

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

ALINORM 10/33/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty third Session

Geneva, Switzerland, 5 - 9 July 2010

REPORT OF THE FORTY FIRST SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

San Diego, United States of America, 16 – 20 November 2009

NOTE: *This report includes Codex Circular Letter CL 2009/35-FH*

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CX 4/20.2

CL 2009/35 - FH

TO: Codex Contact Points
Interested International Organizations

FROM: 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 first Session of the Codex Committee on Food Hygiene (ALINORM 10/33/13)

The report of the Forty first Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty third Session of the Codex Alimentarius Commission, (Geneva, Switzerland, 5 - 9 July 2010).

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

Draft Standards at Steps 5/8 of the Procedure

- 1. Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruit and Vegetables (N04-2008)(ALINORM 10/33/13 para. 85 and Appendix II);**
- 2. Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* spp. in Seafood) (N05-2008) (ALINORM 10/33/13 para. 98 and Appendix III);**
- 3. Proposed Draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish) (N05-2008) (ALINORM 10/33/13 para. 109 and Appendix IV);**
- 4. Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene (ALINORM 10/33/13 para. 150 and Appendix VII)**

Governments and interested international organizations are invited to comment on the above texts and should do so in writing, preferably by e-mail to Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy : codex@fao.org or fax: +39 06 570.54593), **before 31 March 2010.**

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SUMMARY AND CONCLUSIONS

The Forty first Session of the Codex Committee on Food Hygiene reached the following conclusions:

MATTERS FOR ADOPTION BY THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward the Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruit and Vegetables for adoption at Step 5/8 (see ALINORM 10/33/13 para. 85 and Appendix II);
- agreed to forward the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* spp. in Seafood for adoption at Step 5/8 (see ALINORM 09/32/13 para. 70 and Appendix III);
- agreed to forward the Proposed Draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish for adoption at Step 5/8 (see ALINORM 10/33/13 para. 98 and Appendix IV); and
- agreed to forward the Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene for adoption (see ALINORM 10/33/13 para. 150 and Appendix VII).

MATTERS FOR ACTION BY THE COMMISSION

NEW WORK

- agreed to propose to the Commission to approve new work on the revision of the:
 - Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral waters (CAC/RCP 33-1985) (see ALINORM 10/33/13, paras 129-132 and Appendix V); and
 - Proposed Revision of Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997) (see ALINORM 10/33/13, paras 133-137 and Appendix VI).

MATTERS OF INTEREST TO THE COMMISSION AND/OR TO FAO/WHO

The Committee:

- agreed to inform the Commission that it had considered the hygiene provisions in the Draft Code of Hygienic Practice for Fish and Fishery products (Sections on Lobsters and Crabs) and the Draft Standard for Sturgeon Caviar at Step 8 and endorsed them (ALINORM 10/33/13, paras 8-12).
- renamed the title of the Proposed Draft Code of Hygienic Practice for Control of Viruses in Food (N07-2009) to the Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (ALINORM 10/33/13, para. 119);
- agreed to request FAO/WHO to implement an expert meeting with a view to constructing more applicable models for wide use among countries with the terms of reference as outlined in para. 110 of ALINORM 10/33/13.

MATTERS OF INTEREST TO OTHER COMMITTEES**Committee on Fish and Fishery Products**

The Committee endorsed the hygiene provisions in the Draft Code of Hygienic Practice for Fish and Fishery Products (Sections on Lobsters and Crabs) and the Draft Standard for Sturgeon Caviar as Step 8 (ALINORM 10/33/13, paras 8-12).

The Committee noted that the CCFPP would meet in April 2011 and therefore agreed to consider the endorsement of the hygiene provisions of the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish and the Proposed Draft Standard for Fish Sauce at its next session (ALINORM 10/33/13, paras 9-12).

Committee on General Principles

The Committee agreed to forward the Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene to the 33rd Session of the Commission for adoption and subsequent inclusion in Section VI of the Codex Alimentarius Procedural Manual (ALINORM 10/33/13, paras 139 - 150). The Committee noted that some inconsistencies might exist between the main document on CCFH Risk Analysis Principles and Procedures and Annex on the Process by Which the Codex Committee on Food Hygiene Will Undertake its Work and agreed to ask the CCGP to take care of these inconsistencies while reviewing these texts.

Committee on Food Labelling

The Committee referred for endorsement Sections 9.3 on Labelling of the:

- Proposed Draft Annex on Leafy Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruits and Vegetables (ALINORM 10/33/13 para. 82 and Appendix II); and
- Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* Species in Seafood (ALINORM 10/33/13 paras 93-94 and Appendix III).

LIST OF ABBREVIATIONS

ALA	Asociación Latinoamericana de Avicultura
ALOP	Appropriate Level of Protection
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CRD	Conference Room Document
CCEXEC	Executive Committee of the Codex Alimentarius Commission
EFBW	Groupement international des sources d'eaux naturelles et d'eaux conditionees
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GHP	Good Hygienic Practice
HACCP	Hazard Analysis and Critical Control Point System
IACFO	International Association of Consumer Food Organizations
IBFAN	International Baby Food Action Network
ICA	International Confectionery Association
ICA	International Co-operative Alliance
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
IICA	Inter-American Institute for Cooperation on Agriculture
ILCA	International Lactation Consultant Association
ISDI	International Special Dietary Foods Industries
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
MRA	Microbiological Risk Assessment
OIE	World Organization for Animal Health
WHO	World Health Organization

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Forty first Session in Coronado, San Diego, the United States of America, from 16 to 20 November 2009, at the kind invitation of the Government of the United States of America. Dr Emilio Esteban, Science Advisor for Laboratory Services and Research Coordination, the United States Department of Agriculture, Food Safety and Inspection Service (FSIS), Office of Public Health Science, chaired the meeting. The Session was attended by 192 delegates representing 79 member countries, one member organization and 9 international organizations including FAO and WHO. A complete list of participants, including the Secretariats, is attached as Appendix I, of which 30 were supported by the Codex Trust Fund.

OPENING OF THE SESSION

2. The Session was opened by Dr Margaret Hamburg, the Commissioner of the USA Food and Drug Administration.

3. Mr Robert Paterson, the Representative of FAO; Dr Peter Ben Embarek, the Representative of WHO; Mr Frank Yiannis, the Vice-President of Walmart; and Dr Karen Hulebak, the Chairperson of the Codex Alimentarius Commission addressed the delegates.

Division of Competence

4. The Committee noted the division of competence between the European Community and its Member States, according to paragraph 5, Rule II of the Procedure of the Codex Alimentarius Commission, as presented in CRD 2.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

5. The Committee agreed to the proposal of the Chairperson to consider Agenda Item 5 before Item 4 and Agenda Item 10(b) after Agenda Item 8. With these modifications, the Committee adopted the Provisional Agenda as its Agenda for the session.

Other matters

6. In response to the request of the Codex Alimentarius Commission to finalize risk analysis documents elaborated by relevant Codex Committees so that they can be reviewed by the Codex Committee on General Principles (CCGP) by 2011, the Committee agreed to establish an in-session working group, led by India and working in English, to review comments received on the proposed draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene (Agenda Item 10(b)) and to prepare a revised version of this document for consideration by the Plenary.

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

7. The Committee was informed about matters arising from the 32nd Session of the Codex Alimentarius Commission (CAC), as presented in document CX/FH 09/41/2. The Committee noted that most of the matters referred by the CAC were for information purposes.

Endorsement of Hygiene Provisions in the Codex Standards and Codes of Practice

Draft Code of Practice for Fish and Fishery Products (sections on Lobsters and Crabs)³ at Step 8; and Draft Standard for Sturgeon Caviar⁴ at Step 8.

8. The Committee endorsed the hygiene provisions as forwarded by the 30th Session of the Codex Committee on Fish and Fishery Products (CCFFP):

¹ CX/FH 09/41/1; CRD 2 (Division of competence between the European Community and its Member States, prepared by the European Community).

² CX/FH 09/41/2; CRD 27 (prepared by Canada, Norway and ICMSF)

³ ALINORM 10/33/18, Appendix II

⁴ ALINORM 10/33/18, Appendix V

Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish⁵ and Proposed Draft Standard for Fish Sauce⁶ at Step 5

9. In order to clarify the possible variation of the interpretation, including sampling plan of histamine criterion among countries, the Delegation of the European Community proposed the addition of the following text to the relevant section on histamine of the proposed draft standards: *As sampling plans and their accompanying evaluation criteria for histamine may vary between countries, it is acknowledged that the actual application of the histamine criterion may also vary among countries.*”.

10. In this regard, one delegation noted that the proposed draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish included a sampling plan for histamine in Section 8.3 “Determination of histamine”.

11. With regard to Annex 2 “Examples of combinations of product attributes that minimize the likelihood of *Clostridium botulinum* toxin formation” of the proposed draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish, one observer raised concerns about the lower temperature at which *Clostridium botulinum* could produce toxin and about aerobic packaging as a safe control option (see CRD 27).

12. After some discussion, the Committee noted that the CCFPP would meet in April 2011 and therefore agreed to consider the endorsement of the hygiene provisions of the proposed draft standards for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish and for Fish Sauce at its next session taking into account the above discussion.

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

PROGRESS REPORTS ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS (Agenda Item 3(a))⁷

13. The Representative of FAO, on behalf of FAO and WHO, while referring to the document CX/FH 09/41/3 provided an overview of the work of JEMRA during the past year, relevant to the work of the Committee.

14. The Representative summarized the work that had been undertaken by the FAO/WHO Technical Meeting on *Salmonella* and *Campylobacter* in Chicken Meat (Rome, Italy, May 2009) in order to assess and review all available scientific information on control of *Salmonella* and *Campylobacter* at relevant stages of the broiler supply chain. The Representative indicated that the draft report of the meeting had been circulated through the Codex system and had been made available to support the work of the working group on the development of the proposed draft guidelines for the control of *Campylobacter* and *Salmonella* spp. in chicken meat.

15. The feasibility of developing a web-based risk management decision support tool was discussed and supported by the Technical Meeting. The prototype of the web-based tool was presented to the CCFH working group in September 2009 and to the Committee at the present session (CRD 14). The web-based tool enables countries to evaluate combinations of control measures available within their processing systems. The Representative also informed that, as follow-up to the development of the web based tool for assessing the impact of control measures on *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered infant formula, and in light of user feedback, FAO and WHO had commissioned work through JEMRA to develop a stand alone tool to estimate the impact of microbiological sampling plans. The tools for *Salmonella* and *Campylobacter* and for sampling plans will undergo a user review and technical peer-review in 2010. It is estimated that the web-based tool will be ready for public release by mid 2010.

⁵ ALINORM 10/33/18, Appendix VI

⁶ ALINORM 10/33/18, Appendix IX.

⁷ CX/FH 09/41/3, CRD 9 (comments of United States of America); CRD 14 (comments of FAO/WHO); CRD 15 (Updated information on fresh produce commodities of greatest food safety concern by FAO/WHO)

16. The Representative also informed that the publicly available executive summary of the FAO and WHO Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing (27-30 May, 2008) had been provided to the FAO/WHO Technical Meeting on *Campylobacter* and *Salmonella* in Chicken Meat. The final report of the Joint FAO/WHO Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing will be available early 2010.

17. The Representative presented the outcome of an FAO/WHO electronic discussion group on microbiological hazards in fresh produce which reviewed the risks associated with fresh produce presented in the 2007 Expert Meeting on the same subject following the continuing occurrence of outbreaks linked to fresh produce.

18. The updated information on fresh produce commodities of greatest food safety concern was presented in CRD 15.

19. The Representative emphasized that new JEMRA reports on *Vibrio cholerae*, *Vibrio vulnificus* and viruses and draft reports on *V. parahaemolyticus* had been made available to the CCFH working groups which developed the current draft documents on vibrios (Agenda Items 6 and 7) and viruses in foods (Agenda Item 8).

20. The Representative expressed appreciation for the financial support provided by the government of Japan for the development of the above web-based tool on the control of *Campylobacter* and *Salmonella* as well as the support provided by the United States of America through GIFSA for the Technical Meeting on *Campylobacter* and *Salmonella* in chicken meat. Appreciation was also extended to all Codex members and nongovernmental organizations that provided data and information to support the work on scientific advice on the above issues.

21. The Representative of WHO also informed the Committee that a scientific workshop on the research and public health aspects of Nipah and Hendra viruses had been organized by WHO in collaboration with FAO and OIE in Brisbane, Australia (September 2009) and that this workshop also addressed the recent discovery of Reston Ebola virus in swine in the Philippines. The workshop noted the foodborne aspects of Nipah virus, the detection of Nipah virus in many parts of South and South East Asia and the potential food handling concerns associated with Reston Ebola virus in swine.

22. The Committee expressed its appreciation to FAO and WHO for the provision of extensive scientific advice which greatly facilitated and contributed to the quality of the work of the Committee.

INFORMATION FROM THE WORLD ORGANIZATION FOR ANIMAL HEALTH (OIE) (Agenda Item 3 (b))⁸

23. The Observer of OIE, referring to the document CX/FH 09/41/3-Add.1, informed the Committee that the OIE had actively been working to review and update the Terrestrial Animal Health Code chapter relevant to salmonellosis in poultry. The Observer indicated that a new chapter 6.5 "Prevention, detection and control of *Salmonella* in poultry" had been adopted in May 2009 and included in the Terrestrial Code. Chapter 6.4 "Hygiene and disease security procedures in poultry breeding flocks and hatcheries" had been extensively reviewed and circulated to OIE Members for comments and was proposed for adoption in May 2010.

24. The Observer indicated that OIE would continue to address animal production food safety issues as high priority in its standards setting work and that it would continue to work closely with Codex and with other international bodies in promoting safe trade in animal products.

25. The Committee expressed its appreciation to OIE for the information and noted the need for continued collaboration in areas of mutual interest.

⁸ CX/FH 09/41/3-Add.1.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *CAMPYLOBACTER* AND *SALMONELLA* SPP. IN CHICKEN MEAT AT STEP 4 (Agenda Item 4)⁹

26. The Committee recalled that at its 40th session it had agreed to return the proposed draft guidelines to Step 2 for further elaboration by a physical working group led by New Zealand and Sweden, circulation for comments at Step 3 and consideration by the current session of the Committee.

27. The Delegation of Sweden, in introducing the report of the working group as presented in document CX/FH 09/41/4, recalled the history of the development of the Guidelines and that three physical working groups had been established for its development. The Committee was informed that the physical working group, which met in Foz de Iguacu (Brazil) in September 2009, had agreed to a new draft incorporating the new scientific advice from the FAO/WHO Technical Meeting on *Salmonella* and *Campylobacter* in chicken meat (Rome, Italy, May 2009). The working group strongly supported the approach taken by FAO/WHO (JEMRA) in the development of the prototype of the web-based risk management decision support tool (“web-based tool”), which was appropriately structured to address the requests made by the 40th CCFH.

28. The Committee was informed that: the section on primary production had been extensively reviewed to include only guidance that was supplementary to the guidance already available in OIE texts and other relevant Codex texts; that some examples included in the earlier stage of development for educational purposes had been removed; and that explanatory text had been condensed.

29. The Delegation of New Zealand, on behalf of the working group, emphasized that the revised Guidelines together with the web-based tool were science and risk-based; had a farm-to-plate structure for HACCP application; had specific GHP controls for *Campylobacter* and *Salmonella*; had specific hazard-based controls that were quantitative examples and the choice on their use was made at national level; and the availability of the web-based tool would assist managers in making choices in a risk assessment environment. The Delegation also emphasized that the FAO/WHO Technical Meeting on *Salmonella* and *Campylobacter* in Chicken Meat had confirmed through a rigorous review process, a number of hazard-based controls for inclusion in the Guidelines, the choice and validation of which were the domain of national governments and industry. The Delegation of New Zealand reported that the members of the working group were in favor of the progress of the Guidelines in the Step process.

General comments

30. The Committee thanked the working group for the important progress made in the development of the proposed draft guidelines, which provided all inclusive approaches for the control of *Salmonella* and *Campylobacter* in chicken meat.

31. The Delegation of the European Community reiterated their position that the use of decontaminants (hazard-based control measures) could not be seen as a replacement of good hygienic practice (GHP) at farm level and slaughterhouses masking poor hygienic practices. The Delegation drew the attention of the Committee to the fact that the final report of the FAO/WHO expert meeting¹⁰ on active chlorine was not available and recalled that this report was a key piece of scientific advice on antimicrobial treatment, which in their view constitute the main part of hazard based control measures in the draft guidelines. The Delegation also referred to scientific assessments carried out in the European Community to evaluate the risks and benefits of antimicrobial treatments and pointed out a number of outstanding concerns as regards the potential environmental risks caused by substances used for antimicrobial treatments and also underlined issues in relation to the health of workers exposed to these substances. The potential for increased antimicrobial resistance was also highlighted.

⁹ CX/FH 09/41/4; CX/FH 09/41/4-Add.1 (comments of Australia, Costa Rica, Cuba, India, Japan, Kenya, Mexico, Philippines and OIE); CX/FH 09/41/4-Add.2 (comments of European Community, Guatemala, Thailand, United States of America and IACFO); CRD 8 (comments of European Community and United States of America); CRD 9 (comments of the United States of America); CRD 10 (comments of Uruguay); CRD 11 (comments of Indonesia); CRD 13 (comments of Mali); CRD 14 (comments of FAO/WHO); CRD 17 (comments of Paraguay); CRD 21 (comments of Republic of Korea); CRD 24 (comments of Bolivia); CRD 26 (comments of New Zealand).

¹⁰ Joint FAO/WHO Expert meeting on the benefits and risks of the use of chlorine-containing disinfectants in food production and food processing, Ann Arbor, USA, 27-30 May 2008.

32. In addition to the scientific uncertainties and concerns related to the use of antimicrobial substances for decontamination of poultry, the delegation of the European Community underlined that there was also very strong consumer opposition in the European Union to the issue of chemical treatments for decontamination of poultry.

33. In concluding, the Delegation of the European Community stated that they could not support the inclusion of references to antimicrobial treatments in the draft guidelines; therefore, at this moment they proposed not to consider advancing the proposed draft Guidelines until the final report of the FAO/WHO expert meeting on active chlorine becomes available.

34. The delegations of Switzerland and Norway shared the concerns expressed by the European Community. The Delegation of Norway was of the view that the use of chemical disinfectants could mask poor hygienic practice and that the possible development of antimicrobial resistance due to the use of chemical decontamination had not been sufficiently addressed. However, the Delegation of Switzerland expressed its willingness to discuss the document in the Step process.

35. The Representative of FAO drew the attention of the Committee to the conclusions of the FAO/WHO expert meeting on active chlorine, as contained in the publicly available executive summary, that “there is no evidence to indicate that the use of chlorine containing disinfectants and their alternatives are associated with acquired antimicrobial resistance to therapeutic agents” and that there were no differences between the conclusions of the executive summary and the final report of the Expert meeting on active chlorine.

36. The Delegation of the United States of America emphasized the important work in this document and supported the continued development of the guidelines in accordance with the original purpose of providing an all-inclusive approach toward intervention for control of *Salmonella* and *Campylobacter* in chicken meat. In light of the strong science basis of the document and the 6,000 references considered by the working group, including data on chemical intervention, the Delegation favoured discussion of the document with the aim of advancing it to Step 5 at this session.

37. Many other delegations from several regions shared these comments and supported discussing the document aiming at its advancement to Step 5. These delegations pointed out: that the proposed draft Guidelines included many examples of hazard-based control measures the use of which was a matter of choice at national level; that the use of chemical decontaminants, such as chlorine-containing disinfectants, represented a good opportunity for many countries in view of their low cost and simple formula and the scientific results that showed that their use of was not dangerous; that the non availability of the report of the FAO/WHO expert meeting on active chlorine should not prevent the further advancement of the document in the Step procedure; that the matter had been considered by the Committee for several years; that a considerable amount of resources had been invested by the working group and by FAO/WHO to provide a scientific basis to the document; that it was important to make progress on the document because exposure to *Salmonella* and *Campylobacter* from consumption of poultry poses a significant risk to consumers in every world region; and that the proposed draft Guidelines, addressed poultry production in controlled environment systems and also included small poultry producers.

38. With regard to consumer acceptance of poultry decontamination, the observer from IACFO noted that there were differences in preferences among consumers in different regions of the world and pointed out that while European consumers might not approve the use of chemical decontamination, North American consumers were not against its use. The observer of IACFO stressed that, in a number of developing countries, the use of chlorine and other decontamination methods were essential because water quality might be otherwise unacceptable.

39. After considerable discussion, the Committee noted that in view of the strongly divergent opinions, it was not a good use of time to continue discussion on this Agenda Item as there appeared to be a lack of willingness to reach consensus on advancement of this document in the Step procedure. Therefore, the discussion at this session on this Agenda item was suspended as there was no consensus

40. The Committee agreed to establish an electronic working group, led by New Zealand and Sweden with active participation and support from Brazil, to revise the proposed draft guidelines on the basis of the written comments submitted at the present session, while ensuring that the revised document be maintained as close as possible to the current structure and content. The electronic working group would work in English only.

Status of the Proposed Draft Guideline for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (N08-2007)

41. The Committee agreed to return the proposed draft Guidelines at Step 2 for redrafting by the above electronic working group, circulation at Step 3 for comments and consideration by the next session of the Committee.

Web-based risk management decision support tool

42. The Committee thanked FAO/WHO for the steps taken in the development of the web-based risk management decision support tool (“web-based tool”). The demonstration of the web-based tool, arranged by FAO/WHO during the current session of the Committee, had shown that the web-based tool was useful and could be easily used by countries for making clear and informed risk management decisions. The Committee reiterated its strong support to FAO/WHO for the further development and finalization of the web-based tool as planned.

PROPOSED DRAFT ANNEX ON LEAFY GREEN VEGETABLES INCLUDING LEAFY HERBS TO THE CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES AT STEP 4 (Agenda Item 5)¹¹

43. The Committee recalled that at its 40th session it had agreed to return the proposed draft Annex to Step 2 for further elaboration by an electronic working group, led by the United States of America.

44. The Delegation of the United States of America introduced the document and highlighted outstanding issues that needed consideration:

- Whether herbs should be mentioned in the title, noting that herbs were considered as part of leafy greens in the scope;
- The ranking of irrigation water-sources from highest to lowest risks;
- Health status of workers;
- Reference to re-circulated or recycled water noting that re-circulated water referred to water in closed cooling systems whereas recycled water referred to reclaimed water; and
- Whether to include written food safety plans.

45. The Committee considered the document section by section and in addition to editorial amendments made the following comments and changes.

