and updated whenever there is a change in the product, process or staff and monitored for effectiveness and modified when necessary.

Appropriate training records should be kept.
1. **Purpose and Scope of the Standard**

The Code of Hygienic Practice for Low-Moisture Foods would apply to the control of microbiological hazards in foods having a water activity of 0.85 or below that are exposed to the processing environment following a microbial inactivation step, products that are not subjected to an inactivation step, or products in which low-moisture ingredients, which may be contaminated with pathogens, are added after an inactivation step. The Code would be applicable to various products that include, but are not limited to, peanut butter, cereals, dry protein products (such as dried dairy products) confections (such as chocolate), snacks (such as spiced chips), tree nuts, desiccated coconut, seeds for consumption, and spices.

2. **Relevance and Timeliness**

A number of outbreaks have been linked to low-moisture foods and have implicated *Salmonella* and *Escherichia coli* O157:H7. These outbreaks underscore the need to ensure appropriate hygienic practices in the production of such foods. Codex has currently a number of Codes of Hygienic Practice for low-moisture foods and there is an interest in updating them.

3. **Main aspects to be covered**

The Code of Hygienic Practice for Low-Moisture Foods would follow the structure of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and include only provisions of particular importance for the safety of low-moisture foods. It would include:

- Minimizing contamination at primary production
- Preventing the entry and spread of enteric pathogens in the processing facility
- Hygienic practices and control where the low-moisture food is exposed to the environment
- Hygienic design principles for buildings and equipment
- Procedures to prevent or minimize the growth of *Salmonella* in the facility
- Validation of control measures to minimize or prevent hazards
- Procedures for verification of control measures

4. **Assessment against the Criteria for the establishment of work priorities**

4.1 The Code needs 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 the control of microbial hazards such as *Salmonella* spp. and *E. coli* O157:H7, which are common public health problems world-wide. This document will provide guidance to all countries on the hygienic productions of these products.

4.2 Consideration of the global magnitude of the problem or issue

There is the potential for contamination of products covered by this Code from multiple sources and under different processing environments.

5. **Relevance to the Codex strategic objectives**

The proposed work directly relates to the following Codex Strategic Goals from the 2008-2013 Strategic Plan.

**Goal 1: Promoting Sound Regulatory Frameworks**

The development of this Code is consistent with the development of international standards, guidelines and recommendations based on scientific principles for the reduction of health risks along the entire food chain. This Code will provide important information for all countries in order to achieve a higher level of food safety.
Goal 2: Promoting the widest and consistent application of Scientific Principles and Risk Analysis
Risk analysis as it applies to food safety across the food chain is an internationally accepted discipline and will require ongoing and sustained input from Codex, its parent organizations and national governments to promote its understanding and application at the international and national levels.

Goal 3: Strengthening Codex Work-Management Capabilities
More expeditious and efficient work by Codex is necessary to provide members and international organizations with the standards, guidelines and recommendations that they need. In light of recent outbreaks implicating low-moisture foods, this work will be very timely.

Goal 5: Promoting Maximum and Effective Participations of Members
The development of this Code should generate interest and participation from all country members. We anticipate having a first face-to-face meeting following by an electronic working group using email exchanges and web meetings.

6. Information on the relation between the proposal and other existing Codex documents
The Code will build on the General Principles of Food Hygiene (CAC/RCP 1-1969) and will provide additional recommendations, as needed. In addition, a review of existing Codex codes of hygienic practice will be done to determine whether they adequately address the products identified in the scope in order to avoid duplication of efforts.

7. Identification of any requirement for and availability of expert scientific advice
We anticipate that there may be a need for scientific advice from FAO/WHO (JEMRA) on the pathogen-specific hazards associated with various food types. We will be seeking expert advice from FAO/WHO to determine which low-moisture foods represent the highest priority. The advice will then be used to better define the Scope of the document and determine if annexes should be used to include specific guidance due to the variety of food products included in the Scope.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for
In addition to scientific expert advice from JEMRA, technical input may be requested from the International Commission of Microbiological Specifications for Foods, especially if the working group would want to entertain the development of microbiological criteria.

9. 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
Proposed time lines:
A five-year timeline is proposed for the completion of the Code of Hygienic Practice for Low-Moisture Foods. A proposed draft Code would be ready for initial discussion by the CCFH in 2013, with a proposed date for adoption at Step 5 in 2015 and adoption at Step 8 in 2016.