General comments

46. The Delegation of Brazil expressed the view that only bagged leafy vegetables should be covered by the Annex since these were the main products traded and implicated in foodborne disease outbreaks. The Delegation was of the view that broadening the scope to unpacked leafy vegetables would be too prescriptive and burdensome for especially small holders who were the main producers of unpacked leafy vegetables and that such products were sufficiently covered by the main Code (Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)).

47. It was noted that many unpacked leafy vegetables such as herbs were widely marketed and that some unpacked leafy vegetables were also implicated in foodborne disease.

48. The Delegation of the European Community while noting its support for the document, expressed the view that more specific recommendations were needed in some cases to better address the risk related to these products; that other recommendations were considered to be overly prescriptive (e.g. personal hygiene, training); that there was a need to better link the Annex with the main Code, and for clarity as regards the approach to define the different sources and level of water quality and supported the finalization of the document.

¹¹ CX/FH 09/41/5; CX/FH 09/41/5-Add.1 (comments of Argentina, Australia, Brazil, Egypt, Japan, Mexico, New Zealand, Peru and Thailand); CX/FH 09/41/5-Add.2 (comments of Costa Rica, European Community, India, Kenya; CRD11 (comments of Indonesia); CRD 12 (comments of Ghana); CRD 13 (comments of Mali); CRD 15 (Updated Information of fresh produce commodities of greatest food safety concern provided by FAO/WHO); CRD 16 (comments of Thailand); CRD 18 (comments of Philippines); CRD 23 (comments of Bolivia).

49. The Delegation of Japan indicated that the document should focus more on specific issues and avoid duplication of text already covered in the main Code and that more precise description on the quality of water at the different steps especially at farm level was necessary.

50. Other delegations that spoke expressed their support for the finalization of the document.

Specific comments

Introduction

51. The Committee agreed to amend the last paragraph of the introduction to indicate that examples of control measures in the Annex were for illustrative purposes only and that their use may vary between countries.

Objective / Scope

52. In view of the earlier general discussion, the Committee agreed to retain the current scope unchanged, but to consider differentiating between recommendations for bagged and unpacked leafy vegetables as appropriate throughout text.

53. It was further agreed to more clearly illustrate that leafy green vegetables covered by the scope intended to be consumed without any further microbiocidal steps.

54. In order not to limit the leafy vegetables mentioned in the scope, it was agreed to indicate that these were examples.

2.2 Use

55. The Committee agreed to more clearly indicate that the annex was supplemental to the *Code of Practice Hygienic Practice for Fresh Fruit and Vegetables* (CAC/RCP 53-2003) and the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969) and in view of this agreed not to repeat provisions covered by the aforementioned Codes unless necessary and to delete sections by reference only.

3.1.1 Location of the production site

56. In the first paragraph, it was agreed to replace “microbial risk” with “probability of microbial contamination” as more correct.

57. In the second paragraph, the Committee agreed to limit the number of examples.

3.1.3 Wildlife, livestock and human activity

58. The Committee agreed to amend the title to read “wild and domestic animals and human activity”.

59. The Committee agreed to delete the examples of animals in the first paragraph, but to include human activity and to indicate in the first bullet that measures to exclude domestic and wild animals were to be applied where feasible taking into account the difficulties to always exclude wild and domestic animals from production and handling areas.

60. In the second paragraph, it was agreed that human activity should also be monitored, since unauthorized human activity could also pose a risk for contamination.

3.2.1.1 Water for primary production

61. The Committee revised this section taking into account the need to reflect that water for primary production was not restricted to potable water only and the fact that the description in the upper half of section 3.2.1.1.1 “Water for irrigation” should also be applied to other waters used during primary production. Therefore, the Committee agreed to amend this section by: incorporating relevant text from 3.2.1.1.1; clarifying the ranking of water from the lowest risk to highest risk; and emphasizing that all water sources need to be assessed to ensure that they are of appropriate quality.

62. The Committee did not agree with the proposal of the Delegation of Brazil to indicate that the source of water should comply with local, regional and national regulations.

3.2.1.1.1 Water for irrigation

63. The Committee agreed to add an additional sentence to the first paragraph in order to clarify that water used for irrigation purposes should be of suitable quality for its intended use.

3.2.1.1.3 Hydroponic water

64. The Committee amended this section to emphasize that hydroponic water presents an increased risk of microbiological contamination.

3.2.1.2 Manure, biosolids and natural fertilizers

65. The title was amended for consistency with the corresponding title in the main Code to read “manure, biosolids and other natural fertilizers”.

66. The Committee did not agree to the proposal to exclude human waste for use as fertilizers noting that in many countries such wastes were allowed and that the section provided sufficient flexibility.

67. In the third paragraph, first sentence, the Committee agreed to replace “heat treatment” with “physical treatment” as more appropriate.

3.2.3 Personnel health, hygiene and sanitary facilities

68. The Committee agreed to delete paragraph 2 and the fourth bullet point as these aspects were covered in the main Code.

69. It was agreed to replace “operators” with “businesses operating primary production” as standard operating procedures (SOPs) were more suitable to larger operators than smallholders. The Committee did not agree with a proposal to indicate that SOPs should be documented in a comprehensive food safety plan since food safety plans were not warranted for vegetables at primary production and would be burdensome for smallholders.

3.2.3.1 Personnel hygiene and sanitary facilities

70. The Committee agreed to transfer the first bullet in section 3.2.3.4 Personal behaviour to 3.2.3.1 as more appropriate.

3.2.3.2 Health status

71. A new bullet point was inserted to indicate the need for medical examination of food handlers when there was a clinical or epidemiological indication to do so.

3.2.3.3 Personal cleanliness

72. The bullet point was amended to indicate that workers should bathe daily.

3.3.1 Prevention and cross-contamination

73. The third sentence of the second paragraph was clarified by adding at the end an example of a specific control measure.

3.3.2 Storage and transport from the field to the packaging facility

74. The Committee clarified the last sentence of the second paragraph to make it clear that transporters should have their standard operating procedures.

75. An additional sentence in relation to the exclusivity of receptacles transporting foodstuffs was added at the end of the third paragraph.

76. The first bullet point in relation to optimal temperatures was amended to make it also more appropriate to tropical countries' conditions.

4.1.1 Establishments

77. The Committee noted that two bullet points in Section 4.1.2 were more related to establishments than to equipment, therefore agreed to move these bullet points to Section 4.1.1 and deleted the reference to Section 4.1.2 Equipment.

5.2.2.3 Chemical treatments

78. The Committee added an additional sentence to clarify that certain post harvest treatments such as paraffin and fungicides should not be used for fresh leafy green vegetables.

5.2.3 Microbiological and other specifications

79. The last sentence of this section was amended to clarify that analysis and testing should be undertaken to evaluate the effectiveness of food safety control systems.

5.7 Documentation and records

80. Some delegations expressed concerns that small holders would have difficulty in preparing a written food safety plan. However, the Committee also noted that this was an important activity to ensure food safety control and to manage hazards. After some discussion, the Committee agreed to delete the square brackets and amended the first sentence to make it less prescriptive.

5.8 Traceability and recall procedures

81. The Committee replaced the term “traceability” with “traceability/product tracing” for consistency with other Codex documents and clarified that traceability/product tracing systems should be designed and implemented according to the relevant Codex guidance (CAC/GL 60-2006).

9.3 Labelling

82. The Committee deleted the reference to the Code of Refrigerated Packaged Foods with Extended Shelf Life as it was not applicable and deleted the footnote in relation to the reference to “use by date” of consumption, as it was already covered by the newly added reference to the *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985). It also amended the first and last sentences for clarity.

9.4 Consumer education

83. The first bullet point was amended to make it less restrictive and to clarify that handling of fresh leafy vegetables was necessary in order to minimize microbiological contamination. The reference to “discoloration” was deleted as not relevant to the safety of leafy greens.

10.2 Training and education programmes

84. The Committee amended the first sentence of the second section to clarify that personnel should receive periodic training where required.

Status of the Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruits and Vegetables at Step 4 (N04-2008)

85. The Committee agreed to forward the Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruits and Vegetables to the 33rd Session of the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix II).

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD (Agenda Item 6)¹²

86. The Committee recalled that at its 40th session it had agreed to return the proposed draft Code of Hygienic Practice for pathogenic *Vibrio* species in seafood to Step 3 for comments and further consideration at its present session. The Committee also recalled that it had agreed to establish a physical working group, led by Japan, which met immediately prior to the present session to review comments submitted and prepare proposals for consideration by the Plenary.

87. The Delegation of Japan introduced the report of the working group as presented in CRD 5, and highlighted the key changes proposed by the working group as follows:

¹² CL 2009/23-FH; ALINORM 09/23/13 Appendix IV; CX/FH 09/41/6 (comments of Australia, Costa Rica, European Community, Egypt, India, Japan, Kenya, New Zealand, Nicaragua, Norway, Thailand and the United States of America); CX/FH 09/41/6-Add.1 (comments of Australia, Brazil and Peru); CRD 5 (report of the physical working group on *Vibrio*); CRD 11 (comments of Indonesia); CRD 16 (comments of Thailand).

- Agreed to option 2 “Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* Species in Seafood” for the title to better reflect the content of the Code and for consistency with other Codex texts;
- Deleted reference to ready-to-eat foods;
- Amended the definition for “partially treated” to better reflect the content; and included the definition of “clean water” as revised by the Committee on Fish and Fishery Products;
- Transferred paragraphs 29 to 31 to the Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Bivalve Molluscs (see Agenda Item 7) as more appropriate;
- Incorporated footnote 8 into the text as it contained important points; and
- Deleted repetitive texts from the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

88. The Committee considered the revised text (Annex I of CRD 5) and generally agreed with the proposals made. In addition to editorial amendments, including amendments to the Spanish translation, made the following comments and changes.

General comments

89. The Committee noted the observation by the Delegation of Chile that measures for *V. parahaemolyticus* were not necessarily the same for *V. cholerae* and that some measures in the text might therefore not be sufficient to control *V. cholerae*.

2.3 Definition

90. A delegation questioned the definition for seafood, noting that seafood normally did not include fish, shellfish and other aquatic vertebrates from fresh water sources. It was clarified that this definition had been extensively discussed and that it best reflected what was covered by the Guidelines.

5.2.2.3 Food processing practices

91. The Committee amended paragraph 73 (new paragraph 71) to indicate that a sodium chloride concentration of more than 10% could minimize growth or reduce levels of *Vibrio* spp. and to clarify that the food processing practices listed in this section could be used singly or in combination.

92. Paragraph 75 (new paragraph 73) was amended to reflect that the technologies listed, including additional technologies such as freezing and extended storage, could inactivate not only *V. parahaemolyticus*, but all *Vibrio* species. In response to a question on the meaning of “mild heating”, it was clarified that the FAO/WHO Risk Assessments of *Vibrio parahaemolyticus* in Seafood and of *Vibrio vulnificus* in Raw Oysters referenced in this section mentioned temperatures associated with this technology.

9.3 Labelling

93. This section was amended to indicate that seafood at high risk of being contaminated with pathogenic *Vibrio* spp. should be labelled to alert at-risk consumers.

94. The Committee discussed whether to retain reference to the “alive or not alive” nature of products. It was noted that the working group had had considerable discussion on this matter and that there was agreement that the text should be retained since in some countries labelling of dead or alive products was essential consumer information.

9.4 Consumer Education

95. In the seventh indent of bullet point 1 of paragraph 102 (new paragraph 99), “finished seafood” was replaced with “finished product” for clarity.

9.4.1 Special attention to susceptible subpopulations

96. For purposes of clarity, the second bullet point was amended to indicate that seafood should be thoroughly cooked, rather than heated.

10.1 Awareness and responsibilities

97. It was agreed to delete reference to consumers since training by industry was mainly aimed at its employees and was in line with the corresponding section in the General Principles on Food Hygiene.

Status of the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* Species in Seafood (N05-2008)

98. The Committee agreed to forward the renamed Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* Species in Seafood to the 33rd Session of the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix III).

PROPOSED DRAFT ANNEX ON CONTROL MEASURES FOR *VIBRIO PARAHEAMOLYTICUS* AND *VIBRIO VULNIFICUS* IN MOLLUSCAN SHELLFISH (Agenda Item 7)¹³

99. The Committee recalled that at its 40th session it had agreed that a physical working group led by Japan, would develop an Annex on control measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish for circulation for comments at Step 3 and consideration by the current session of the Committee.

100. The Delegation of Japan briefly introduced the report of the physical working group (document CX/FH 09/41/7) on the development of the proposed draft Annex on control measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish, which met in Kyoto (Japan) on 26-29 May 2009. The Delegation explained that the working group had agreed that: the Annex should only address bivalve molluscs; that Part 1 of the Annex would cover “live” and “raw” bivalve molluscs including those receiving “post-harvest processing”; and that Part 2 would cover bivalve molluscs which were partially treated before consumption. The working group had further agreed that the Annex would not address “thoroughly treated” bivalve molluscs for direct consumption, which were adequately covered in the main document, i.e. Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* species in Seafood (see Agenda Item 6).

101. The Delegation informed the Committee that the physical working group on the Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* species in Seafood, which had met immediately before the current session (see Agenda Item 6) had also considered the proposed draft Annex.

102. The Committee considered the text revised by the working group (Annex II of CRD 5) and generally agreed with their proposals. In addition to some editorial changes, including amendments to the Spanish translation, it agreed to the following:

Introduction

103. The Committee reinstated footnote 2, which was inadvertently removed in Annex II of CRD 5, and deleted “recently completed” in relation to FAO/WHO risk assessment.

2.1 Scope

104. In paragraph 3, the Committee included common examples of bivalve molluscs and clarified that bivalve molluscs consumed after a vibriocidal treatment were not covered in the Annex.

2.2 Definition

105. The Committee amended the definition of “post-harvest processing” to recognise that post-harvest treatment technologies might be developed, which can achieve reduction of *V. parahaemolyticus* and *V. vulnificus* to non-detectable levels while retaining the sensory characteristics of live bivalve molluscs.

¹³ CX/FH 09/41/7; CX/FH 09/41/7-Add.1 (comments of Australia, Brazil, Costa Rica, Egypt, Mexico, Peru and United States of America); CX/FH 09/41/7-Add.2 (comments of European Community, India, Japan, New Zealand, Philippines, Thailand, IACFO); CRD 5 (report of the physical working group on *Vibrio*); CRD 12 (comments of Ghana); CRD 16 (comments of Thailand); CRD 19 (comments of China)

3.3 Handling, storage and transport

106. The Committee noted that paragraph 17 provided measures for preventing cross-contamination between bivalve molluscs destined to be consumed alive or untreated raw and those subject to post-harvest processing or other treatment, recognising that four categories of bivalve molluscs were marketed: (i) alive; (ii) untreated raw; (iii) raw after post-harvest treatment; and (iv) partially treated.

107. The Committee deleted the last part of the first bullet point in paragraph 18 to recognise that the purpose of all control measures was to achieve the appropriate level of protection.

Table 1

108. The Committee agreed to delete Table 1, which included information on growth rates of *V. parahaemolyticus* and *V. vulnificus* populations in raw oysters (*Crassostrea virginica*) in specific environmental conditions, as it did not provide additional guidance in the document.

Status of the Proposed Draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in molluscan shellfish

109. The Committee agreed to forward the renamed proposed draft Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Bivalve Molluscs (Annex to the Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic *Vibrio* species in Seafood) to the 33rd Session of the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix IV).

Request for a FAO/WHO Expert Meeting

110. The Committee recognised the need to validate predictive risk models with a view to constructing more applicable models for wide use among countries. Therefore, the Committee endorsed the recommendation of the working group to request FAO and WHO to convene an Expert meeting with the following terms of reference:

- Conduct validation of the predictive risk models developed by the United States of America, based on the FAO/WHO risk assessments, with a view to constructing more applicable models for wide use among member countries, including adjustment of strain virulence variations and ecological factors;
- Review the available information on testing methodology, and recommend microbiological methods for *Vibrio* spp. in order to monitor the levels of pathogenic *Vibrio* spp. in seafood and/or water; and
- Conduct validation of the growth rates and doubling times for *V. parahaemolyticus* and *V. vulnificus* in *Crassostrea virginica* provided in Table 1 of the proposed draft Annex (CX/FH 09/41/7), with view of including more strains isolated from different parts of world, and different bivalve molluscs species.

111. The FAO and WHO Representatives highlighted the need for data on prevalence and concentrations of *V. parahaemolyticus* and *V. vulnificus* in different bivalve molluscs and in sea waters, as well as on water temperature, salinity and ecological factors for validating the predictive risk models.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR CONTROL OF VIRUSES IN FOOD AT STEP 4 (Agenda Item 8)¹⁴

112. The Committee recalled that at its 40th session it had agreed to start new work on viruses in food and had agreed to establish a physical working group, led by The Netherlands, to develop the Code of Hygienic Practice for Control of Viruses in Food for circulation for comments at Step 3 and consideration of the current session of the Committee.

¹⁴ CX/FH 09/41/8; CX/FH 09/41/8-Add.1 (comments of Australia, Costa Rica, Cuba, Jamaica, Malaysia, Mexico, New Zealand, Peru and United States of America); CX/FH 09/41/8-Add.2 (comments of Canada, Chile, Egypt and Japan); CRD 6 (comments from the EC, Guatemala, Colombia, India and IACFO); CRD 11 (comments from Indonesia); CRD 13 (comments from Mali); CRD 16 (comments from Thailand); CRD 17 (comments from Paraguay); CRD 25 (comments from Bolivia).

113. The Delegation of The Netherlands introduced the document and indicated that a new title, *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food*, was proposed to better reflect the content of the document. The Delegation emphasized that many useful and extensive comments both technical and editorial had been submitted making it evident that more work was needed to improve the current document.

114. The Delegation summarized these comments as follows:

- Structure of the document. Some members suggested to include these guidelines for viruses into existing documents, such as the *Code of Practice for Fish and Fishery Products* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* or to add the virus guidelines as an annex to the *Recommended International Code of Practice-General Principles of Food Hygiene*. The Delegation indicated that this was a reasonable suggestion and that the Committee might consider doing so in the future when these documents would be revised. However, for the moment it was better to proceed with the development of a specific code for viruses in food, considering the public health importance of this issue;
- Some members considered the current draft as being too general and were asking for more specific information to be added. However, a lack of more precise scientific information prevented more specific advice in certain sections;
- There was a need to revise several definitions such as “food handler”, “fresh produce” and to clarify the definition of ‘viruses’. It was necessary to decide on whether the Committee would be dealing only with human enteric viruses, such as NoV and HAV, or all viruses. The objectives and the scope of the current draft were inconsistent as in the objectives ‘enteric viruses’ were mentioned, while in the scope only viruses in general were indicated. The Delegation was of the view that it was better to focus on all viruses, taking into account the possible emergence of other viruses, especially zoonotic viruses, in the future;
- The document should be more precise on the different types and use of water and it should be better defined which type of water should be used at the different stages;
- Cleaning and disinfection procedures should be described in more detail, especially better guidance should be given on disinfectants that can be used to inactivate viruses, though only limited information was available on this matter;
- More detailed guidance should be given for hand washing procedures to remove virus particles;
- More information should be given on the availability and efficiency of validated intervention procedures other than sanitation and personal hygiene, such as on the effects of heating, high pressure and other techniques. While scientific information available on this matter was limited at the moment, and much research in this field was currently ongoing.
- Additional work was necessary on when a food handler was allowed to return to work after the symptoms of the infection have ended. Should a medical examination or clinical diagnostic test be carried out? What measures have to be taken in relation to food handling by this person after their return to work? Is regular testing of food handlers for HAV in endemic areas needed and feasible?
- The need for labelling, especially regarding bivalve molluscs, and the way to do this labelling should be better defined, including aspects of traceability;
- Annex I on the control of viruses in RTE food was for the greater part a repetition of what was already covered by the main body of the document; therefore suggestions to delete this Annex and to move the information in this Annex to the main text were supported;
- Annex II on bivalve molluscs: Better guidance had to be given on the measures to be taken after virus contamination of growing waters. Guidance should be given on the need and feasibility of monitoring growing waters and bivalve molluscs. As regards monitoring, there was still a lack of standardized validated methods and limitations of the use of organisms, such as *E. coli*, as indicators for the possible presence of viruses need to be appreciated;
- Annex III on fresh produce. Consistency with the draft Annex on leafy green vegetables should be ensured.

115. One delegation indicated that the scope of the Guidelines was too broad and not targeted to specific foods and proposed that the main document should focus on ready to eat food which was a high risk food for virus-contamination and that the scope of the main Code, Annex II and Annex III need to be reviewed.

116. The Delegation of the European Community while supporting the comprehensive approach taken in the draft document drew the attention of the Committee to a project "Integrated monitoring and control of food borne viruses in European food supply chains" (VITAL) which aimed at developing a code of practice for control of virus contamination of food supply chains. The output of the project might be useful in the further development of the Codex guidelines.

117. The Committee noted that additional work was necessary on the development of the Guidelines and that additional information especially on the issues indicated above, would be very useful.

118. The Committee agreed to establish a physical working group, led by The Netherlands and working in English only, to revise the proposed draft Guidelines taking into account comments received at the current session and additional information to be gathered on the issues above. This working group was tentatively scheduled to be held in The Netherlands, 25-26 March 2010.

Status of the Proposed Draft Code of Hygienic Practice for the Control of Viruses in Food (N07-2009)

119. The Committee agreed to return the renamed *Proposed Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* to Step 2 for revision by the above working group. The revised version would be circulated for comments at Step 3 and considered by the next Session of the Committee.

INCONSISTENCIES ARISING IN DOCUMENTS ELABORATED BY THE CCFH AND ADOPTED BY THE COMMISSION (Agenda Item 9)¹⁵

120. The Committee recalled that at its 40th session it had requested the Secretariat to look at inconsistencies that might have arisen from previous revocations and amendments and to make proposals for consideration by the Committee.

121. The Secretariat introduced document CX/FH 09/41/9 to seek the Committee's agreement on a number of editorial amendments to Codex texts on food hygiene for possible transmission to the Commission for adoption.

122. The Committee noted that there were inconsistencies in the way some Codex texts, in particular the General Principles of Food Hygiene, were referenced and agreed that it was not possible to take a firm decision on whether to reference by title or section only, and that this would be considered on a case-by-case basis.

123. In the case of the last sentence of section 7.7.5 of the *Recommended International Code of Hygienic Practice for the Processing of Frog Legs* (CAC/RCP 30-1983), the Committee noting that the guidance as referenced here no longer existed, agreed to delete this sentence and not to develop detailed requirements for construction and operation of a freezer store. The Committee agreed to all other editorial amendments as proposed.

124. The editorial amendments will be forwarded by the Secretariat to the 33rd Session of the Codex Alimentarius Commission for adoption. Members and interested international organizations were also invited to inform the Secretariat or the Committee of any further inconsistencies in food hygiene texts.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 10)

(a) DISCUSSION OF THE REPORT OF THE WORKING GROUP FOR ESTABLISHMENT OF CCFH WORK PRIORITIES¹⁶

125. The Delegation of Guatemala, the chair of the working group for establishment of CCFH work priorities, held immediately before the present session, introduced this item and provided an overview of discussions and outcomes of the working group as presented in CRD 1.

¹⁵ CX/FH 09/41/9; CRD 7 (comments of the European Community)

¹⁶ CX/FH 09/41/10; CRD1 (Report of the CCFH working group for the establishment of CCFH work priorities); CRD3 (Proposals of new work and/or revising existing standards)

126. The Committee noted that the working group had considered three requests for new work on: (i) revision of the *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985); (ii) revision of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997); and (iii) elaboration of a Code of Hygienic Practice for the Production and Processing of Cocoa (Cacao) and Chocolate.

127. The Committee noted that the working group assigned the first priority to the work on revision of the *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985) and the second priority to the work on revision of *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997), noting that it was not less important that the work on the revision of the Code on natural mineral waters.

128. With regard to the elaboration of a Code of Hygienic Practice for the Production and Processing of Cocoa (Cacao) and Chocolate, the Committee agreed with the conclusion of the working group that this proposal could be reconsidered in the future.

Revision of the *Code of Hygienic Practices for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985)

129. Based on the recommendations of the working group, the Committee agreed to request the 33rd Session of the Commission to approve new work on the revision of the Code.

130. The Committee considered the project document for new work on the revision of the *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985) and made some editorial amendments in the text.

131. The Committee agreed to forward the project document for new work on the revision of the Code, included in CRD 3 and with some minor editorial amendments, to the 64th Session of the Executive Committee and the 33rd Session of the Commission for approval as new work (see Appendix V).

132. The Committee agreed to establish a physical working group, led by Switzerland, open to all interested parties and with interpretation in English, French and Spanish, to revise the *Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* for circulation for comments at Step 3 and consideration by the next session of the Committee, pending approval of the Commission. The physical working group was tentatively scheduled to be held in Switzerland in June 2010.

Revision of *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997)

133. Based on the recommendations of the working group, the Committee agreed to request the 33rd Session of the Commission to approve new work on revision of *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

134. The Committee considered the project document for new work on the proposed revision and made some editorial amendments in the text.

135. The Committee noted that no specific scientific advice from FAO/WHO was anticipated for the new work as the revision of the Principles was mainly aimed at: reflecting latest practice and knowledge on microbiological criteria; introducing the new risk management metrics not currently dealt with in the Principles; and providing guidance on the use of these new metrics and on how they relate to the new risk management measures. The Committee was informed by FAO and WHO of the ongoing development of a web-based sampling tool (see paragraph 15) that would be useful for the work of this working group.

136. The Committee agreed to forward the project document for new work on the revision of the Principles, to the 64th Session of the Executive Committee and the 33rd Session of the Commission for approval as new work (see Appendix VI).

137. The Committee agreed to establish a physical working group, led by Finland and co-chaired and hosted by Japan, open to all interested parties and working in English only, to revise the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) for circulation for comments at Step 3 and consideration by the next session of the Committee, pending approval of the Commission. The physical working group was tentatively scheduled to be held in Japan in April/May 2010.

Other matters

138. The Committee thanked the Delegation of Guatemala for their excellent work in chairing the working group and accepted the offer of the Delegation of Finland to chair the next working group, which will meet the day before the next session of the Committee.

PROPOSED DRAFT RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE CODEX COMMITTEE ON FOOD HYGIENE (Agenda Item 10(b))¹⁷

139. The Committee recalled that the 26th Session of the Commission had adopted the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* and that it requested all Codex Committees to develop or complete specific guidelines on risk analysis in their respective areas for inclusion in the Procedural Manual. It was also noted that these texts would be submitted to the Codex Committee on General Principles in order to ensure coordination of work and consistency with overarching Working Principles. The Committee further recalled that at the 39th Session of the CCFH it accepted the offer of the Delegation of India to lead the work on the development of the Risk Analysis Policies and Procedures.

140. The Delegation of India introduced the report of the in-session working group (see Agenda Item 1) as presented in CRD 28 and indicated that the working group had reviewed the extensive comments submitted and had prepared a revised version of the CCFH Risk Analysis Principles and Procedures. The Delegation pointed out that the clarity of the scope was enhanced, a new section on preliminary risk management activities was introduced, the presentation and flow of text has been improved and that redundancies were deleted.

141. The Committee thanked the Delegation of India and the working group for their work and considered the proposed draft Risk Analysis Principles and Procedures Applied by the Committee on Food Hygiene paragraph by paragraph, as presented in CRD 28. In addition to editorial amendments, the Committee made the following decisions:

Section II Preliminary risk management activities

142. The Committee moved paragraph 21 in relation to referring pathogen-commodity combinations to JEMRA from Section VI to the end of Section II, as this sentence was more relevant to preliminary risk management activities.

143. The last sentence of the second paragraph and the penultimate sentence in paragraph 3 were amended for clarity.

144. The Committee inserted the reference to the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/RCP 30-1999) in paragraph 6, as relevant for the FAO/WHO work on risk assessment.

Section IV Risk management

145. The Committee amended paragraph 9 for clarity and the last sentence of paragraph 11 (CX/FH 09/41/11) to clarify that the CCFH might establish microbiological criteria for foods to be used for sensitive populations by countries and/or provide enabling tools for the countries to apply MRM metrics.

146. The Committee discussed on whether to re-insert the original paragraph 18 which was less restrictive or to maintain the current paragraph 13 as presented in CRD 28. Some delegations were of the view that microbiological criteria should not be limited to quantitative risk assessments. Other delegations expressed the view that microbiological criteria should only be developed on the basis of quantitative risk assessment.

147. After some discussion, the Committee agreed to maintain the current paragraph 13 as presented in CRD 28 and amended the first sentence of this paragraph to make it less restrictive.

Section V Risk communication

148. The Committee agreed to move paragraph 17 from the section to the section VI on Interaction Between Risk Manager and Risk Assessor as it provided an additional clarification on the iterative process.

¹⁷ CX/FH 09/41/11; CX/FH 09/41/11-Add.1 (comments from Australia, Costa Rica, Cuba, European Community, Japan, United States of America, ICMSF and IDF); CRD 22 (comments from FAO/WHO); CRD 28 (report prepared by the in-session working group led by India)

149. The Committee noted that some inconsistencies might exist between the main document on CCFH Risk Analysis Principles and Procedures and Annex on the Process by Which the Codex Committee on Food Hygiene Will Undertake its Work and agreed to ask the CCGP to take care of these inconsistencies while reviewing these texts.

150. The Committee agreed to forward the Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene to the 33rd Session of the Commission for adoption and subsequent inclusion in Section VI of the Codex Alimentarius Procedural Manual (see Appendix VII).

OTHER MATTERS

151. The Delegation of Chile proposed to request the Commission that the CCGP establish procedures to be followed when situations such as the one observed during the Session when discussing Agenda item 4, where there was a lack of willingness on the advancement of the document in the Step procedure at this session. Because of this, delegations were not able to discuss this agenda item at this meeting and expressed concern that the discussion would continue through an electronic working group, working exclusively in English. In addition, since the next meeting was most likely to be held in Uganda, most developing Latin American countries would have difficulties attending and therefore their contribution to this topic would be further limited.

152. The Delegation expressed the opinion that avoiding the discussion of the topic was not the appropriate decision. A significant amount of items had been advanced in the step process following section by section consideration. They further expressed the opinion that situations, such as the one on bovine somatotropine, where the document had been put on-hold indefinitely, should be avoided.

153. For this reason, the Delegation of Chile requested that repetition of similar situation be avoided in future sessions.

154. Mexico, as regional coordinator for the Latin America and Caribbean region (CCLAC) together with delegations of Bolivia, Colombia, Dominican Republic, Honduras, Guatemala, Jamaica, Nicaragua, Uruguay, supported the intervention from Chile.

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

155. The Delegation of Uganda offered to co-host the 42nd Session of the CCFH in Uganda, which was tentatively scheduled from 29 November to 3 December 2010. The exact venue and dates would be determined by the host Government in consultation with the Codex Secretariat and would be communicated to all members and observers at a later stage.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 10/33/13
Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruit and Vegetables	5/8	Governments, 33 rd CAC	para. 85 and Appendix II
Proposed Draft Code of Hygienic Practice for Pathogenic <i>Vibrio</i> spp. in Seafood	5/8	Governments, 33 rd CAC	para. 98 and Appendix III
Proposed Draft Annex on Control Measures for <i>Vibrio parahaemolyticus</i> and <i>Vibrio vulnificus</i> in Molluscan Shellfish	5/8	Governments, 33 rd CAC	para. 109 AND Appendix IV
Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene	Procedure	Governments, 33 rd CAC	para. 150 and Appendix VII
Proposed Draft Guideline for the Control of <i>Campylobacter</i> and <i>Salmonella</i> spp in Chicken Meat	2/3	EWG led by New Zealand and Sweden, Governments, 42 nd CCFH	para. 41
Proposed Draft Guidelines for the Control of Viruses in Food (Renamed <i>Proposed Draft Guidelines on the Application of General principles of Food Hygiene to the Control of Viruses in Food</i>) (N07-12009)	2/3	PWG led by the Netherlands, governments, 42 nd CCFH	para. 119
New Work			
Proposed Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985)	1/2/3	PWG led by Switzerland, 33 rd CAC, governments, 42 nd CCFH	paras 129-132 and Appendix V
Proposed Revision of Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)	1/2/3	PWG led by Finland and hosted by Japan, 33 rd CAC, governments, 42 nd CCFH	paras 133-137 and Appendix VI

**LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES**

**Chairperson:
Président:
Presidente:**

Dr Emilio ESTEBAN
Science Advisor for Laboratory Services
U.S. Department of Agriculture
Food Safety and Inspection Service
950 College Station Rd.
Athens, GA 30605
Tel: 706-546-3429
Email: emilio.esteban@fsis.usda.gov

Assistant to Chairperson :

Dr Carl SCHROEDER
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Washington, DC 20250
Tel : 202-720-8124
Email: carl.schroeder@fsis.usda.gov

ALGERIE-ALGÉRIE-ARGELIA

Abdelhamid BOUKAHNOUNE
Directur General
Ministere du Commerce
Cite Zerhouni Mokhtar el Mohammadia Alger
Tel : 213661599313
Fax : 21321890251
Email : hboukahnoune@yahoo.fr

AUSTRALIA – AUSTRALIE

Amanda HILL
Principal Advisor, Food Safety
Food Standards Australia New Zealand
55 Blackall Street
Barton ACT 2610
Australia
Tel: 61 2 6271 2632
Fax: 61 2 6271 2278
Email: amanda.hill@foodstandards.gov.au

Dr Catherine MCLEOD

Senior Scientist (Seafood Safety)
South Australian Research & Development Institute
33 Flemington St.
Glenside 5065, SA
Australia
Tel: 61 8 8207 7904
Fax: 61 8 8207 7854
Email: cath.mcleod@sa.gov.au

Richard SOUNESS

General Manager
Food Department of Agriculture, Fisheries and Forestry
GPO Box 858
Canberra ACT 2601
Australia
Tel : 61 2 6272 4899
Fax : 61 2 6272 3025
Email : richard.souness@daff.gov.au

AUSTRIA - AUTRICHE**Dr Dietmar ÖSTERREICHER**

Senior Official
 Food Safety and Consumer Protection
 Federal Ministry of Health
 Bundesministerium für Gesundheit
 Radetzkystrasse 2
 A-1030 Wien/Vienna
 Tel: 43 1 71100 4792
 Fax: 43 1 7137952
 Email: dieter.oesterreicher@bmg.gv.at

BELGIUM – BELGIQUE - BÉLGICA**Isabel DE BOOSERE**

Food Expert
 Federal Public Service Health,
 Food Chain Safety and Environment
 Place Victor Hortaplein 40 box 10
 1060 Brussels, Belgium
 Tel: 32 2 524 73 84
 Fax: 32 2 524 7399
 Email: isabel.deboosere@health.fgov.be

BHUTAN – BHOUTAN - BHUTÁN**Jambay DORJI**

Food Safety Officer
 Bhutan Agriculture and Food Regulatory Authority
 P.O. Box No. 1071
 Thimphu, Bhutan
 Tel: 975 2 327031
 Fax: 975 2 327032
 Email: jamsdor77@gmail.com

Thuji TSHERING

Chief Regulatory and Quarantine Officer
 Bhutan Agriculture and Food Regulatory Authority
 P.O. Box No. 1071
 Thimphu, Bhutan
 Tel: 975 2 327031
 Fax: 975 2 327032
 Email: thujitshering@yahoo.com
tshering@moa.gov.bt

BOLIVIA - BOLIVIE**Katherine RODRIGUEZ ORTIZ**

Food Hygiene National Committee
 Coordinator-Lecturer
 Nuestra Señora de La Paz University
 Calle Presbítero Medina No. 2412
 Sopocachi
 La Paz, Bolivia
 Tel: 591 2 422323 int. 132
 Fax: 591 2 2410255
 Email: katherine.rodriguez@unslp.edu.bo
rodriguezkatherine@yahoo.fr

BOSNIA AND HERZEGOVINA
BOSNIE-HERZÉGOVINE
BOSNIA Y HERZEGOVINA
Dr Dzemil HAJRIC

Assistant Director
 Food Safety Agency of B&H
 Dr. Ante Starcevic B.B.
 88 000 Mostar
 Bosnia and Herzegovina
 Tel: 387 36 397 217
 Fax: 387 36 397 206
 Email: hajric@fsa.gov.ba

BRAZIL – BRÉSIL – BRASIL**Andre OLIVEIRA**

Ministry of Agriculture, Livestock and Food Supply
 MAPA – DIPOV/SDA
 Esplanada dos Ministérios
 Bloco D Sala 342-B
 CEP: 70043-900
 Brasília-DF
 Tel: 55 61 32182627
 Fax: 55 61 32244322
 Email: dipov@agricultura.gov.br

Andrea SILVA

Expert on Regulation and Health Surveillance
 National Health Surveillance Agency
 SIA, Trecho 5, Area especial 57
 Bloco D, 2º andar
 CEP: 71205-050
 Brasília-DF
 Tel: 55 61 34625377
 Fax: 55 61 34625315
 Email: andrea.oliveira@anvisa.gov.br
gicra@anvisa.gov.br

Denise RESENDE

General Manager of Food National Health Surveillance Agency
 SIA, Trecho 5, Area especial 57
 Bloco D, 2º andar
 CEP: 71205-050
 Brasília-DF
 Tel: 55 61 34626514
 Fax: 55 61 34625315
 Email: denise.resende@anvisa.gov.br
alimentos@anvisa.gov.br

Dr Vladimir PINHEIRO

DO NASCIMENTO
 Professor of Avian Medicine
 Dean Faculty of Veterinary Medicine
 Federal University of RGS (UFRGS)
 Rua Gen. Couto de Magalhães
 1155/204
 Porto Alegre (RS)
 CEP 90. 540-131
 Tel: 55 51 3308 6939
 Fax: 55 51 330 7305
 Email: vladimir@ufrgs.br

BULGARIA - BULGARIE**Dr Galya Stoycheva KOSTADINOVA**

State Veterinary Expert
 Ministry of Agriculture and Food
 55 Hristo Botev Blvd.
 1040 Sofia, Bulgaria
 Tel: 359 2 985 11305
 Fax: 359 2 981 6732
 Email: Gkostadinova@mzh.government.bg

BURUNDI**Dr Pierre Claver KAZIHISE**

Director General
 National Institute of Public Health, Ministry of Health
 P.O. Box 6807 Bujunbura
 Tel: 257 22 21 75 65
 Fax: 257 22 22 82 49
 Email: kazihise@yahoo.fr

CAMEROON – CAMEROUN - CAMERÚN**Colette Wolimoum Booto A NGON**

Chief of Service of Dairy Industry
 Ministry of Livestock, Fisheries and Animal Industries
 BP 5674
 Nlongkak-Yaoundé
 Tel: 237 77 659750
 Fax: 237 22 221405
 Email: booto25@yahoo.fr

Charles Booto A NGON

Director of Standartizaion
 Ministry of Industry
 BP 5674
 Yaoundé
 Tel: 237 99937621
 Fax: 237 22226496
 Email: bootoangon@yahoo.fr

CAMBODIA – CAMBODGE - CAMBOYA**Dr Sivutha PAU ANN**

Chief of Food Safety Bureau
 Department of Drugs and Food
 Ministry of Health
 No. 8 Street Ung Pokun
 Khan 7 Makara
 Phnom Penh, Cambodia
 Tel: 855 16 988 366
 Fax: 855 23 722 150
 Email: FDASPA@online.com.kh
pa_sivutha@yahoo.com

CANADA - CANADÁ**Helene COUTURE**

Head of Delegation
 Chief, Evaluation Division
 Bureau of Microbial Hazards
 Health Canada
 251 Sir Frederick Banting Drive way
 Address Locator 2204E
 Tunney's Pasture
 Ottawa, Ontario K1A 0K9
 Tel: 613 957 1742
 Fax: 613 952 6400
 Email: Helene_Couture@hc.sc.gc.ca

Amelie VEGA

Canadian Food Inspection Agency
 Codex Coordination Unit
 1400 Merivale Road
 Tower 1, Floor 5, Room 337
 Ottawa, Ontario K1A 0Y9
 Tel: 613 773 6018
 Fax: 613 773 5693
 Email: Amelie.Vega@inspection.gc.ca

Dr Jeff FARBER

Health Canada
 Director, Bureau of Microbial Hazards
 251 Sir Frederick Banting Drive way
 Address Locator 2203B
 Tunney's Pasture
 Ottawa, Ontario K1A 0K9
 Tel: 613 957 0880
 Fax: 613 954 1198
 Email: Jeff_farber@hc-sc.gc.ca

Dr Rejean BOUCHARD

Assistant Director
 Policy and Dairy Production
 Dairy Farmers of Canada
 21 Florence Street
 Ottawa, Ontario K2P 0W6
 Tel: 613 236 9997
 Fax: 613 236 0905
 Email: rejean.bouchard@dfc-plc.ca

CAPE VERDE – CAP-VERT – CABO VERDE**João José MENDONCA BARROS**

Advanced Technician
 Ministry of Economy
 Growth and Competitiveness
 Directorate General for Industry and Energy
 Republic of Cape Verde
 City of Praia – Achada Sto. Antonio
 Street City of Funcaal
 Postal code No. 145
 Tel: 238 260 4815/4800
 Fax: 238 261 3315
 Email: Joao.barros@govcv.gov.cv

CHILE - CHILI**Antonia URRUTIA**

Ingeniero Agronomo
 Servicio Agrícola y Ganadero
 Ministerio de Agricultura
 Av. Bulnes 140
 Santiago, Chile
 Tel: 56 2 3451585
 Fax: 56 2 3451578
 Email: Antonieta.urrutia@sag.gob.cl

Jaime CORNEJO CATALAN

Asesor Inocuidad Alimentos
 Ministerio de Salud
 Enrique Mac-Iver 459
 8 Piso
 Peñalolen
 Santiago, Chile
 Tel: 56 2 574 0474
 Email: Jcornejo@minsal.cl

CHINA – CHINE**Prof Xiumei LIU**

National Institute of Nutrition and Food Safety
7 Panjiayuan Nanli
Beijing 100021
China
Tel: 86 10 677 70158
Fax: 86 10 677 111813
Email: Xmliu01@yahoo.com

Prof Xiaoqiang GAO

National Center for Health Inspection and Supervision
32 # Beisantiao
Jiao Daokou
Dongcheng District, Beijing 100007
China
Tel: 86 10 8402 7605
Fax: 86 10 8402 7605
Email: gaoxiaoqiang@hotmail.com

Ming LIU

Officer
China MOH
No. 1 Xi Zhimenwai nanhu, Beijing 100044, China
Tel: 86 1068792986
Fax: 86 10 68792408
Email: liumingmoh@163.com

Shaoping GU

Director
Certification and Accreditation Administration of the People's
Republic of China (CNCA)
9# Madian East road, Tower B
Haidian District, Beijing 100088
P.R. China
Tel: 86 10 82262680
Fax: 86 10 82260755
Email: gusp@cnca.gov.cn

Dr Amen MAN-CHIT SO

Medical Officer
Food & Environmental Hygiene
Department
2/F, 4 Hospital Road.
Sai Ying Pun, Hong Kong
Tel: 852 3962 2035
Fax: 852 2810 6717
Email: mcsso@fehhd.gov.hk

Dr Ken Tsz-kit CHONG

Scientific Officer
Food and Environmental Hygiene Department
3/F, 4 Hospital Road
Sai Ying Pun,
Hong Kong
Tel: 852 3962 2064
Fax: 852 2803 0534
Email: ktkchong@fehhd.gov.hk

COLOMBIA – COLOMBIE**Blanca Cristina OLARTE PINILLA**

Profesional Especializada
Ministerio de la Protección Social
Carrera 13 No. 32-76 Piso 14
Bogotá D.C., Colombia
Tel: 57 1 3305000 ext. 1266
Fax: 57 1 3305050 ext. 1280
Email: bolarte@minproteccionsocial.gov.co

María del Pilar SANTOFIMIO SIERRA

Ingeniera de Alimentos
Instituto Nacional de Vigilancia de
Medicamentos y Alimentos-INVIMA
Carrera 68 D No. 17-21
Bogotá, Colombia
Tel: 57 1 2948700 ext. 3844
Fax: 57 1 2948700 ext. 3920
Email: msantofimos@invima.gov.co

**DEMOCRATIC REPUBLIC OF THE CONGO-
RÉPUBLIQUE DÉMOCRATIQUE DU CONGO-
REPÚBLICA DEMOCRÁTICA DEL CONGO****Dr Jean-Marie OLENGA YUMA**

Chef de Division Santé Publique Vétérinaire
Ministere de l'Agriculture, Pêche et Elevage
B.P. 8722 – Kinshasa
Tel: 243 998 867 155
Email: jm_olga@yahoo.com

DENMARK – DANEMARK - DINAMARCA**Annette PERGE**

Danish Veterinary and Food Administration
Morkhøj Bygade 19
2860 Soborg
Tel: 45 33 95 6000
Fax: 45 33 95 6001
Email: ape@fvst.dk

Jens Kirk ANDERSEN

Senior Adviser
National Food Institute
Technical University of Denmark
Mørnhoj Bygade 19
Dk-2860 Soborg
Denmark
Tel: 45 35 887213
Email: JKIA@food.dtu.dk

**DOMINICAN REPUBLIC - RÉPUBLIQUE
DOMINICAINE - REPÚBLICA DOMINICANA****Lic. Raúl PERALTA GIRON**

Director
Departamento de Inocuidad Agroalimentaria
Secretaría de Estado de Agricultura (SEA)
Av. John F. Kennedy
Urb. Jardines del Norte
Km. 6 ½
Santo Domingo, D.N.
Tel: 809 547 3888 ext. 6024
Fax: 809 541 0382
Email: mlecheraulperalta@yahoo.com
codexsespas@yahoo.com
agricultura@inocuidad.gov.do

EGYPT – ÉGYPTE – EGIPTO**Prof Alaa AZOUZ**

Deputy Director, Food Technology Research Institute
9, Cairo University st.
Giza, Egypt
Tel: 202 35718328, 20122152874
Fax: 202 35684669
Email: alaazouz@hotmail.com

Prof Yehia EL-SAMRAGY

Professor of Food Science
Ain-Shams University
P.O. Box 5823
Heliopolis West 11771
Cairo, Egypt
Tel: 201 01445657
Fax: 202 46103822
Email: elsamragy@hotmail.com

**EUROPEAN COMMUNITY – COMMUNAUTÉ
EUROPÉENNE – COMUNIDAD EUROPEA****Dr Jerome LEPEINTRE**

Administrator
European Commission
Directorate General for Health and Consumers
Rue Froissart 101
B-1049 Brussels, Belgium
Tel: 322 299 37 01
Fax: 322 299 85 66
Email: Jerome.Lepeintre@ec.europa.eu

Dr Paolo CARICATO

European Commission
Rue Belliard 232
1040 Brussels, Belgium
Tel: 322 29 93202
Fax: 322 29 69062
Email: paolo.caricato@ec.europa.eu

Dr Risto HOLMA

Administrator
European Commission
Directorate General for Health and Consumers
Rue Froissart 101
B-1049 Brussels, Belgium
Tel: 322 299 8683
Fax: 322 299 85 66
Email: risto.holma@ec.europa.eu

Dr Nigel COOK

Microbiologist
Food and Environment Research Agency
Sand Hutton
York YO41 1LZ
United Kingdom
Tel: +44 1904 462623
Fax: +44 1904 462111
Email: nigel.cook@fera.gsi.gov.uk

FINLAND-FINLANDE-FINLANDIA**Dr Sebastian HIELM**

Senior Veterinary Officer
Ministry of Agriculture and Forestry
Department of Food and Health
P.O. Box 30
00023 Government, Finland
Tel: 358 9 1605 3126
Fax: 358 9 1605 3338
Email: sebastian.hielm@mmm.fi

FRANCE - FRANCIA**Dr Paul MENNECIER**

Director
Food Safety Division Ministry of Food, Agriculture and Fisheries
Directorate General for Food
251 rue de Vaugirard
F-75732 Paris Cedex 15
Tel : 33 1 49 55 84 18
Fax : 33 1 49 55 56 80
Email : paul.mennecier@agriculture.gouv.fr

Pascal AUDEBERT

CCP France
SGAE
2 boulevard Diderot
75572 Paris, CEDEX 12
Tel : 33 1 44 87 16 03
Fax : 33 1 44 87 10 18
Email : sgae-codex-fr@sgae.gouv.fr

Anselme AGBESSI

D.G.C.C.R.F.
59, boulevard Vincent Auriol
TELEDOC 051
75703 Paris Cedex 13
Tel : 33 1 44 97 32 07
Fax : 33 1 44 97 24 86
Email : anselme.agbessi@dgccrf.finances.gouv.fr

GERMANY – ALLEMAGNE – ALEMANIA**Prof Walther HEESCHEN**

Director & Professor em.
Dielsweg 9
D-24105 Kiel, Germany
Tel: 49 431 34106
Fax: 49 431 338973
Email: Heesch@t-online.de

Dr Luppó ELLERBROEK

PD Dr. med. Vet., Dipl.-Chem., Dipl. ECVPH
Federal Institute for Risk Assessment
Unit Food Hygiene and Safety Concepts
Diedersdorfer Weg 1
12277 Berlin
Tel: 49 30 8412 2121
Fax: 49 30 8412 2966
Email: Lellerbroek@bfr.bund.de

Dr Petra LUBER

Scientific Officer
Federal Office of Consumer Protection and Food Safety (BVL)
Mauerstr. 39-42
D-10117 Berlin
Tel: 49 30 1844410618
Fax: 49 30 1844410699
Email: petra.luber@bve.bund.de

Dr Andrea SANWIDI

Head of Unit 328 (Food Hygiene)
Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)
Rochusstr. 1,
53123 Bonn, Germany
Tel: 49 228 99529 3828
Fax: 49 228 99529 4944
Email: 328@bmelv.bund.de

GHANA**Dr Steven Kwabena OPUNI**

Chief Executive
Food & Drugs Board
P.O. Box CT 2783
Accra, Ghana
Tel: 233 21 233222, 233 21 22 92 61
Fax: 233 21 229794
Email: skopuni@fdbghana.gov.gh

John ODAME-DARKWA

Deputy Chief Executive (Food)
Food and Drugs Board
P.O. Box CT 2783
Accra, Ghana
Tel: 233 21 233200
Fax: 233 21 229794
Email: jodamedarkwa@fdbghana.gov.gh

John OPPONG-OTOO

Codex Contact Point Officer
Ghana Standards Board
P.O. Box MB 245
Accra
Tel: 233 21 519758
Fax: 233 21 500092
Email: joppong-otoo@ghanastandards.org

GUATEMALA**Dr Antonio FERRATE, MSC**

Jefe del Area de Inocuidad de los Alimentos no Procesados y
Punto Focal del Codex
Ministerio de Agricultura, Ganadería y Alimentación
7° avenida 12-90 zona 13.
Tel: 502 2413 7455
Fax: 502 2413 7454
Email: antonio.ferrate@yahoo.com

Ing. Ana Gabriela MARROQUIN, MA

Codex Alimentarius Coordinator
Ministry of Agriculture,
Livestock and Food
7ª Avenida 12-90 zona 13
Edificio Infoagro
Segundo Nivel, Oficina 4
Tel: 502 2413 7466
Fax: 502 2414 7454
Email: codexguatemala@yahoo.com

GUINE-BISSAU - GUINÉE-BISSAU - GUINEA-BISSAU**José Carlitos IALA**

Presidente de Instituto
Inst. Nacion. De Invest. E Tecnol. Aplicada
Guiné-Bissau, CP 251
Tel: 245 5218362/6117627
Fax: 245 3221019
Email: yalacarlitos@yahoo.com.br

HONDURAS**Dr Floridalma MORALES**

Comision Nacional del Codex Alimentarius
Universidad Pedagógica Nacional
Calle El Dorado enfrente Mall Plaza
Miraflores
Tel: 504 239 8037
Fax: 504 231 1257
Email: flormorales2002@live.com
fmorales2002@gmail.com

HUNGARY – HONGRIE – HUNGRÍA**Dr Mária SZEITNE SZABO**

General Director
Hungarian Food Safety Office
H-1097 Budapest
Gyáli út 2-6
Tel: 36 1 439 0355
Fax: 36 1 387 9400
Email: maria.szabo@mebih.gov.hu

INDIA – INDE**Dave SANJAY**

Director
Agricultural & Processed Food Products Export
Development Authority (APEDA)
Govt. of India
Ministry of Commerce
New Delhi, 3rd Floor, Ncui Building, 3 Siri
Institutional Area
August Kranti
Marg, New Delhi, India
Tel: 91 11 26513162
Fax: 91 11 26519259
Email: director@apeda.com

Aditya Kumar JAIN

Manager Food Standards
National Dairy Development Board (NDDB)
Anand- 388 001
Gujarat, India
Tel: 91 2692 226256
Fax: 91 2692 260157
Email: aditya@nddb.coop

Dr Sarita BHALLA

Joint Director (Medical)
Ministry of Agriculture
Directorate of Plant Protection
Quarantine & Storage
Central Insecticides Laboratory
NH IV, Faridabad, Haryana
Tel: 91 129 2412049
Email: saritabhalla3@gmail.com
toxtil@nic.in

INDONESIA – INDONÉSIE**Edi SUHARTO**

Consul for Economic Affairs
Consulate General of the Republic of Indonesia
3457 Wilshire Blvd.
Los Angeles, U.S.A.
Tel: 2133835126
Fax: 2134873971
Email: edisuharto@yahoo.com

Tinuk Uchdiati BAHIROH

Section of Conformance of Fishery Quality Control
 Ministry of Marine Affairs and Fishery
 Jl. Medan Merdeka Timur No. 16
 Jakarta, Indonesia
 Tel: 62 21 3500149
 Fax: 62 21 3500149
 Email: tien_fish@yahoo.com

Sri MUKARTINI

Directorate of Veterinary Public Health
 Ministry of Agriculture
 Gedung C Lt. 8
 Jl. Harsono RM No. 3 Ragunan
 Jakarta, Indonesia
 Tel: 62 21 7827466
 Fax: 62 21 7827466

Tethy Helfery SIHOMBING

National Agency for Drug and Food Control
 Percetalcar Negara 23
 Jakarta, Indonesia
 Email: tethyhelfery@yahoo.com

IRAQ**Abdulah TAHA**

Specialist Bacteriologist
 Director of Center Public Health Lab.
 (CPHL)
 Ministry of Health
 Baghdad-Iraq
 Tel: 9641 7780453
 Mobil: 9641 7902439070
 Email: taha_moh47@yahoo.com

IRELAND – IRLANDE - IRLANDA**Kilian UNGER**

Head of Delegation
 Superintending Veterinary Inspector
 Department of Agriculture, Fisheries & Food
 Agriculture House
 Kildare Street
 Dublin 2
 Tel: 353 1 6072844
 Email: kilian.unger@agriculture.gov.ie

Dr Wayne ANDERSON

Director Food Science & Standards
 Food Safety Authority of Ireland
 Abbey Court
 Lower Abbey Street
 Dublin 1
 Tel: 353 1 8171321
 Fax: 353 1 8171221
 Email: wanderson@fsai.ie

ISRAEL – ISRAËL**Hana MARKOWITZ**

Head of Delegation
 Senior Food Engineer
 Head, HACCP & GMP section
 Ministry of Health
 12 Haarbba St.
 P.O. Box 20301
 Tel Aviv 61203
 Tel: 972 50 6242312
 Fax: 972 3 5619549
 Email: hanna.markovitz@moh.health.gov.il

ITALIY – ITALIE - ITALIA**Dr Brunella LO TURCO**

Segretario Generale Comitato
 Nazionale Italiano per il "Codex Alimentarius"
 Ministero delle Politiche Agricole, Alimentari e Forestali
 Via XX Settembre, 20
 00187 Roma
 Tel: 39 06 46656042
 Fax: 39 06 4880273
 Email: B.loturco@politicheagricole.gov.it

Dr Ciro IMPAGNATIELLO

Ministero delle Politiche Agricole, Alimentari e Forestali
 Via XX Settembre, 20
 00187 Roma
 Tel: 39 06 46656046
 Fax: 39 06 4880273
 Email: c.impagnatiello@politicheagricole.gov.it

JAMAICA - JAMAÏQUE**Dr Linnette PETERS**

Policy & Programme
 Director Veterinary Public Health
 Ministry of Health
 2-4 King Street
 Kingston
 Jamaica, West Indies
 Tel: 876 967 1100/1/3
 Email: petersl@moh.gov.jm
linnettep@hotm.com

JAPAN – JAPON - JAPÓN**Dr Hajime TOYOFUKU**

Section Chief (Food Safety)
 Department of Education and Trainings Technology
 Development
 National Institute of Public Health
 2-3-6 Minami Wako-shi
 Saitama 351-0197
 Japan
 Tel: 81 48 458 6111
 Fax: 81 48 469 1573
 Email: toyofuku@niph.go.jp

Dr Yoshimasa SASAKI

Assistant Director
 Ministry of Agriculture, Forestry and Fisheries
 1-2-1 Kasumigaseki Chiyoda-ku
 Tokyo, Japan 100-8950
 Tel: 81 3 3502 5722
 Fax: 81 3 3597 0329
 Email: yoshimasa_sasaki@nm.maff.go.jp

Noriko ISEKI

Senior Technical Officer
 International Affairs-Food Safety & Codex
 Division of Policy Planning and Communication Division
 Department of Food Safety
 Ministry of Health, Labour and Welfare
 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo
 100-8916, Japan
 Tel: 81 3 3595 2326
 Fax: 81 3 3503 7965
 Email: codexj@mhlw.go.jp

Kenji URAKAMI

Deputy Director
Standards and Evaluation Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo
100-8916 Japan
Tel: 81 3 3595 2341
Fax: 81 3 3501 4868
Email: codex@mhlw.go.jp

Toshitaka HIGASHIRA

Deputy Director
Inspection and Safety Division
Department of Food Safety Pharmaceutical and Food Safety
Bureau
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo
100-8916 Japan
Tel: 81 3 3595 2337
Fax: 81 3 3503 7964
Email: codex@mhlw.go.jp

Dr Mamoru NODA

Section Chief (Food Virology)
Division of Biomedical Food Research,
National Institute of Health Sciences
1-18-1, Kamiyoga
Setagaya-Ku, Tokyo
158-8501, Japan
Tel: 81 3 3700 9104
Fax: 81 3 3700 9527
Email: mamorunoda@nihs.go.jp

Prof Mitsuaki NISHIBUCHI

Center for Southeast Asian Studies
(CSEAS, Kyoto University)
46 Shimoadachi-cho,
Yoshida Sakyo-ku, Kyoto
606-8501 Japan
Tel: 81 75 753 736
Fax: 81 75 753 7350
Email: nisibuti@cseas.kyoto-u.ac.jp

Reiko KIWAMOTO

Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan 100-8950
Tel: 81 3 5512 2291
Fax: 81 3 3507 4232
Email: reiko_kiwamoto@nm.maff.go.jp

Tomoko GOSHIMA

Ministry of Agriculture, Forestry and Fisheries
1-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan 100-8950
Tel: 81 3 3592 0306
Fax: 81 3 3580 8592
Email: tomoko_goshima@nm.maff.go.jp

Rumi Matsumoto

Risk Assessment Division
Food Safety Commission Secretariat
Cabinet Office
5-2-20 Akasaka, Minato-ku, Tokyo 107-6122 Japan
Tel: 81 3 6234 1101
Fax: 81 3 3584 7391

KENYA**Dr Moses GICHIA**

Senior Assistant Director of Veterinary Services
Department of Veterinary Services
Private Bag 00625
Kangemi Nairobi
Kenya
Tel: 254733557134
Email: medwrin@yahoo.com

Zipporah MAIMBA

Quality Assurance Officer
Kenya Bureau of Standards
P.O. Box 54974 00200
Tel: 254 02 605490
Fax: 254 02 4031
Email: maimbaz@kebs.org
info@kebs.org

Dedan MUNGAI

Principal Fisheries Officer
Ministry of Fisheries Development
P.O. Box 58187-00200
Nairobi
Tel: 254721346233
Fax: 254203743699
Email: ddmungai@yahoo.com

KINGDOM OF BAHRAIN**Shaima AL-FARAJ**

Public Health Specialist
Ministry of Health
P.O. Box 12
Tel: 9733 6767263
Fax: 9731 7279253
Email: Shaima.alfaraj@gmail.com

KYRGYZTAN – KIRGHISISTAN - KIRGUISTÁN**Ilzat TEMIROV**

Assistant Director
National Institute for Standards and Metrology
“Kyrgyzstandard”
197, Panfilov Street
Bishkek, 720040
Kyrgyz Republic
Tel: 996 312 660165
Fax: 996 312 661367
Email: st.il777@mail.ru
nism@nism.gov.kg

**LAO PEOPLE'S DEMOCRATIC REPUBLIC -
RÉPUBLIQUE DÉMOCRATIQUE POPULAIRE LAO -
REPÚBLICA DEMOCRÁTICA POPULAR LAO****Viengxay VANSILALOM**

Deputy Director of Food Control Division
Food and Drug Department
Ministry of Health
Simouang Road
Vientiane Capital 01000
Tel: 856 21 2141013/4
Fax: 856 21 2141015
Email: vsyanshouth@yahoo.com
Codexcontactpoint_lao@yahoo.com

LEBANON-LIBAN-LÍBANO**Samir E. MAJDALANI**

Agricultural Engineer
 Ministry of Agriculture
 Embassies Street
 Bir Hasan
 Beirut, Lebanon
 Tel: 961 1 849600 ext. 110
 Email: sem@cyberia.net.lb

MADAGASCAR**Roger A. REJO**

Chef de Département "Environnement Et Qualité de la Vie"
 Centre National de Recherche sur L'Environnement
 39, rue Rasamimanana Fiadanana
 BP1739 Antananarivo (101)
 Madagascar
 Tel: 261 33 12 890 09
 Email: rogerrejo@yahoo.fr

Nirina SITEFANA RATAHINJANAHARY

Responsable Qualité au Laboratoire de Chimie et de
 Microbiologie du Ministère du Commerce de Madagascar
 Lot II J159 bis Ivaudry
 Madagascar
 Tel: 261 324096293
 Email: nirina_tahina2008@yahoo.fr

MALAWI**Janet GUTA**

Principal Nutritionist
 Ministry of Health (Nutrition Unit)
 P.O. Box 30377
 Lilongwe 3
 Tel: 265 1 788 201
 Cell: 265 8 888 50 923
 Fax: 265 1 788 232
 Email: janetnyachulu2000@yahoo.co.uk
janet.guta@gmail.com

MALI-MALÍ**Mahamadou SAKO**

Directeur General Adjoint
 Agence Nationale de la Securité Sanitaire des Aliments
 Bamako
 PE 2362
 Tel: 223 20220756
 Fax: 223 20220747
 Email: mahamadousako@yahoo.fr

MEXICO – MEXIQUE - MÉXICO**Jose Noe LIZARRAGA CAMACHO**

Subdirector Ejecutivo de Dictamen
 Sanitario de Productos y Servicios de Consumo, Uso y
 Publicidad
 Comisión Federal para la Protección Contra Riesgos
 Sanitarios, Secretaría de Salud
 Monterrey # 33 Piso 3
 Col. Roma
 Delegación Cuauhtémoc, México
 D.F. C.P. 06700
 Tel : 52 55 14 14 70
 Fax 52 55 50 80 52 00 ext. 1150
 Email : nlizarraga@cofepris.gob.mx

Dr Juan Antonio LEOS-RODRIGUEZ

Universidad Autónoma Chapingo
 Km 38.5 Carretera Mexico-Texcoco
 Chapingo
 Estado de México 56230
 Tel: 595 10893 84
 Fax: 595 95216 68
 Email: jleos45@gmail.com

Prof Marco Antonio LEON FELIX

Director General
 Lefix y Asociados
 Cerro Cópore 19
 Col. Campestre Churubusco
 04200
 D.F. C.P. 04815
 Tel : 55 5684 3301
 Fax : 55 5684 3889
 Email: lefix04@yahoo.com.mx
lefix@prodigy.net.mx

MONGOLIA**Byambasuren LAMJAV**

Director
 Capital City Professional Inspection Department,
 Mongolia, State Building # 2
 Revolutionary Avenue 15
 Ulaanbaatar 211238
 Tel: 976 11 311509
 Fax: 976 11 311509
 Email: L.byambaa@yahoo.com

Oyunchimeg DALKHJAV

Head, Health Inspection Department
 General Specialized Inspection Agency
 Government building # 13
 Chingeltei District
 Ulaanbaatar 211238
 Tel: 919 19818 (work) 263305
 Fax: 976 263305
 Email: Oyunchimeg_0610@yahoo.com

MOROCCO – MAROC - MARRUECOS**Abdelkrim BERRADA**

Head Service of Product Control
 Ministry of Agriculture and Fisheries
 Quartier Administratif
 B.P. 476 Haut Agdal
 Rabat-Morocco
 Tel: 212 5 37 68 82 78
 Fax: 212 5 37 68 82 94
 Email: berrada@mpm.gov.ma

MOZAMBIQUE**Dr Mualide DE SOUSA**

Ministry of Health
 Av. Eduardo Mondlane # 1008
 Maputo-Mozambique
 Tel: 258214615
 Tel: 258827006170 (mobile)
 Fax: 25821462714-25821326164
 Email: mualide@gmail.com

NAMIBIA**Mooy IITAMALO**

Food Safety Program Manager
Ministry of Health
Plbag 13198
Windhoek, Namibia
Tel: 264 61 2032741
Fax: 264 61 234083
Email: mooyni@gmail.com

NETHERLANDS – PAYS-BAS – PAÍSES BAJOS**Dr Arie OTTEVANGER**

CVO PH
Ministry of Health, Welfare and Sport
P.O. Box 20350
2500 EJ The Hague
The Netherlands
Tel: 31 70 3406886
Fax: 31 70 3405554
Email: a.ottevanger@minvws.nl

Ir. Enne DE BOER

Food and Consumer Product Safety Authority (VWA)
7200 AE Zutphen
Netherlands
Tel : 31 575 588100
Fax : 31 575 588200
Email : enne.de.boer@vwa.nl

NEW ZEALAND – NOUVELLE-ZÉLANDE – NUEVA ZELANDIA**Dr Steve HATHAWAY**

Director, Science
New Zealand Food Safety Authority
P.O. Box 2835
Wellington
New Zealand
Tel: 64 9 867 1144
Fax: 64 4 868 5207
Email: steve.hathaway@nzfsa.govt.nz

Judi LEE

Principal Advisor, Risk Management
New Zealand Food Safety Authority
P.O. Box 2835
Wellington
New Zealand
Tel: 64 9 428 0621
Fax: 64 4 428 0621
Email: judi.lee@nzfsa.govt.nz

NICARAGUA**Juana Agustina Castellón, CASTELLON**

Ing. Industrial
Ministerio de Salud
Apartado Postal 107
Tel : 505 22897607
Fax : 505 22894700
Email : jcastellon@minsa.gob.ni

Clara Ivania SOTO ESPINOZA

Licenciada en Ciencias de los Alimentos
Ministerio de Salud
Apartado Postal 107
Tel : 505 22897607
Fax : 505 22894700
Email : clarasot@yahoo.com
eta@minsa.gob.ni

NIGER - NÍGER**Aissatou Cisse Madame HASSANE**

Chef Service Alimentation et Nutrition
Ministère du Développement Agricole
Direction Generale de l'Agriculture
BP 323 Niamey
Tel: 227 96 96 94 23
Email: Hassan_hamid_sido@yahoo.fr

NIGERIA-NIGÉRIA**Hauwa KERI**

Director (EID)
National Agency for Food Drug Administration and Control (NAFDAC)
Plot 2032, Olusegun Obasanjo Way
Zone 7, Wuse, Abuja, Nigeria
Tel: +2348023123432
Email: hkeri@yahoo.com

Shekinah AMIENKUMO

Principal Regulatory Officer
National Agency for Food Drug Administration and Control (NAFDAC)
Plot 2032, Olusegun Obasanjo Way
Zone 7, Wuse, Abuja, Nigeria
Tel: +2348035047313
Email: kinakumo2@gmail.com

Alebode ISEDU

Deputy Director, Operations
National Food Reserve Agency
3rd Floor, Plot 590
Nace Building, Zone A0
Central Area, Abuja
Tel: +2348059610851
Email: aisedu@hotmail.com

NORWAY – NORVÈGE - NORUEGA**Gunn Harriet KNUTSEN**

Advisor
Norwegian Seafood Federation
P.O. 5471 Majorstuen
0305 Oslo, Norway
Tel: 47 99 11 00 00
Fax: 47 23 08 87 31
Email: gunn.knutsen@fhl.no

Kjersti Nilsen BARKBU

Senior Adviser
Norwegian Food Safety Authority,
Head Office
P.O. Box 383
N-2381 Brumunddal, Norway
Tel: 47 23 21 67 83
Fax: 47 23 21 6801
Email: kjnba@mattilsynet.no

Bjoern GONDROSEN

Norwegian Food Safety Authority,
Head Office
P.O. Box 383
N-2381 Brumunddal, Norway
Tel: 47 92251521
Fax: 47 23216801
Email: bjgon@mattilsynet.no

PAPUA NEW GUINEA - PAPOUASIE-NOUVELLE-GUINÉE - PAPUA NUEVA GUINEA**Terry DANIEL**

CEO, Food Sanitation Council Secretariat
Ministry of Health
P. O. Box 807
Waigani, NCD
Papua New Guinea
Tel: 675 301 3713
Fax: 675 325 0568
Email: Terry_daniel@health.gov.pg

PHILIPPINES - FILIPINAS**Almueda DAVID**

Food Drug Regulation Officer IV
Food & Drug Administration
Department of Health
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City 1770
Philippines
Tel: +32 842 4625
Fax: 32 842 4625, + 32 807 0751
Email: acdavid_fda@yahoo.com

Karen Kristine ROSCOM

Chief Science Research Specialist
Bureau of Agriculture and Fisheries Product Standards
Department of Agriculture
Bureau of Plant Industry Compound
Visayas Avenue
Quezon City
Philippines
Tel: +632 920 6131
Fax: +632 455 2858
Email: bafpsda@yahoo.com.ph

PORTUGAL**Dr Miguel CARDO**

Direcção Gral. de Veterinária
Largó da Academia Nacional das
Belas Artes, 2
1249-105 Lisbon, Portugal
Tel: +35 1213239500
Fax: +35 1214767500
Email: miguel.cardo@dgv.min-agricultura.pt

REPUBLIC OF KIRIBATI**Beia TIM**

Chief Health Inspector
Ministry of Health & Medical Services
Tungaru Central Hospital, Nawerewere
Tarawa, Kiribati
Tel: 686 28100
Fax: 686 28100 ext. 212
Email: beia.u.tim@gmail.com

REPUBLIC OF KOREA - RÉPUBLIQUE DE CORÉE - REPÚBLICA DE COREA**Dr In Gyun HWANG**

Director
Korea Food & Drug Administration
194 Tongil-ro
Nokbun-dong Eunpyung-ku
Seoul, 122-704, Korea
Tel: 82 2 380 1681
Fax: 82 2 355 6036
Email: inghwang@korea.kr

Dr Soon Han KIM

Deputy Director
Korea Food & Drug Administration
194 Tongil-ro
Nokbun-dong Eunpyung-ku
Seoul, 122-704, Korea
Tel: 82 2 380 1690
Fax: 82 2 382 4892
Email: lambndog@korea.kr

Dae Weon CHOI

Assistant Director
Korea Food & Drug Administration
194 Tongil-ro
Nokbun-dong Eunpyung-ku
Seoul, 122-704, Korea
Tel: 82 2 380 1635
Fax: 82 2 354 8620
Email: cdaewon@korea.kr

Keun Hwa CHOI

Senior Researcher
Korea Food & Drug Administration
194 Tongil-ro
Nokbun-dong Eunpyung-ku
Seoul, 122-704, Korea
Tel: 82 2 380 1820
Fax: 82 2 354 8520
Email: skysm98@korea.kr

Dr Yun-Ji KIM

Principal Researcher
Korea Food Research Institute
516 Baekhyun-dong Bundang
Seongnam, Kyunggi-do 463-746
Korea
Tel: 82 31 780 9085
Fax: 82 31 709 9876
Email: yunji@kfri.re.kr

Prof Soohyung LEE

Researcher
Rural Development Administration
249, Seodun-dong
Gwonseon-gu Suwon-si
Gyeonggi-do, 441-707
Republic of Korea
Tel: 82 31 290 0450
Fax: 82 31 290 0407
Email: nolmoe@rda.go.kr

Hong-Seup LEE

DVM Director
National Veterinary Research & Quarantine Service
Livestock Products Safety Division
480, Anyang 6-dong
Manan-gu, Anyang-city
Gyeonggi-do
Republic of Korea
Tel: 82 31 467 1961
Fax: 8231 467 1974
Email: leehs03@nvrqs.go.kr

SI Wook SONG

Veterinary Official
National Veterinary Research &
Quarantine Service
173 Jungangro, Manan-gu
Anyang-city
Gyeonggi-do
Korea 430-757
Tel: 82 31 467 1973
Fax: 82 31 467 1974
Email: songsw@nvrqs.go.kr

Young Jo KIM

Veterinary Official
NVRQS
480 Anyang 6 Dong
Anyang-city
Gyeonggi-do
Korea
Tel: 82 31 467 4390
Fax: 82 31 467 1889
Email: fmd2000@nvrqs.go.kr

RWANDA**John Ruziga RUSHALAZA**

Technical Director
RTI/NMCP – MoH
P.O. Box 612
Kigali-Rwanda
Tel: 250 788302621
Fax: 250 788302622
Email: ruzigaj@yahoo.com

SAMOA

Andrew PETERU
Assistant CEO
Ministry of Health
Private Bag
Apia, Samoa
Tel: 685 68100
Fax: 685 26553
Email: AndrewP@health.gov.ws

SENEGAL - SÉNÉGAL

Hanne Alhousseynou MOCTAR
Chef de Bureau Controle Phytosanitarie, Gestionnaire Du
Point National des Mesures Sanitaires et Phytosanitaires
DPV/ Ministère de l'Agriculture, Pisciculture et Biocarburant
Km 15 Rte de Rufisque
BP 20054
Thiaroye, Dakar
Tel: 221 77 6 40 75 17
Fax: 221 33 8 34 28 54-338532252
Email: almhanne@yahoo.fr

SOUTH AFRICA - AFRIQUE DU SUD - SUDÁFRICA**Dipuo SEISA-MOETI**

Chief Food Safety and Quality Assurance Officer
Department of Agriculture Forestry And Fisheries
30 Hamilton Street
Arcadia
Pretoria, 0001
South Africa
Tel: 27 12 319 6060
Fax: 27 12 319 6055
Email: DipuoS@daff.gov.za

Penelope CAMPBELL

Deputy Director
Biological Safety
Department of Health
Private Bag X828
Pretoria 0001
Tel: 27 12 3120159
Fax: 27 12 312 3180/62
Email: campbp@health.gov.za

SPAIN – ESPAGNE - ESPAÑA**Beatriz MARTINEZ ZAMORANO**

Jefe de Servicio Subdirección General de Gestión de Riesgos
Alimentarios
Agencia Espanola de Seguridad
Alimentaria y Nutrición
Mo. De Sanidad y Politica Social
Alcalá, 56
28071 Madrid, Espana
Tel: 34 913380400
Fax: 34 913380169
Email: bmartinezz@msps.es

SAINT VINCENT AND THE GRENADINES**D'obre Haydeen CHARLES**

Standards Officer
St. Vincent and the Grenadines Bureau of Standards
(SVGBS)
Campden Park
P.O. Box 1506
Kingstown, St. Vincent and The Grenadines
Tel: 784 457 8092
Fax: 784 457 8175
Email: svgbs@vincysurf.com

SWAZILAND - SWAZILANDIA**Dube DUDU**

Senior Health Inspector
Ministry of Health
Box 5
Mbabane, Swaziland
Tel: 268 6629280
Fax: 268 4047420
Email: duduzdube@yahoo.co.uk

SWEDEN – SUÈDE - SUECIA**Kerstin JANSSON**

Deputy Director
Ministry of Agriculture
SE-103 33 Stockholm
Sweden
Tel: 46 8 405 1168
Fax: 46 8 20 6496
Email: kerstin.jansson@agriculture.ministry.se

Lars Plym FORSHELL

Senior Vet. Insp.
National Food Administration
P.O. Box 622
SE 75126 Uppsala
Sweden
Tel: 46 18 175582
Fax: 46 18 105848
Email: lapl@slv.se

Dr Viveka LARSSON

Senior Veterinary Officer
National Food Administration
P.O. Box 622
SE 75126 Uppsala
Sweden
Tel: 46 18 17 55 88
Fax: 46 18 17 53 10
Email: bvila@slv.se

Antonio ATAZ

Administrator
General Secretariat of the Council of the European Union
(EU) Swedish Presidency
Rue de la Loi 175
(office 4040 GM 36)
1048 Brussels, Belgium
Tel: 32 2 281 4964
Fax: 32 2 281 6198
Email: Antonio.ataz@consilium.europa.eu

SWITZERLAND – SUISSE - SUIZA**Christina Gut SJOBERG**

Scientific Advisor
Consumer Protection Directorate
Food Safety Division
Swiss Federal Office of Public Health
CH-3003 Bern, Switzerland
Tel : 41 31 322 68 89
Fax : 41 31 322 95 74
Email : christina.gut@bag.admin.ch

THAILAND-THAILANDE-TAILANDIA**Pisan PONGSAPITCH**

Senior Expert
National Bureau of Agricultural
Commodity and Food Standards
50 Phaholyotin Rd.
Chatuchak
Bangkok 10900, Thailand
Tel: 662 5612277 ext. 1421
Fax: 662 561 3357
Email: pisan@acfs.go.th

Suwimon KEERATIVIRIYAPORN

Director Samutsakorn Fish Inspection Center
Department of Fisheries
P.O. Box 39
Muang, Samutsakorn
Thailand
Tel: 66 34 457423
Fax: 66 34 857192
Email: suwimonk@ji-net.com

Apinan KONGNURAT

Senior Veterinary Officer
Department of Livestock Development
69/1 Phaya Thai Road
Ratchadewee
Bangkok 10400 Thailand
Tel: 66 2 653 4931
Fax: 66 2 653 4917
Email: apinan_krt@yahoo.com

Nitaya NIJTHAVORN

Senior Veterinary Officer
Department of Livestock Development
91 Moo 4, Tivanont Road
Pathum Thani
Thailand
Tel: 662 501 1215
Fax: 662 501 1215
Email: nithavorn65@gmail.com

Dr Virachnee LOHACHOOMPOL

Standards Officer
National Bureau of Agricultural Commodity and Food
Standards
50 Paholyathin Rd.
Jatujak, Bangkok
10310, Thailand
Tel: 662 561 2277 ext. 1422
Fax: 662 561 3357
Email: virachnee@hotmail.com

Patchana SUPASOON

Department of Agriculture
Ministry of Agriculture & Cooperatives
50 Phaholyothin Rd.
Chatuchak
Bangkok, Thailand
Tel : 66 29406995
Fax : 66 29406996
Email : d_patchana@hotmail.com

Dr Suwimon KEERATIPIBUL

Associate Professor
Food Industry Group
The Federation of Thai Industries
Queen Sirikit
Convention Center, Zone C
Floor 4th
Bangkok, Thailand
Tel: 668 1 333 1794
Fax: 662 2544314
Email: Suwimon.k@chula.ac.th

Linda PLEANPRASERT

Administrative Manager
 Thai Food Processors' Association
 170/21-22, 9th Ocean Tower 1
 Ratchadaphisek Rd.
 Bangkok 10110
 Tel: 662 261 2684
 Fax: 662 261 2996
 Email: linda@thaifood.org

Pornphan INTUSATITAYAKUL

Information Center
 Thai Frozen Foods Association
 92/6 6th Floor, Sathornthani II
 Bangrak, Bangkok 10500
 Tel: 662 2355622
 Fax: 662 2355625
 Email: pornphan@thai-frozen.or.th

TAJIKISTAN**Dr Kosim KURBONOV**

Head Specialist
 State Sanitary and Epidemiological Surveillance Service
 8 Tchapaeva Street
 Dushanbe, Tajikistan
 Tel: 992372274947
 Fax: 992372274947
 Email: kosim.kurbonov@gmail.com
repses@yandex.ru

TONGA**Dr Malakai AKE**

Chief Medical Officer
 P.O. Box 59
 Nukualofa, Tonga
 Tel : 6768778418
 Fax : 67627985
 Email : drmalakaiake@gmail.com

TURKEY-TURQUIE-TURQUÍA**Betul VAZGECER**

Engineer
 Ministry of Agriculture and Rural
 Affairs-General Directorate of
 Protection and Control
 Tarım ve Köyisleri Bakanlığı
 Koruma ve Kontrol Genel Müdürlüğü
 Akay Cad. No. 3 Bakanlıklar
 Ankara, Turkey
 Tel: 90 312 4174176 ext. 6202
 Fax: 90 312 425 44 16
 Email: betulv@kkgm.gov.tr

Prof Dr Irfan EROL

Member of the National Food Codex Committee
 Ankara Univ. Veterinary Faculty
 Diskapi 06110 Ankara
 Turkey
 Tel: 90 312 3170010 ext. 351
 Fax: 90 312 3179910
 Email: erol@veterinary.ankara.edu.tr
Irfan.Erol@veterinary.ankara.edu.tr

UGANDA-UGANDA**Dr Ben MANYINDO**

Deputy Executive Director
 Uganda National Bureau of Standards
 P.O. Box 6329
 Kampala, Uganda
 Tel: 256 772 516 848
 Fax: 256 41 428 6123
 Email: ben.manyindo@unbs.go.ug

Dr Edson Friday AGABA

Food Safety Coordinator
 National Drug Authority
 P.O. Box 23096
 Kampala, Uganda
 Tel: 256 772 691236
 Fax: 256 414 255758
 Email: agabafriday@hotmail.com
agaba_friday@yahoo.co.uk

Hope KABIRISI

Special Presidential Assistant
 State House
 P.O. Box 1781
 Kampala, Uganda
 Tel: 256 772 505646
 Email: kabirisih@yahoo.co.uk

UNITED KINGDOM – ROYAUME-UNI – REINO UNIDO**Keith MILLAR**

Hygiene & Microbiology Division
 Food Standards Agency
 Aviation House
 125 Kingsway
 London WC2B 6NH
 Tel: 44 207 276 8472
 Fax: 44 207 276 8910
 Email: keith.millar@foodstandards.gsi.gov.uk

Dr Paul COOK

Hygiene & Microbiology Division
 Food Standards Agency
 Aviation House
 125 Kingsway
 London WC2B 6NH
 Tel: 44 207 276 8950
 Fax: 44 207 276 8910
 Email: paul.cook@foodstandards.gsi.gov.uk

UNITED STATES OF AMERICA- ÉTATS-UNIS D'AMÉRIQUE – ESTADOS UNIDOS DE AMÉRICA**Dr Donald ZINK**

Senior Science Advisor
 Center for Food Safety and Applied Nutrition
 Food and Drug Administration
 Room 4A-004 Harvey W. Wiley Federal
 Building
 5100 Paint Branch Parkway
 College Park, Md 20740
 Tel: 301-436 1693
 Email: Donald.Zink@fda.hhs.gov

Dr Kerry DEARFIELD

Scientific Advisor for Risk Assessment
US Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave. SW
380 Aerospace Building
Tel: 202-690-6451
Fax: 202-690-6337
Email: kerry.dearfield@fsis.usda.gov

Jack MOWBRAY

Senior Policy Advisor
Office of Food Safety
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Room 3A-006 Harvey W. Wiley Building
5100 Paint Branch Parkway
College Park, MD 20740
Tel: 301-436-1490
Email: John.Mowbray@fda.hhs.gov

Dr Patty BENNETT

Veterinary Medical Officer
US Department of Agriculture Food Safety and Inspection
Service
Room 2-2113 George Washington Carver
Center
5601 Sunnyside Ave.
Beltsville, MD 20705
Tel: 301-504-0842
Email: patricia.bennett@usda.gov

Dr Angelo DEPAOLA

Lead Scientist for Seafood Microbiology
US Food and Drug Administration
FDA Gulf Coast Seafood Laboratory
P.O. Box 158
1 Iberville Dr.
Dauphin Island, AL 36528
Tel: 251-690-3367
Fax: 251-694-4477
Email: angelo.depaola@fda.hhs.gov

Amy GREEN

Science Policy Analyst
Office of Food Safety
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
HFS-317 Wiley Building
5100 Paint Branch Parkway
College Park, MD 20740
Tel: 301-436-2025
Fax: 301-436-2651
Email: amy.green@fda.hhs.gov

Kenneth HINGA

International Trade Specialist
US Department of Agriculture
Foreign Agricultural Service
1400 Independence Avenue, SW
Washington, DC 20250
Tel: 202-720-0969
Email: kenneth.hinga@fas.usda.gov

Dr Marianne MILIOTIS

Microbiologist
US Food and Drug Administration
Center for Food Safety and Applied Nutrition
8301 Muirkirk Road
Laurel, MD 20708
Tel: 301-210-6125
Fax: 301-210-6093
Email: marianna.miliotis@fda.hhs.gov

Dr Joyce SALTSMAN

Interdisciplinary Scientist
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Safety
HFS-317
5100 Paint Branch Parkway
College Park, MD 20740
Tel: 301-436-1641
Fax: 301-436-2651
Email: joyce.saltsman@fda.hhs.gov

Jenny SCOTT

Senior Advisor
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
HFS-300
5100 Paint Branch Parkway
College Park, MD 20740
Tel: 301-436-2166
Fax: 301-436-2632
Email: jenny.scott@fda.hhs.gov

Kathleen STALEY

Food Safety Officer
US Department of Agriculture
Agricultural Marketing Service
Fruit and Vegetable Programs
1400 Independence Avenue, SW
Washington, DC 20250
Tel: 202-720-0202
Fax: 202-690-1527
Email: Kathleen.Staley@ams.usda.gov

Dr Michael WEHR

Senior Advisor and Codex Program Manager
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20816
Tel: 301-436-1724
Fax: 301-436-2618
Email: michael.wehr@fda.hhs.gov

Karen STUCK

U.S. Codex Manager
US Department of Agriculture
4861 South Building
12th & Independence Avenue, SW
Washington, DC 20250
Tel: 202-720-2057
Fax: 202-720-3157
Email: karen.stuck@osec.usda.gov

Barbara MCNIFF

Senior International Issues Analyst
US Department of Agriculture
4870 South Building
1400 Independence Avenue, SW
Washington, DC 20250
Tel: 202-690-4719
Fax: 202-720-3157
Email: barbara.mcniciff@fsis.usda.gov

Emily MATHUSA

Associate Scientist, Microbiology
Grocery Manufacturers Association
1350 I St. NW, Suite 300
Washington, DC 20005
Tel: 202-637-4807
Fax: 202-639-5993
Email: emathusa@gmaonline.org

Dr Alling YANCY

VP Food Safety and Production
US Poultry and Egg Association
1530 Cooledge Road
Tucker, GA 30084
Tel: 770-493-9401 ext. 145
Fax: 770-493-9257
Email: ayancy@poultryegg.org

URUGUAY**Adriana NABON**

Quimico Farmaceutico
Ministerio de Salud Publica
Avenida 18 de Julio
1892 C.P. 11200
Tel: 403-1725 int. 114
Fax: 403-1725 int. 106
Email: adma@adinet.com.uy

VIET NAM**Thi Tu Cau THACH**

Officer
Vietnam National Codex Committee
70 Tran Hung Dao, Street
Hanoi, Vietnam
Tel: 844 39428030
Fax: 844 38222520
Email: codex@tcvn.gov.vn or
Ttcau_codex@yahoo.com

ZAMBIA-ZAMBIE**Delphin M. KINKESE**

Chief Environmental Health Officer
Food Safety and Occupational Health
Ministry of Health
P.O. Box 30205
Lusaka, Zambia
Tel: 260 211 25304015
Fax: 260 211 253344
Email: dmkinkese@gmail.com

**ASOCIACIÓN LATINOAMERICANA DE
AVICULTURA (ALA)****Dra Simone da Costa ALVES MACHADO**

Director de la Delegación
ALA
Rua Mauá, 920
Centro Cívico – Curitiba-PR
Brazil- 80030-200
Tel: 55 41 2117 8641
Fax: 55 41 2117 8641
Email: simone.machado@sadia.com.br
simachad@hotmail.com

Manuel HOFFMAN

Medico Veterinario
ALA
Ave. Reforma 1-50, Z.9
Edif. El Reformador 4to. Nivel
Tel: 502 2360 3084
Fax: 502 2360 3161
Email: mhoff@anaviguatemala.org
mmorales@anaviguatemala.org

**GROUPEMENT INTERNATIONAL DES SOURCES
D'EAUX NATURELLES ET D'EAUX CONDITIONNEES
(EFBW)****María Teresa CARBONELL de PABLO**

Membre du Groupe Technique et Reglementaire
Groupe International Des Sources D'eaux Naturelles et
d'eaux conditiones
Fédération Européenne des eaux Embouteillees
Guiselec/EFBW
Rue de L'Association 32
1000 Bruxelles
Tel: 32 2 210 2032
Fax: 32 2 210 2035
Email: info@efbw.org

**INTERNATIONAL ASSOCIATION OF CONSUMER
FOOD ORGANIZATIONS (IACFO)****Caroline SMITH DE WAAL**

International Association of Consumer Food Organizations
c/o CSPI
1875 Connecticut Avenue NW
Washington, DC 20009
Tel: 202-332-9110
Fax: 202-265-4954
Email: csmithdewaal@cspinet.org

**INTERNATIONAL COMMISSION ON
MICROBIOLOGICAL SPECIFICATIONS FOR FOOD
(ICMSF)****Prof Leon GORRIS**

Head of Delegation
Unilever
Colworth Science Park
Sharnbrook
MK44 1 LQ
United Kingdom
Tel: 44 1234264798
Fax: 44 1234264929
Email: Leon.Gorris@Unilever.com

INTERNATIONAL CONFECTIONERY ASSOCIATION (ICA)**Christopher MAHONY**

Executive Director
ICA
885 Don Mills Rd.
Toronto, Ontario
Canada, MSC IV9
Tel: 416 510 8034

INTERNATIONAL CO-OPERATIVE ALLIANCE / ALLIANCE COOPÉRATIVE INTERNATIONALE / ALIANZA COOPERATIVA INTERNACIONAL (ICA)**Kazuo ONITAKE**

Head of Unit, Safety Policy Service
Japanese Consumer's Cooperative Union
Co-op Plaza, 3-29-8 Shibuya
Shibuya-Ku
Tokyo, Japan 150-8913
Tel: 81 3 5778 8109
Fax: 81 3 5778 8125
Email: Kazuo.onitake@jccu.coop

INTER-AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE (IICA)**Alejandra DIAZ**

Especialista Regional en Sanidad e Inocuidad-Centroamerica
600 m Norte del Cruce Ipis-Coronado
Apartado 55-2200
San Isidro de Coronado
San José, Costa Rica
Tel: 506-22160303
Email: alejandradiaz20@gmail.com
alejandra.diaz@iica.int

NATIONAL HEALTH FEDERATION**Dr Dan KENNER**

P.O. Box 688
Monrovia, CA 91017
Tel: 626-357-2181
Fax: 626-303-0642
Email: contact-us@thenhf.com

WORLD ORGANISATION FOR ANIMAL HEALTH/ORGANISATION MONDIALE DE LA SANTÉ ANIMALE/ORGANIZACIÓN MUNDIAL DE SANIDAD ANIMAL (OIE)**Gillian Elizabeth MYLREA**

World Organisation for Animal Health (OIE)
Chargee de Mission
12, rue de Prony
Paris, 75017
France
Tel : 33 1 44 15 18 88
Fax : 33 1 42 67 09 87
Email : g.mylrea@oie.int

FAO PERSONNEL - PERSONNEL DE LA FAO - PERSONAL DE LA FAO**Dr Maria de Lourdes COSTARRICA GONZALEZ**

Senior Officer, Food Quality Liaison Group
FAO
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: 39 06 570 56060
Fax: 39 06 570 54593
Email: lourdes.costarrica@fao.org

Dr Iddya KARUNASAGAR

Senior Fishery Industry Officer
FAO
Room F615
Viale delle Terme di Caracalla
00153 Rome
Italy
Tel: 39 06 570 54873
Email: iddya.karunasagar@fao.org

**WHO PERSONNEL
PERSONNEL DE L'OMS
PERSONAL DE LA OMS****Dr Peter K. BEN EMBAREK**

Food Safety and Nutrition
World Health Organization
401 Dongwai Diplomatic Office Bldg.
23 Dongzhimenwai Ave.
Chaoyang District
Beijing 100600, China
Tel: 86 1065327189
Fax: 86 1065322359
Email: BenembarekP@wpro.who.int

Kazuko FUKUSHIMA

Technical Officer
Department of Food Safety and Zoonoses (FOS)
World Health Organization
20, Avenue Appia
1211 Geneva 27, Switzerland
Tel: 41 22 791 2920
Fax: 41 22 791 4807
Email: fukushimaka@who.int

FAO/WHO EXPERTS**Geoffrey MEAD**

Temporary Advisor – FAO/WHO
Expert
Food Hygiene Consultant
17 Harbutts, Bathampton
BATH, Somerset; BA2 6TA
United Kingdom
Tel: 44 1225 445180
Email: mead.geoff@gmail.com

Gregory M. PAOLI

Temporary Advisor – FAO/WHO
Expert
Principal Risk Scientist
Risk Sciences International, Inc.
449 Sussex Drive
Suite 200, Ottawa, Ontario
K1N 6Z4 Canada
Tel: 613 260 1424 ext. 151
Fax: 613 260 1443
Email: gpaoli@risksciencesint.com

US SECRETARIAT**Samuel G.L. BALAGADDE**

International Liaison Officer
Uganda National Bureau of Standards
Plot M 217 Nakawa
Industrial Area
P.O. Box 6329 Kampala, Uganda
Tel: 414 222 367/505 995
Fax: 256 414 286 123
Email: sglbalagadde@gmail.com
samuel.balagadde@unbs.go.ug

Maria T. ESPINOZA

Secretary, U.S. Codex
United States Department of Agriculture
Food Safety and Inspection Service
Room 4861 South Building
1400 Independence Avenue, SW
Washington, D.C. 20250
Tel : 202-205-7760
Fax : 202-720-3157
Email : mariateresa.espinoza@fsis.usda.gov

Giovanna WIGGINGTON

Management Specialist
United States Department of Agriculture
Food Safety and Inspection Service
Room 3137 South Building
1400 Independence Avenue, SW
Washington, D.C. 20250
Tel : 202-720-4849
Fax : 202-205-0301
Email : giovanna.wiggington@fsis.usda.gov

Patrick PARNELL

Program Analyst
United States Department of Agriculture Food
FSIS/OPPD/PID
1400 Independence Avenue, SW
Washington, D.C. 20250
Tel: 202-205-0299 Fax : 202-690-0486
Email: patrick.parnell@fsis.usda.gov

CODEX SECRETARIAT**Dr Jeronimas MASKELIUNAS**

Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome
Italy
Tel: +39 06 570 53967
Fax: +39 06 570 54593
Email : jeronimas.maskeliunas@fao.org

Verna CAROLISSEN

Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome
Italy
Tel: 39 06 570 55629
Fax: 39 06 570 54593
Email: verna.carolissen@fao.org

Annamaria BRUNO

Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome
Italy
Tel : 39 06 570 56254
Fax : 39 06 570 54593
Email : annamaria.bruno@fao.org

Appendix II

PROPOSED DRAFT ANNEX ON FRESH LEAFY VEGETABLES
(Annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables)
(At Step 5/8 of the Procedure)

INTRODUCTION

Fresh leafy vegetables are grown, processed and consumed in multiple ways and in diverse conditions throughout the world. They are grown on farms that vary from very large to very small. Fresh leafy vegetables are marketed both locally and globally to provide year round availability to consumers and are sold as fresh, fresh-cut, pre-cut or ready-to-eat products such as pre-packaged salads.

International and national concerns have grown in response to recent outbreaks and reported illnesses linked to fresh leafy vegetables. A broad array of microbial pathogens have been associated with fresh leafy vegetables as reported in international outbreak data, including Enterohemorrhagic *Escherichia coli*, *Salmonella enterica*, *Campylobacter* spp, *Shigella* spp, Hepatitis A virus, Norovirus, *Cyclospora cayetanensis*, *Cryptosporidium parvum*, *Yersinia pseudotuberculosis* and *Listeria monocytogenes*. Epidemiological evidence, outbreak investigations and risk assessments have identified areas of risk for pathogen contamination of leafy vegetables including key risks from water, animals, workers and manure based soil amendments. Fresh leafy vegetables are grown and harvested in large volume, often for export and increasingly in places that are new to harvesting and distributing fresh leafy vegetables, therefore the potential for human pathogens to spread has also grown. Fresh leafy vegetables are marketed as diverse products including whole, unprocessed heads, loose leaves, mixed cut leaves and fresh herbs, and pre-cut packaged products. Fresh leafy vegetables are packed in diverse ways including field packed direct for market, in packing houses and processed for pre-cut products in sophisticated processing plants. As fresh, fresh-cut, pre-cut or ready to eat leafy vegetables move through the supply chain, there is also the potential for the introduction and growth of pathogens. There is no further processing treatment that would eliminate or inactivate the target microorganisms. Examples of control measures are illustrative only and their use and approval may vary between member countries.

1. OBJECTIVE OF THE ANNEX

The objective of this Annex is to provide specific guidance to reduce the microbial food safety risks associated with fresh leafy vegetables that are intended to be consumed without cooking during their production, harvesting, packing, processing, storage, distribution, marketing and consumer use. This includes fresh, fresh-cut, pre-cut or ready-to-eat products such as pre-packaged salads. Because of the diversity of leafy vegetables and practices and conditions used throughout the supply chain, recommendations to minimize microbial contamination will be most effective when adapted to specific operations.

2. SCOPE, USE AND DEFINITIONS**2.1 SCOPE**

This Annex covers specific guidance related to the production, harvesting, packing, processing, storage, distribution, marketing, and consumer use of fresh leafy vegetables that are intended to be consumed without further microbiocidal steps.

Fresh leafy vegetables for purposes of this Annex include all vegetables of a leafy nature where the leaf is intended for consumption. Thus, leafy vegetables include but are not limited to all varieties of lettuce, spinach, cabbage, chicory, endive and radicchio and fresh herbs such as coriander/cilantro, basil, and parsley).

2.2 USE

This Annex follows the format of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003) including the Annex for Ready-To-Eat Fresh Pre-Cut Fruits and Vegetables. This Annex provides additional guidance to the documents above.

3. PRIMARY PRODUCTION OF FRESH LEAFY VEGETABLES

3.1 ENVIRONMENTAL HYGIENE

The following should be considered:

Potential sources of environmental contamination should be identified prior to production activities. Assessment of environmental conditions is particularly important because subsequent steps may not be adequate to remove contamination that occurs during production and in some cases may lead to conditions that enable the growth of microbial pathogens.

Particular attention should be given to potential sources of faecal contamination in the production area, on near-by sites and to vectors which may introduce faecal contamination to the production and handling areas. These vectors include, but are not limited, to humans, domestic and wild animals, or indirectly via contaminated water, insects, workers, or fomites such as dust, tools and equipment.

3.1.1 Location of the Production Site

Production sites (indoor and outdoor) should be located to minimize the probability of microbial contamination to the growing sites from the nearby sites. Consideration of land location should include evaluating the slope, topographical, flood risk, and hydrological features of nearby sites in relationship to the production site.

Assessing environmental hygiene is particularly important in evaluating risks that arise from use of land nearby the production sites, for example feed lots, other animal production operations, hazardous waste sites, municipal and industrial waste treatment facilities. The presence of such sites should be evaluated for their potential to contaminate the production site with microbial or other environmental hazards via, for example, run-off, fecal material, aerosols or organic waste.

Where the environment presents a risk to the production site, measures should be implemented to minimize the contamination of the fresh leafy vegetable production sites. Landscape changes, such as the construction of a shallow ditch, to prevent runoff from entering the field or in the case of aerosols, construction of an effective wind-break (natural such as trees or constructed) or use of a covering are examples of measures that can be used to reduce pathogen contamination of the production site.

3.1.2 Previous and current use of the site

If the evaluation of previous and present usage of the primary production area and the nearby sites identifies potential microbial hazards that are at levels that pose a risk to humans, including faecal and other organic waste contamination and potential environmental hazards, fresh leafy vegetables should not be grown on the land until the risks have been reduced to acceptable levels.

3.1.3 Wild and domestic animals and human activity

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.

- Domestic and wild animals should be excluded from production and handling areas, to the extent feasible, using appropriate biological, cultural, physical and chemical pest control methods. Methods selected should comply with local, regional, and national environmental and animal protection regulations.
- Production and handling areas should be properly maintained (*e.g.* minimizing standing water and/or access to water sources, keeping areas free of clutter and waste) to reduce the likelihood of vector attraction.

- Existing practices should be reviewed to assess the prevalence and likelihood of deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh leafy vegetable growing areas from animals. When appropriate, this may require the use of physical barriers (*e.g.* fences), active deterrents (*e.g.* noise makers, scarecrows, images of owls, foil strips) and/or cultural methods (*e.g.* crop rotation).

Wild animals represent a particularly difficult risk to manage because their presence is intermittent and harder to track. Fields should be monitored for human and animal activity (*e.g.* presence of tracks, faeces, crop damage from grazing, etc.), particularly near harvesting. If present, consideration should be given to the risks and whether affected crop areas should be harvested.

3.2 HYGIENIC PRIMARY PRODUCTION OF FRESH LEAFY VEGETABLES

3.2.1.1 Water for primary production

An appropriate and adequate supply of water of a suitable quality for use in different operations in the primary production of fresh leafy vegetables should be available. The source of the water used for production and the method of delivery can affect the risk of contamination for fresh leafy vegetables. Growers should seek appropriate guidance on water quality and delivery methods to minimize the potential for contamination with microbial pathogens.

The quality of water may vary. Water for primary production that has substantial contact with the edible portion of the leafy vegetable should meet the standards for potable or clean water. Examples of water sources that present the lowest risk of contamination are:

- Rain water, provided the integrity of the water distribution system is maintained
- Water in deep wells, provided they are maintained, monitored and capped
- Water in shallow wells provided they are maintained, monitored and capped

Water sources that pose a higher risk of contamination may need further treatment such as:

- Surface water

Options such as sand filtration or storage in catchments or reservoirs to achieve partial biological treatment should be considered. The efficacy of these treatments should be evaluated and monitored.

- Reclaimed or wastewater

Before using reclaimed or wastewater for crop irrigation, consult with an expert to assess the relative risk and determine the suitability of the water source. Reclaimed wastewater subjected to different levels of treatment should be in compliance with WHO guidelines for safe use of wastewater, excreta and grey water, wastewater use in agriculture, in agricultural production specifically on irrigating vegetables marketed to consumers as fresh, fresh-cut, pre-cut or ready-to-eat.

Growers and harvesters 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 these waters as follows:

- Assess the potential for microbial contamination (*e.g.*, from livestock, human habitation, sewage treatment, manure and composting operations) and the water's suitability for its intended use and re-assess the potential for microbial contamination if events, environmental conditions or other conditions indicate that water quality may have changed.
- Identify corrective actions to prevent or minimize contamination. Possible corrective actions may include fencing to prevent large animal contact, appropriate well casing and head maintenance and placement of wells, filtering water, not stirring the sediment when drawing water, building settling or holding ponds, and water treatment facilities. Settling or holding ponds that are used for subsequent irrigation may be microbiologically safe but may attract animals or in other ways increase the microbial risks associated with water for irrigating crops. If water treatment is needed, consult with water safety authorities.

- Determine if analytical 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 what tests need to be performed, how often tests should be conducted, what the test outcomes indicate, and how tests will be used to define corrective actions. The frequency of testing will partially depend on the water source (less for adequately maintained deep wells, more for surface water) and the risks of environmental contamination including intermittent or temporary contamination (*e.g.* heavy rain, flooding, *etc.*). If testing is limited to non-pathogenic indicators, frequent water tests may be useful to establish the baseline water quality so that changes in the levels of contamination can be identified. Obtain municipal water test results when available. If the water source is found to have unacceptable levels of indicator organisms or is known to be contaminated, 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.

3.2.1.1.1 Water for irrigation

Water used for irrigation purposes should be of suitable quality for its intended use. The type of irrigation or application method affects the risk of contamination. The timing, the quality of water used, and whether the water has direct contact with the edible portion of the plant should all be considered when selecting the type of irrigation or application method to use.

Growers should:

- Evaluate the water distribution system to determine if a contamination source is evident and can be eliminated.
- Establish no-harvest zones if irrigation source water is known to or likely to contain human pathogens and where failure at connections results in overspray of plants or localized flooding.

Overhead irrigation presents the highest risk of contamination because it wets the edible portion of the crop. The duration for wetting can be several hours, and the physical force of water droplet impact may drive contamination into protected sites on the leaf. Therefore, only the clean water should be used for this type of irrigation.

Subsurface or drip irrigation that results in no wetting of the plant is the irrigation method with the least risk of contamination, although these methods can still experience localized problems. For drip-irrigation, care should be taken to avoid creating pools of water on the soil surface or in furrows that may come into contact with the edible portion of the crop.

Irrigation of fresh leafy vegetables that have physical characteristics such as rough surfaces where water may accumulate, a vase-like growth characteristic, or high density seeding or transplant rates should be irrigated with only clean water. Irrigation of these products should be applied in a way to minimize wetting of the edible portion because the plant characteristics can provide niches for microbial attachment and survival.

3.2.1.1.2 Water for fertilizers, pest control and other agricultural chemicals

Clean water should be used in the application of aqueous fertilizers, pesticides, and other agricultural chemicals that are directly applied to edible portions of the fresh leafy vegetables, especially close to harvest. Human pathogens can survive and grow in many agrichemicals including pesticides. The application of pesticide solutions contaminated with human pathogens to the surface of leafy vegetables is known to constitute a risk, particularly near harvest time.

3.2.1.1.3 Hydroponic water

Microbial risks of water used in growing fresh leafy vegetables hydroponically may differ from the microbial risks of water used to irrigate leafy vegetables in soil because the water in hydroponic production is used for both irrigation and as the growth medium and presents therefore a higher risk of microbiological contamination. The growth medium may enhance the survival of pathogens. It is especially critical in hydroponic operations to maintain the water quality to reduce the risk of contamination and survival of pathogens.

3.2.1.1.4 Water for harvesting and other agricultural uses

Water for other agricultural uses includes dust abatement, hydration, as a lubricant, and to maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where fresh leafy vegetables are exposed. If sprinkling water using mechanical means to minimize dust on dirt roads within or near the fields, then use clean water to avoid the aerosolization and spread of pathogens.

Fresh leafy vegetables may be sprayed with small amounts of water during machine harvest or in the field container just after harvest to hydrate crops. Water may also be used to facilitate the handling of leafy vegetables in the field. Clean water should be used in processes where there is direct contact between the water and edible portions of the leafy vegetables. It is understood that products at this point are not considered ready-to-eat and may be washed or further processed.

3.2.1.2 Manure, biosolids and other natural fertilizers

Manure, biosolids and other natural fertilizers may contain human or animal waste, animal parts or products, or be composed primarily of plant materials. Because of this, natural fertilizers and other soil amendments may contain human pathogens that may persist for weeks or even months, particularly if treatment of these materials is inadequate.

Proper treatment of biosolids, manures and by-products (e.g. physical, chemical, or biological treatment) will reduce the risk of potential human pathogen survival. The persistence of human pathogens in soil depends on many factors (soil type, relative humidity, temperature, Ultraviolet Index¹ and pathogen type among other known factors). Composting, if done properly, can be a practical and efficient method to inactivate human pathogens in manure. When using aerobic composting methods, compost heaps should be regularly and thoroughly turned so that all of the material will be exposed to elevated temperatures because pathogens can survive for months on the heap surface. Anaerobic methods can also effectively inactivate pathogens; however, special consideration should be given to determine the length of time needed to inactivate pathogens that may be present. In general, only fully decomposed animal waste or plant materials should be applied to fresh leafy vegetables.

Fresh leafy vegetables may be contaminated through direct contact with contaminated soil amendments. Therefore untreated and/or partially treated manure, biosolids, and other natural fertilizers should not be applied to leafy vegetables after plant emergence unless it can be demonstrated that product contamination will not occur. Field soil contaminated with human pathogens may also provide a means of fresh leafy vegetables contamination via rain splash or plant uptake. Therefore, establishing suitably conservative pre-plant fertilizer intervals appropriate for specific regional and field conditions is an effective step towards minimizing risk. Competent authorities should provide guidance on appropriate intervals.

3.2.2 Indoor facilities associated with growing and harvesting (protective agricultural structures)

Protective agricultural structures, including greenhouses, high tunnels, hoop houses, and shade house structures, provide some degree of control over various environmental factors.

3.2.2.1 Location, design and layout

The following should be considered:

3.2.2.3 Protective agricultural structures

Some protective agricultural structures are located in the field (hoop houses, high tunnels, etc.) Factors that influence the magnitude and frequency of the transfer of pathogenic microorganisms in the field, such as the climate, weather, topology, hydrology and other geographic characteristics in or nearby the field may pose a similar risk for certain protective structures.

The methods for adequate maintenance of the environment around the structures include, but are not limited to:

¹ Ultraviolet Index (UVI): a measure of the solar ultraviolet intensity at the earth's surface that indicates the day's exposure to ultraviolet rays. The UV Index is measured around noon for a one-hour period and rated on a scale of 0 to 15 based on international guidelines for UVI reporting established by the World Health Organization.

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- Adequately draining areas that may contribute contamination to food by
 - providing a breeding place for pests
 - runoff, leakage, or pooled/settled water flowing into food growing areas,
 - transfer of contaminants via equipment or foot traffic
- The land nearby certain protective structures (high tunnel, hoop house, *etc.*) should not be a significant source of contamination. Appropriate measures should be taken to minimize any relative risks from surrounding land use or environment. These measures may include berms, fences, ditches, buffer zones or other strategies to effectively mitigate any hazards.

3.2.2.2 Water supply

Refer to 3.2.1.1.1 (Water for Irrigation) and 3.2.1.1.3 (Hydroponic Water)

3.2.2.3 Drainage and waste disposal

The following should be considered:

- Good drainage should be maintained around the structure to eliminate standing water.
- Waste disposal systems and facilities should be provided. All refuse should be disposed of in containers with lids and stored away from the facility to prevent harborage of pests.
- Refuse containers should be emptied regularly.

3.2.2.4 Cleaning, maintenance and sanitation

- Workers and visitors should take effective measures (e.g., wash hands) before entering greenhouses.
- Plant debris and cull piles should be removed promptly from inside the structure. There should be no plant refuse around the outside of the structure or nearby to attract or harbor pests.

3.2.3 Personnel health, hygiene and sanitary facilities

The following should be considered:

- Each businesses 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 workers to practice proper hygiene, and company policies relating to expectations for worker hygiene as well as illness reporting.
- All workers should properly wash their hands using soap and clean, running water before handling leafy vegetables, particularly during harvesting and post harvest handling. Workers should be trained in proper technique for hand washing and drying.
- 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 readily cleaned and sanitized, should be cleaned as needed and stored appropriately. If disposable gloves are used, they should be discarded when they become torn, soiled, or otherwise contaminated.
- Non-essential persons and casual visitors, particularly 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

The following should be considered

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

- All workers should be trained in proper use of hygienic facilities. Training should include toilet use, proper disposal of toilet paper or equivalent, and proper hand washing and drying procedures.

As far as possible, such 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 workers will relieve themselves in the field. Facilities should be in sufficient number to accommodate personnel (e.g. 1 per 10 people) and be appropriate for both genders if workforce contains males and females.
- Portable facilities should not be located or cleaned in cultivation areas or near irrigation water sources or conveyance systems. Growers should have a standard plan that identifies the areas where it is safe to put portable facilities and to prevent traffic in case of a spill.
- Facilities should include clean running water, soap, toilet paper or equivalent, and single use paper towels or equivalent.

3.2.3.2 Health status

The following should be considered:

- Farm and packinghouse managers should be encouraged to observe symptoms of diarrheal or food transmissible communicable diseases and reassign workers as appropriate.
- Employees should be encouraged to notice and report symptoms of diarrheal or food transmissible communicable diseases.
- Medical examination of food handlers 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 water proof dressings, they should wear gloves to cover the bandages thereby providing a secondary barrier between them and the fresh leafy vegetables they handle.

- Workers should wear clean clothes and bathe daily.

3.2.3.4 Personal behavior

- Personal items (e.g., purses, backpacks, clothes, etc.) should be stored away from production areas.

3.2.4 Equipment associated with growing and harvesting

Growers and harvesters should adopt the following sanitary practices:

- Employees should be trained to follow SOPs for the maintenance requirements of equipment used for growing and harvesting.
- All safety guards should be used and maintained according to manufacturers' instructions. Such equipment should be maintained in good order.
- Equipment used to harvest leafy vegetables by cutting or mowing should be thoroughly cleaned and sanitized before use and cutting edges should be kept smooth and sharp.

3.3 HANDLING, STORAGE AND TRANSPORT

3.3.1 Prevention of cross-contamination

The following should be considered:

- The field should be evaluated for the presence of hazards or contamination prior to harvest to determine if the field should be harvested.
- Written SOPs should be developed for appropriate handling, storage, and transport.
- Excessive dirt and caked mud should be removed from product and/or containers during harvest.

- If water is used to remove dirt and debris from leafy vegetables in the field, clean water should be used.

Harvesting methods vary depending upon the characteristics of the product. Mechanical harvesting provides opportunity for increased surface contact exposure and may cause damage that could lead to penetration of plant tissues by microorganisms. Specific control measures should be implemented to minimize the risk of contamination from microorganisms associated with the method, such as prevention of sucking up soils and other field contaminants and components that may damage or cut plants.

- Personal hygiene is critical with manual harvesting due to the amount of human handling that could lead to contamination of the leafy vegetables.
- Proper cleaning and sanitation of equipment is also important for manual and mechanical harvesting, since knives and other equipment used can wound fresh leafy vegetables, lead to cross contamination, and provide entry for contaminants that may be in soil and water.
- Over-filling of totes and bins should be avoided to prevent transfer of contaminants to produce during stacking.

3.3.2 Storage and transport from the field to the packing facility

Refer to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food (CAC/RCP 47-2001). In addition, the following should be considered:

Fresh leafy vegetables may be transported to the packing, cooling and cold storage facility by numerous modes of transportation. Transportation should be managed to reduce or control the risk of contamination. Each transporter should have its own SOP for shipping containers/trailers to verify that they are clean, sanitary, and in good structural condition.

Fresh produce should not be transported in vehicles used previously to carry animal manure or biosolids. Receptacles in vehicles and/or containers are not to be used for transporting anything other than foodstuffs where this may result in contamination. Where conveyances and/or containers are used for transporting anything in addition to foodstuffs or for transporting different foodstuffs at the same time, there is, where necessary, to be effective separation of products.

Fresh leafy vegetables are perishable products that should be carefully handled. Damage will adversely affect the quality of the product and may increase its potential for microbial contamination. Damaged product should be discarded.

- Maintaining optimum temperatures of leafy vegetables between 1-5°C throughout the supply chain or minimizing the time they are exposed to higher temperature will limit microbial proliferation and, depending on the type of the product, may be optimum for quality. Consideration should be given to the type of product, particularly certain fresh herbs (e.g. basil and shiso) that are chill sensitive and may require higher storage temperatures to prevent quality deterioration that could leave the product vulnerable to foodborne pathogens. For this type of product, minimizing the time it is exposed to a higher temperature might be preferable to maintaining the temperature below 5°C.
- Cover product to maintain integrity of the load.

3.4 CLEANING, MAINTENANCE AND SANITATION

3.4.1 Cleaning programs

The following should be considered:

- Harvesting containers that come into direct contact with leafy vegetables should not be utilized for purposes other than holding product (e.g., should not hold personal items, waste, etc.).
- Single use primary containers such as cardboard boxes or clamshells should not be reused in food contact applications.
- Containers should be covered and stored in a location and in a manner to prevent possible contamination (e.g., pests, birds, rodents, dust, water, etc.).
- Damaged containers should be repaired or replaced.

- Containers that come into direct contact with the soil should not be stacked in such a manner as to allow soil and debris to contaminate fresh leafy vegetables.
- Policies should be established for the control of equipment when it is not in use, including policies for the removal of equipment from the work area or site and for the use of scabbards, sheathes or other storage equipment.
- Harvesting equipment, including hand harvesting implements (knives, pruners, corers, machetes) that come in direct contact with fresh leafy vegetables, should be cleaned and sanitized at least daily or as the situation warrants.
- Clean water should be used to clean all equipment directly contacting fresh leafy vegetables, including farm machinery, harvesting and transportation equipment, containers and implements.

3.4.2 Cleaning procedures and methods

The following should be considered:

- Cleaning and disinfection programs should not be carried out in a location where the rinse might contaminate fresh leafy vegetables.
- Where appropriate or necessary, cleaning and sanitizing procedures should be tested to ensure their effectiveness.

4. PACKING ESTABLISHMENT: DESIGN AND FACILITIES

Refer to 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). In addition, the following should be considered:

Packing activities can occur in the field or in facilities. Field pack operations should implement the same sanitary practices where practical or modify as needed to minimize risks.

The provisions below apply to facilities that pack, cool and process fresh leafy vegetables.

4.1.1 Establishments

The following should be considered:

- Floors and walls should be of a material that is easily cleanable and does not pose a risk for harborage or growth of foodborne microorganisms.
- Pipes should not leak and condensation should be minimized to avoid dripping on product or packing equipment

4.2 Drainage and waste disposal

The following should be considered:

Adequate drainage is critical to packing, cooling and processing facilities to avoid the risk of contaminating the fresh leafy vegetables. To ensure adequate drainage of standing water:

- Drainage in the facility should be designed with sloped floors to effectively drain standing water.
- Floors should be kept as dry as possible using appropriate methods.
- Food handlers should have proper training to remove standing water or push standing water to the drains.
- Drains should be cleaned periodically to prevent build-up of biofilms that may contain organisms of concern (e.g., *Listeria monocytogenes*).
- Areas for garbage recyclables and compostable waste should be identified and all waste should be stored and disposed of in a manner to minimize contamination.
- Waste should be disposed of on a frequent basis to avoid attracting pests (e.g. flies, rodents).

5. CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

Establishments should pay special attention to product flow and segregation from incoming soiled to outgoing washed product to avoid cross-contamination.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.2.1 *Receipt and inspection of raw materials*

Prior to preparation, damaged or decayed material (both at harvest and at the processing plant) should be trimmed and/or discarded.

5.2.2.2 *Post-harvest water use*

The following should be considered:

- Water quality management will vary throughout all operations. Packers should follow GMPs to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water should be dependent on the stage of the operation. For example, clean water could be used for initial washing stages, whereas water used for final rinses should be of potable quality.
- Clean or preferably potable water should be used when water is applied under pressure or vacuum during washing as these processes may alter the leaf structure and force pathogens into plant cells.
- Where appropriate, the pH, hardness, temperature of the post-harvest water should be controlled and monitored, e.g., where these impact the efficacy of the antimicrobial treatments.
- Water recirculated for reuse in the establishment should be treated and maintained in conditions that do not constitute a risk to the safety of fresh leafy vegetables. For example the following may be used to maintain the suitability of the water: primary screening, secondary filtration, and antimicrobial treatment process.

5.2.2.3 *Chemical treatments*

Certain post harvest treatments, i.e. paraffin and fungicides, should not be used for fresh leafy green vegetables.

5.2.2.4 *Cooling of fresh leafy vegetables*

The following should be considered:

Fresh leafy vegetables can be cooled immediately after harvest by either using ice (parsley), forced-air cooling, vacuum cooling (iceberg lettuce), hydrocooling, or spray-vacuum (hydrovac) cooling. Water used in post-harvest operations may contaminate fresh leafy vegetables if there is direct contact of water containing human pathogens with edible portions of the plant.

For fresh leafy vegetables and the control of inputs such as water used for cooling, particular attention should be paid to:

- Water used to cool fresh leafy vegetables should be free from human pathogens.
- Water that is used in hydrovacs should be clean or preferably potable. Water that is used only once and is not recirculated is preferable. If recirculated water is used, water disinfectant at sufficient levels to reduce the potential risk of cross-contamination should be used and monitored.
- Cooling equipment should be cleaned and sanitized on a regular basis according to written procedures to ensure that the potential for cross contamination is minimized.

5.2.2.6 *Cutting, slicing, shredding, and similar pre-cut processes*

The following should be considered:

- Maintain sharpness and condition of knives and cutting edges to maintain product quality and safety.
- Cutting equipment should be cleaned and sanitized on a regular basis according to written procedures to ensure that the potential for cross contamination is minimized

5.2.3 Microbiological and other specifications

The following should be considered:

Microbiological testing can be a useful tool to evaluate and verify the effectiveness of safety and sanitation practices, 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.

5.7 DOCUMENTATION AND RECORDS

The following should be considered:

Where practicable, a comprehensive written food safety control plan that includes a written description of each of the hazards identified in assessing environmental hygiene and the steps that will be implemented to address each hazard should be prepared by the businesses operating primary production. The description should include, but is not limited to: 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 testing results and trend analyses
- Water testing results
- Employee training records
- Pest control records
- Cleaning and sanitation reports
- Equipment monitoring and maintenance records
- Inspection/audit records

5.8 TRACEABILITY/PRODUCT TRACING AND RECALL PROCEDURES

The following should be considered:

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 food throughout the supply chain. The information should include, if available, the packer name, address, and phone, date packed, date released, type of food including brand name and specific variety (*e.g.*, Romaine lettuce rather than just lettuce), lot identification, and number of items,
- The following are examples of the types of records that should be retained to facilitate traceability:
 - Shipping documents
 - Invoices
 - Other records maintained by the firm that identifies the supplier and the buyer
 - Operators such as growers and producers and, in cases where contract harvesters are used, harvesters should keep current all relevant information on agricultural activities such as information concerning each lot, date harvested, grower contact information, harvest practices, if water used in harvesting, water quality.

- In fresh-cut, pre-cut or ready-to-eat salad operations, multiple ingredients from different sources may be combined in a single package. This practice can complicate efforts to trace leafy vegetables to their source. The processors should consider establishing and maintaining records to identify the source of each ingredient in the product.

8. TRANSPORTATION

Refer to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food (CAC/RCP 47-2001).

9.3 LABELING

Refer to the General Standard for the Labelling of Pre-packaged Food (CODEX STAN 1-199) and In addition, the following should be considered:

- Consumer's handling information should provide specific directions for product storage and use, including regarding the 'use-by' date or other shelf-life indicators when provided. Consumers need clear guidance on keeping washed RTE bagged fresh leafy vegetables refrigerated until used.

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 fresh leafy vegetables safely to avoid giving contradictory advice and causing confusion.

Consumer information on handling fresh leafy vegetables safely should cover:

- Selecting produce in the marketplace (supermarkets, retailers). Many fresh leafy vegetables such as lettuce are fragile and should be handled with care to avoid mechanical damage and to minimize and microbiological contamination.
- Transporting to home. Increases in product temperatures during transportation can be considerable. Time in transit for fresh leafy vegetables between retail/markets and the home should be kept as short as possible.
- Storage/ refrigeration of fresh leafy vegetables
- Washing leafy vegetables as appropriate with potable running water. Products labeled washed and ready-to-eat should not be rewashed.
- Correct hand washing methods using soap and potable water before handling fresh leafy vegetables should continue to be promoted to consumers.
- Cross-contamination. Consumers need to handle, prepare and store fresh leafy vegetables safely to avoid cross-contamination with pathogens from various sources *e.g.* hands, sinks, cutting boards, raw meats.
- Specific information for fresh-cut, pre-cut or ready-to-eat bagged salads. Consumers need specific and clear guidance on how to safely handle fresh-cut, pre-cut or ready-to-eat (RTE) leafy vegetables. Clear labeling is therefore important. There is anecdotal evidence to suggest that some consumers find it difficult to distinguish between produce that can be consumed without further washing and that which requires washing before consumption, particularly bagged produce such as herbs and spinach.

10. TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

The following should be considered:

- Making education and training a priority for all personnel

10.2 TRAINING AND EDUCATION PROGRAMMES

The following should be considered:

Where required personnel involved in fresh leafy vegetable operations should receive training appropriate to their tasks and should be periodically assessed while performing their duties to ensure tasks are being completed correctly. Training should be delivered in a language and manner to facilitate understanding of the information and expectations. Training programs should be designed to help personnel understand what is expected of them and why and it should emphasize the importance of using hygienic practices. A well-designed training programme considers the barriers to learning of the trainees and develops training methods and materials to overcome those barriers.

To accommodate the complexity of situations that exist in fresh leafy vegetable operations, the following training considerations should be addressed:

- Longstanding entrenched trainee behaviors, attitudes and social taboos
- Transient nature of workforce with no prior training in food safety and hygiene
- Children/infants, who may accompany parents working in the field with the potential for transfer of pathogens with a human reservoir
- Diverse cultural, social and traditional practices
- Literacy and education level
- Language and dialect of trainees
- Need to make food safety practices realistic and easy to implement (identify enabling factors, motivators and incentives)
- Raising awareness among trainees of symptoms and signs of disease and encourage them to act upon it (take personal responsibility for health)
- Importance of food safety training when new crops are being grown for the first time

Training programs should be regular, updated particularly when there is a change in product variety or process recorded, monitored for effectiveness and modified when necessary.

Increased emphasis on training in cold chain logistics and management is recommended in line with advancing knowledge and technologies for both refrigeration and temperature monitoring and expanding international trade.

Appendix III**PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD****(At Steps 5/8 of the Procedure)****INTRODUCTION**

1. During the last few years, there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. As a result, there have been several instances where the presence of pathogenic *Vibrio* spp. in seafood has led to a disruption in international trade. This has been particularly evident with *Vibrio parahaemolyticus* where there has been a series of pandemic outbreaks due to the consumption of seafood, and its emergence has been observed in regions of the world where it was previously unreported. A number of *Vibrio* species are increasingly being recognized as potential human pathogens. The food safety concerns associated with these microorganisms have led to the need for specific guidance on potential risk management strategies for their control.

General Characteristics of Pathogenic Vibrio spp.

2. The genus *Vibrio* contains at least twelve species pathogenic to humans, ten of which can cause food-borne illness. The majority of food-borne illness is caused by *V. parahaemolyticus*, choleraogenic *Vibrio cholerae*, or *Vibrio vulnificus*. *V. parahaemolyticus* and *V. cholerae* are solely or mainly isolated from gastroenteritis cases that are attributable to consumption of contaminated food (both species) or intake of contaminated water (*V. cholerae*). In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (septicaemia, wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood.

3. In tropical and temperate regions, these species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae*, can also be recovered from freshwater reaches of estuaries, where it can also be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments.

4. It is now possible to differentiate environmental strains of *V. cholerae* and *V. parahaemolyticus* between virulent and avirulent strains based on their ability or inability to produce their major virulence factors. The pathogenic mechanisms of *V. vulnificus* have not been clearly elucidated, and its virulence appears to be multifaceted and is not well understood, and therefore all strains are considered virulent.

5. The following are important characteristics common to all *Vibrio* spp.. *Vibrio* spp. are sensitive to low pH but grow well at high pH, and thus infections caused by *Vibrio* spp. are frequently associated with low-acid foods. In addition, the ingestion of a large number of viable cells is needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection. Through cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. Hygienic practices used with all food-borne pathogens will in general control the growth of pathogenic *Vibrio* spp.

6. There are, however, characteristics specific to each of the three major pathogenic species of *Vibrio* that require attention as described below.

Vibrio parahaemolyticus

7. *V. parahaemolyticus* is considered to be part of the autochthonous microflora in the estuarine and coastal environments in tropical to temperate zones. While *V. parahaemolyticus* typically is undetectable in seawater at 10°C or lower, it can be cultured from sediments throughout the year at temperatures as low as 1°C. In temperate zones, the life cycle consists of a phase of survival in winter in sediments and a phase of release with the zooplankton when the temperature of the water increases up to 14 - 19 °C. *V. parahaemolyticus* is characterized by its rapid growth under favourable conditions.

8. The vast majority of strains isolated from patients with diarrhea produce a thermostable direct hemolysin (TDH). It has therefore been considered that pathogenic strains possess a *tdh* gene and produce TDH, and non-pathogenic strains lack the gene and the trait. Additionally, strains that produce a TDH-related hemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic. Symptoms of *V. parahaemolyticus* infections include explosive watery diarrhea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalization have been reported. Virulent strains are seldom detected in the environment or in foods, including seafoods, while they are detected as major strains from faeces of patients.

9. *V. parahaemolyticus* was first identified as a foodborne pathogen in Japan in the 1950s. By the late 1960s and early 1970s *V. parahaemolyticus* was recognized as a cause of diarrhoeal disease worldwide. A new *V. parahaemolyticus* clone of O3:K6 serotype emerged in Calcutta in 1996. This clone, including its serovariants, has spread throughout Asia and to the USA, elevating the status of the spread of *V. parahaemolyticus* infection to pandemic. In Asia, *V. parahaemolyticus* is a common cause of foodborne disease. In general, the outbreaks are small in scale, involving fewer than 10 cases, but occur frequently. This pandemic *V. parahaemolyticus* has now spread to at least 5 continents. There is a suggestion that ballast discharge may be a major mechanism for global spread of pandemic *V. parahaemolyticus*, but a possibility of export/import seafood-mediated international spread cannot be ruled out.

10. From the point of controlling seafood-borne *V. parahaemolyticus* illnesses, harvest is probably the most critical stage, since it is from this point onwards that individuals can actually implement measures to control *V. parahaemolyticus*.

11. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include for example crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, clams, steamed/boiled crabmeat, scallops, squid, sea urchin, mysids, and sardines. These products include both raw and partially treated¹ and thoroughly treated seafood products that have been substantially recontaminated through contaminated utensils, hands, etc.

Vibrio cholerae

12. *V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serogroups have been established for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene and produce cholera toxin (CT) and are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Cholera is exclusively a human disease and human faeces from infected individuals are the primary source of infection in cholera epidemics. Contamination of food production environments (including aquaculture ponds) by faeces can indirectly introduce cholerae *V. cholerae* into foods. The concentration of free-living cholerae *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods.

13. Seven pandemics of cholera have been recorded since 1823. The first six pandemics were caused by the classical biotype strains, whereas the seventh pandemic that started in 1961 and has lasted until now, is due to *V. cholerae* O1 biotype El Tor strains. Epidemic cholera can be introduced from abroad by infected travellers, imported foods and through the ballast water of cargo ships. Detection frequencies of cholerae *V. cholerae* from legally imported foods were very low and they have seldom been implicated in cholera outbreaks. *V. cholerae* O139 has been responsible for the outbreaks of cholera in the Bengal area since 1992, and this bacterium has spread to other parts of the world through travellers. The cholerae *V. cholerae* that spread to different parts of the world may persist, and some factors may trigger an epidemic in the newly established environment.

14. Some strains belonging to the O serogroups other than O1 and O139 (referred as non-O1/non-O139) can cause food-borne diarrhea that is milder than cholera.

¹ “treated” means any vibriocidal treatment (e.g. heat treatment, high pressure.). Refer to Section 2.3 (definition for “partially treated”.

15. Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including bivalve molluscs, crustaceans, and finfish, are most often incriminated in food-borne cholera cases in many countries. While shrimp has historically been a concern for transmission of cholerae *V. cholerae* in international trade, it has not been linked to outbreaks and it is rarely found in shrimp in international trade.

Vibrio vulnificus

16. *V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions, especially liver disease or alcoholism, diabetes, haemochromatosis and HIV/AIDS, following consumption of raw bivalve mollusc. This is a serious, often fatal, disease with one of the highest fatality rates of any known foodborne bacterial pathogen. The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*, but a virulence determinant has not been established and, therefore, it is not clear whether only a particular group of the strains are virulent. The host factor (underlying chronic diseases) appears to be the primary determinant for *V. vulnificus* infection. Incubation period ranges from 7 hours to several days, with the average being 26 hours. The dose response for humans is not known.

17. Of the three biotypes of *V. vulnificus*, biotype 1 is generally considered to be responsible for most seafood-associated human infection and thus the term *V. vulnificus* refers to biotype 1 in this Code.

18. Foodborne illness from *V. vulnificus* is characterized by sporadic cases and an outbreak has never been reported. *V. vulnificus* has been isolated from oysters, other bivalve molluscs, and other seafood worldwide.

19. The densities of *V. vulnificus* are high in oysters at harvest when water temperatures exceed 20°C in areas where *V. vulnificus* is endemic; *V. vulnificus* multiplies in oysters at a temperature higher than 13°C. The salinity optimum for *V. vulnificus* appears to vary considerably from area to area, but highest numbers are usually found at intermediate salinities of 5 to 25 g/l (ppt: parts per thousand). Relaying oysters to high salinity waters (>32 g/l (ppt: parts per thousand)) was shown to reduce *V. vulnificus* numbers by 3–4 logs (<10 per g) within 2 weeks.

FAO/WHO Risk Assessments

20. FAO/WHO risk assessments on *Vibrio vulnificus* in raw oysters and cholerae *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade have been published (2005)^{2,3}. Additional risk assessments on *Vibrio parahaemolyticus* in raw oysters, in raw and undercooked finfish and in *Anadara granosa* (bloody clams) have been completed⁴. These risk assessments constitute the basis of this Code.

SECTION I – OBJECTIVES

21. These Guidelines provides guidance on control of pathogenic *Vibrio* spp. in seafood, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of these Guidelines is to highlight the key control measures that can be used to minimise the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. These Guidelines also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

22. These Guidelines covers seafood that is marketed and may be consumed in a live, raw, chilled/frozen, partially treated, or thoroughly treated state. It is applicable to the whole food chain from primary production to final consumption. Bivalve molluscs are covered more thoroughly in the Annex, which is supplemental to these Guidelines.

² FAO and WHO, 2005. Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological Risk Assessment Series, No.8.

³ FAO and WHO, 2005. Risk assessment of cholerae *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade. Microbiological Risk Assessment Series, No.9.

⁴ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological Risk Assessment Series, No.XX (In press).

23. As major causative agents of foodborne bacterial illnesses associated with seafood, the target microbiological hazards of these Guidelines are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraenic *V. cholerae*. The control measures described in these Guidelines may be applicable to other pathogenic *Vibrio* spp..

2.2 USE OF THE DOCUMENT

24. These Guidelines are supplemental to, and should be used in conjunction with, the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The application of these Guidelines by countries may require modifications and amendments, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp., water temperatures and salinity.

2.3 DEFINITION

25. For the purpose of these Guidelines, the following definitions apply:

Definitions of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

Refrigeration: The lowering of product temperature to limit microbial activity.

Seafood: Fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products which are intended for human consumption.

Partially treated: Any treatment intended to significantly reduce or limit but not completely eliminate *Vibrio* spp. in seafood. As a result of partial treatment, the sensory characteristics of the raw product are lost.

Clean water: means water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish and their products intended for human consumption.

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

26. Refer to Section 3.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). In addition:

27. Generally, pre-harvest controls are more applicable to bivalve molluscs than to other seafood (e.g. open-sea harvested fish). Where relevant to other seafood, pre-harvest controls should be considered for areas where the likelihood of introduction of pathogenic *Vibrio* spp. is significant and can be controlled.

28. Temperature and salinity should be considered for controlling pathogenic *Vibrio* spp. in seafood. Where applicable, specific temperature or salinity levels that can be used as control measures should be identified based on epidemiological and exposure studies as well as monitoring of pre-harvest pathogenic *Vibrio* levels.

29. For monitoring bivalve molluscs, at harvest, refer to the Annex to this Guideline.

30. For seafood grown in coastal localities, especially in cholera-endemic areas, care should be taken to avoid contamination of seafood with faecal choleraenic *V. cholerae*.

3.2 HYGIENIC PRODUCTION OF SEAFOOD SOURCES

31. Refer to Section 3.2 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

3.3 HANDLING , STORAGE AND TRANSPORT

32. For the storage and handling of seafood aboard fish vessels, clean water should be used for seafood intended to be eaten raw, and for preparing ice for such use. The use of sea water taken from near the seashore or from a drainage outlet or river contaminated with sewage should be avoided. Seafood should be held at temperatures that minimise and/or prevent the growth of pathogenic *Vibrio* spp. after harvest, for example, in an ice-water slurry, ice or refrigeration on vessels and at harvest sites. The delay between harvest and refrigeration should be as short as possible.

33. For on-boat cooked (boiled, blanched) seafood products, ice and/or refrigeration should be used to facilitate the rapid cooling. Ice made from clean water should be used to minimize cross-contamination.
34. For the storage of live seafood products, clean water should be used to minimise initial cross-contamination from the water.
35. When the product is required to be washed, whether onboard the boat or at port, clean water should be used.
36. During on-land transportation from the landing port to the on-shore market and/or processing establishments, in order to minimise and/or prevent the growth of pathogenic *Vibrio* spp. in seafood, the time elapsed between harvest and refrigeration or freezing is critical and should be minimised. Ice can be used efficiently to keep seafood under refrigeration during transportation and sale. Live fish and shellfish should be transported at the lowest temperature tolerable for the species. Covered containers should be used for transport to prevent contamination.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

37. Refer to Section 3.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).
38. Refer to Section 7.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). A carrier who is excreting choleraenic *V. cholerae* should not handle seafood or ice for the storage of seafood, which may result in the contamination of the seafood with choleraenic *V. cholerae*.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

39. Equipment and facilities should be designed, constructed and laid out to minimise cross-contamination and recontamination with pathogenic *Vibrio* spp.

4.1 LOCATION

40. Refer to Section 4.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.1.1 Establishments

41. Refer to Section 4.1.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.1.2 Equipment

42. Refer to Section 4.1.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

43. Refer to Section 4.2.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).
44. Whenever feasible, premises and rooms should be designed to keep raw material areas separated from finished seafood product areas. This can be accomplished in a number of ways, including linear product flow (raw materials to finished products) or physical partitions.
45. Where feasible, the washing room for food equipment used in the finished product manufacturing should be physically segregated from the finished product processing area.

4.2.2 Internal structures and fittings

46. Refer to Section 4.2.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.2.3 Temporary/mobile premises and vending machines

47. Refer to Section 4.2.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.3 EQUIPMENT

4.3.1 General

48. Refer to Section 4.3.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.3.2 Food control and monitoring equipment

49. Refer to Section 4.3.2 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

50. The chill room should be equipped with a calibrated thermometer.

4.3.3 Containers for waste and inedible substances

51. Refer to Section 4.3.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.4 FACILITIES

52. Refer to Section 4.4 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

53. Adequate facilities should be provided for the handling and washing of products.

54. Suitable and adequate facilities should be provided for storage and/or production of ice.

4.4.1 Water supply

55. An adequate supply of clean water and/or potable water should be available for handling and washing of seafood to limit the load of pathogenic *Vibrio* spp..

4.4.2 Drainage and waste disposal

56. All drainage and waste lines should be capable of coping with peak demands.

57. Accumulation of solid, semi-solid or liquid wastes should be minimised to prevent contamination, because pathogenic *Vibrio* spp. may grow rapidly in these wastes under certain circumstances.

58. Separate and adequate facilities should be provided to prevent contamination by offal and waste material.

4.4.3 Cleaning

59. Refer to Section 4.4.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.4 Personnel hygiene facilities and toilets

60. Refer to Section 4.4.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.5.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.5 Temperature control

61. Refer to Section 4.4.5 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 4.1 of *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

62. The *Code of Practice for Fish and Fishery Products* indicates maintaining the product at temperature as close to 0°C as possible. For pathogenic *Vibrio* spp., a temperature of 10°C or lower is adequate. In this Code, 10°C is used as the target temperature to prevent/minimize growth of *Vibrio* spp. However, pathogenic bacteriae species such as *Listeria monocytogenes*, *Clostridium botulinum* and histamine formers may also be hazards in addition to *Vibrio* spp. If this is the case, more strict temperature control, as close to 0°C as possible, should be implemented. In the case of bivalve molluscs, a different temperature control specified in the Annex would be required. The facility should be capable of controlling ambient temperature to ensure that product temperature during processing of raw seafood is maintained at a temperature of 10°C or lower.

4.4.6 Air quality and ventilation

63. Refer to Section 4.4.6 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 of *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.7 Lighting

64. Refer to Section 4.4.7 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.3 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.8 Storage

65. Refer to Section 4.4.8 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

66. Refer to Section 5.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

67. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood. At each step the temperature should be controlled and monitored.

5.2.2 Specific process steps

5.2.2.1 Washing and processing

68. Clean water at low temperature should be used for washing and processing seafood at processing establishments. However, the eviscerated cavity of fish intended for raw consumption (e.g. preparation of *sashimi*) should be thoroughly washed with potable running water.

5.2.2.2 Cooking

69. Time and temperature should be determined for each cooking operation to ensure the inactivation and elimination of pathogenic *Vibrio* spp..

70. After cooking and blanching, potable water should be used for cooling.

5.2.2.3 Food processing practices

71. Food processing practices (e.g. acidification to pH below 4.8, salting to a sodium chloride concentration of more than 10% for *V. parahaemolyticus*, food preservatives and/or water activity less than 0.94) can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.

72. Freezing could be used to reduce the level or prevent the growth of pathogenic *Vibrio* spp. in seafood.

73. Several possible technologies such as high pressure, mild heating, freezing and extended storage, have been reported to inactivate *Vibrio* spp.⁵. The use of these technologies should be done in accordance with the legislation of the country of retail sale.

74. Any practice selected to reduce/inactivate pathogenic *Vibrio* spp. in seafood or control/minimize the growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective. Such validation should be performed according to the *Guidelines for the validation of the food safety control measures* (CAC/GL 69-2008).

75. The food processing practices should be closely monitored and verified to ensure that pathogenic *Vibrio* spp. are controlled and/or reduced as intended.

5.2.2.4 Storage

76. Seafood intended for raw consumption should be stored in shallow layers and surrounded by sufficient quantities of finely crushed ice or with a mixture of ice and clean water. Live fish and shellfish should be stored at the lowest temperature tolerable for species (Refer to Section 9 of the *Code of Practice for Fish and Fisher Products* (CAC/RCP 52-2003)).

77. Over-stacking and/or over-filling of containers should be avoided to allow cold air to circulate adequately.

5.2.3 Microbiological and other specifications

78. Refer to Section 5.2.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

5.2.4 Microbiological cross-contamination

79. Refer to Section 5.2.4 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Sections 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.2.5 Physical and chemical contamination

80. Refer to Section 5.2.5 the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.3 INCOMING MATERIAL REQUIREMENTS

81. Refer to Section 5.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 8.5.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.4 PACKAGING

82. Refer to Section 5.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 8.5.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.5 WATER

5.5.1 In contact with food

83. Refer to Section 5.5.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) except cases specified within this Code where clean water could be used.

⁵ Section 3.2 of the Risk assessment of *Vibrio vulnificus* in raw oysters (FAO/WHO Microbiological Risk Assessment Series 8); FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in seafood. Microbiological Risk Assessment Series, No.XX (In press); FAO and WHO, 2005. Risk assessment of choleraenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade. Microbiological Risk Assessment Series, No.9.

84. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, only clean/potable waters should be used in the post-harvest stage.

5.5.2 As an ingredient

85. Refer to Section 5.5.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.5.3 Ice and steam

86. Refer to Section 5.5.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.6 MANAGEMENT AND SUPERVISION

87. Refer to Section 5.6 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.7 DOCUMENTATION AND RECORDS

88. Refer to Section 5.7 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.8 RECALL PROCEDURES

89. Refer to Section 5.8 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

90. Refer to Section 6 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.4 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

91. Refer to Section 7 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.5 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION VIII – TRANSPORTATION

92. Refer to Section 8 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Sections 3.6 and 17 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

93. Transportation is an integral step in the food chain and temperature during this period should be as low as possible and should be controlled, monitored and recorded where appropriate.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

94. Refer to Section 9.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.2 PRODUCT INFORMATION

95. Refer to Section 9.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.3 LABELLING

96. Refer to *the General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

97. In addition, countries should give consideration to labelling of unpackaged live or raw seafood, so that consumers are adequately informed with respect to the safety and true nature (alive or not alive) of these products. In particular, seafood that is at a high risk of being contaminated with pathogenic *Vibrios* spp., should be labelled to alert at-risk consumers to avoid or cook these products, in line with the legislation in the countries where these products are retailed or sold. Any treatment (*e.g.* heat treatment), that is applied to the product should be mentioned in the labelling if consumers would be misled by its omission.

9.4 CONSUMER EDUCATION

98. Since each country has specific food habits, communication and education programs pertaining to pathogenic *Vibrio* spp. are most effective when established by individual governments.

99. Programs should be directed at consumers:

- To educate them on household practices and behaviours as indicated in Five Keys to Safer Food (WHO) “that would specifically keep the numbers of pathogenic *Vibrio* spp. that may be present in foods, to as low a level as possible and minimise the potential of cross-contamination from seafood to hands of food handlers, and then from hands to other foods, or from seafood to utensils (*e.g.*, cutting board), and then from utensils to other foods by:
 - keeping seafood cold to minimise and/or prevent the growth of pathogenic *Vibrio* spp.;
 - keeping refrigerator temperatures as low as practical;
 - using thermometers inside home refrigerators, ice chests or other storage containers;
 - preparing, cooking and/or consuming seafood immediately after removing them from the refrigerator;
 - promptly refrigerating leftover seafood;
 - washing and disinfecting hands, utensils and equipments whenever raw seafood is handled; and
 - separating utensils and equipment used for raw seafood, from those use for finished product, where appropriate.
- To help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafood that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits.

9.4.1 Special Attention to Susceptible Subpopulations

100. Liver disease is a prominent risk factor for human infection with pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors include diabetes, haemochromatosis and HIV/AIDSs.⁶ Subpopulations with increased susceptibility should follow the advice below:

- Avoid the consumption of raw or partially treated seafood; and
- Cook seafood thoroughly before consumption.

SECTION X – TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

101. Refer to Section 10.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

⁶ FAO and WHO, 2005. Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological Risk Assessment Series, No.8.

102. Industry (fishermen, primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations play an important role in providing specific instructions and/or training to employees for the control of pathogenic *Vibrio* spp. Special consideration should be given to possible differences in prevalence of pathogenic *Vibrio* spp. in the harvesting areas and various fishing techniques.

10.2 TRAINING PROGRAMMES

103. Personnel involved in the primary production, harvesting, processing and handling of seafood should have appropriate training for the tasks they are performing. This may include:

- The nature of pathogenic *Vibrio* spp., namely *V. parahaemolyticus*, choleraogenic *V. cholerae* and *V. vulnificus*, their harbourage sites, and their resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- Control measures for reducing the risk of pathogenic *Vibrio* spp. associated with seafood during harvesting, processing, distribution, marketing, use and storage, for preventing cross-contamination and minimizing the growth of pathogenic *Vibrio* spp.; and
- The means for verifying effectiveness of control programs, including sampling and analytical techniques.

10.3 INSTRUCTION AND SUPERVISION

104. Refer to Section 10.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

10.4 REFRESHER TRAINING

105. Refer to Section 10.4 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

Appendix IV**PROPOSED DRAFT ANNEX ON THE CONTROL MEASURES FOR *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Bivalve Molluscs¹****(At Steps 5/8 of the Procedure)****INTRODUCTION**

1. Bivalve molluscs are a well documented vehicle for transmission of illnesses caused by *Vibrio* spp., especially *Vibrio parahaemolyticus* and *Vibrio vulnificus*. Bivalve molluscs are unique in that they are harvested, handled and consumed differently from most other seafood products and therefore present unique risks and control options. They are inherently riskier than other seafood because of their filter feeding activity that concentrates pathogens present in the water. They are often consumed live and raw or after insufficient cooking. According to FAO/WHO risk assessments² for both of these pathogens in many countries, bivalve molluscs are often kept alive out of water for days after harvest at ambient temperatures which allows the growth of *V. parahaemolyticus* and *V. vulnificus*.

SECTION I – OBJECTIVES

2. The purpose of this Annex is to provide guidance on control measures that minimize the risk arising from the presence of pathogenic *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs. It deals with the means to minimize and/or prevent the introduction/contamination and/or the growth of these pathogens, and adequate partial treatment³ of bivalve molluscs before consumption. Control measures required for these pathogens are similar but not the same to the extent that they have different characteristics on the growth and survival. The control measures outlined in this Annex reflects these differences, where they exist. This Annex further provides information that may be of interest to regulatory authorities, the food industry, consumers, and other interested parties.

SECTION II – SCOPE, DEFINITION AND USE OF THE DOCUMENT**2.1 SCOPE**

3. This Annex covers bivalve molluscs that are intended for consumption in a live, raw, or partially treated state. Bivalve molluscs (e.g. clams, mussels and oysters) consumed after a vibriocidal treatment are not covered in this Annex, noting that the control measures presented in the main documents are sufficient to control the safety of these products. The target microbiological hazards of this Annex are only pathogenic *V. parahaemolyticus* and *V. vulnificus*.

4. This Annex highlights the key control measures that influence the introduction/contamination of and minimize levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs and thus the risk of foodborne diseases caused by these pathogens.

5. This Annex provides guidance applicable throughout the food chain, from primary production through to final consumption of bivalve molluscs and particular guidance on post-harvest processing. Controls measures presented in Part I apply to live and raw bivalve molluscs (including those that receive post-harvest processing), while those in Part II apply to bivalve molluscs consumed after partial treatment.⁴

2.2 DEFINITIONS

6. For the purpose of this Annex, the following definitions apply:

¹ Phylum Mollusca: Class Bivalvia

² FAO/WHO has developed and published Risk assessment of *Vibrio vulnificus* in raw oysters (2005), and Risk assessment of *V. parahaemolyticus* in seafood (in Press). This Annex is based on key findings and outcomes derived from these risk assessments and other relevant epidemiological evaluations.

³ Including cooking.

⁴ Risk assessment of *V. parahaemolyticus* in *Anadara granosa* (bloody clams)

Definitions contained in the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*; and live and raw bivalve molluscs production definitions defined in the *Codex Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

Post-harvest processing: processes (e.g. high pressure and mild heating) or treatments (e.g. freezing) intended to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* while essentially retaining the sensory characteristics of live bivalve molluscs (Section 7.7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)).

2.3 USE OF THE DOCUMENT

7. This Annex is supplemental to and should be used in conjunction with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), Hygiene section of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. This Annex may require modifications and amendments in use, taking into account such factors as regional differences in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population.

PART I: BIVALVE MOLLUSCS CONSUMED LIVE AND RAW

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

8. Refer to Section 3.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CAC/RCP 52-2003) and Section 3.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

9. The control measures described in this section generally apply to pre-harvest environmental conditions and practices during and immediately following harvest, typically while under the control of the harvester. Effective control measures for *V. parahaemolyticus* and *V. vulnificus* will typically require an evaluation in terms of the risk associated with environmental factors in the harvesting area and harvesting practices based on epidemiology and environmental conditions (i.e. air and water temperature and salinity). An important element in estimating risk is that *V. parahaemolyticus* grows faster and at colder temperatures than *V. vulnificus*. Predictive tools using these environmental monitoring parameters and growth rates as inputs have been elaborated based on the FAO/WHO risk assessments and, when validated, may be used to estimate corresponding *V. parahaemolyticus* and *V. vulnificus* levels and risk. The predictive ability can be improved by incorporating local data and considering additional factor such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.

10. In cases where predictive models are used to estimate the concentration and risks of pathogenic *Vibrio* spp. in seawater and/or bivalve molluscs based on air and water temperatures and/or salinity, their accuracy would be enhanced by incorporating local data on levels of total and pathogenic *V. parahaemolyticus* and *V. vulnificus* and growth in local bivalve species. Factors such as hydrodynamic effects (e.g. currents, tides, hurricanes and rainfall) and sunlight influences the levels of *Vibrio* spp.. The dose response model used in the predictive tool may need modifications based on epidemiology, as regional differences exist in the prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* including attack rate relative to exposure to *V. parahaemolyticus* strains occurred in those areas concerned.

11. Monitoring of bivalve molluscs at harvest for the levels of total *V. vulnificus* and total and pathogenic *V. parahaemolyticus* should be conducted to determine the regional and seasonal variation. Prevalence of pathogenic strains of *V. parahaemolyticus* and *V. vulnificus* and the epidemiological data, including the susceptibility of the population, should be considered.⁵ This information, and some factors articulated in para. 15, are useful for model inputs and evaluation of model outputs and application of appropriate controls.

12. Additionally, there are some indications that *Vibrio* spp. can be introduced into a harvest area through the release of ballast water. Therefore, the impact of ballast discharge in or around the harvesting area should be controlled regarding the presence of *Vibrio* spp., especially in areas that are in close proximity to international shipping lanes.

13. Factors to be considered in determining the need for controls in a given harvest area include:

- The number of sporadic illnesses and outbreaks of *V. parahaemolyticus* and *V. vulnificus* associated with bivalve molluscs harvested from a distinct hydrographic area, and whether these illnesses are indicative of an annual reoccurrence or an unusual increase of *Vibrio* spp. illnesses is reported;
- Water temperatures representative of harvesting conditions. Water temperatures below 15°C⁶ for *V. parahaemolyticus* and below 20°C for *V. vulnificus* have generally not been historically associated with illnesses;
- Time period to first refrigeration and post-harvest air temperatures above the minimum growth temperatures for *V. parahaemolyticus* (10°C) and *V. vulnificus* (13°C), which may increase risk regardless of harvest water temperature;
- Harvest practices that allow radiant solar heating to raise temperatures of bivalve molluscs to temperatures above ambient air temperatures prior to harvest (i.e. intertidal harvest) and exposure time;
- Salinity ranges and optima are different for *V. parahaemolyticus* and *V. vulnificus*. Environmental and epidemiological data indicate low *V. parahaemolyticus* and *V. vulnificus* levels and few cases of illnesses are associated with bivalve molluscs when salinity exceeds 35 ppt (g/l) and 30 ppt (g/l), respectively.

14. The competent authority should inform food business operators of the control measures contained in Sections 3.2 (Hygienic production of food sources), 3.3 (Handling, storage and transportation) and 5.1 (Control of food hazards) and 5.2 (Key aspects of hygiene control systems) of this Annex when at least:

- Levels of *V. parahaemolyticus* and/or *V. vulnificus*, or environmental parameters exceed testing/monitoring criteria that are based on risk assessment, if applicable.
- An unusual increase of *Vibrio* spp. illnesses is reported.

15. The activities described in this section should be implemented by producers in cooperation with the regulatory authority having jurisdiction.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

16. Pre-harvest and harvest measures should be applied as necessary based upon the factors identified in Section 3.1 above, such as:

- Restrict harvest or otherwise prevent use of product for raw consumption (e.g. close area to harvest or divert product for further processing).
- Where possible, sink bivalve molluscs below the thermocline where the growth of pathogenic *Vibrio* spp. should not occur
- Restrict the time to refrigeration

⁵ As an example, pandemic *V. parahaemolyticus* may require more stringent controls than other strains of pathogenic *V. parahaemolyticus* because epidemiological evidence indicates higher attack rates.

⁶ J. B. McLaughlin, A. DePaola, C. A. Bopp, K. A. Martinek, N. P. Napolilli, C. G. Allison, S. L. Murray, E. C. Thompson, M. M. Bird, and J. P. Middaugh. Outbreak of *Vibrio parahaemolyticus* gastroenteritis associated with Alaskan oysters. *N Engl J Med* 14:1463-1470, 2005.

- Relay bivalve molluscs to areas where risk is sufficiently reduced (e.g. relay bivalve molluscs with *V. vulnificus* to high salinity offshore waters)

3.3 HANDLING, STORAGE AND TRANSPORT

17. Bivalve molluscs destined to be consumed live or untreated raw should be handled separately from those destined for post-harvest processing or other treatment to avoid cross contamination.

18. During handling, storage and transport of harvested bivalve molluscs, the following control measures should be applied as necessary based upon the factors identified in Section 3.1. It is important that any control for *V. parahaemolyticus* and/or *V. vulnificus* is not less than that required for the control of any other pathogenic organisms that may be present in bivalve molluscs.

- Limit time from harvest or first exposure to ambient air temperature to initial refrigeration based on modeling and sampling.
- Minimize time and temperature conditions that would allow the growth of *V. parahaemolyticus* and *V. vulnificus* during wet storage of bivalve molluscs.
- Bivalve molluscs are to be transported at the lowest temperature that minimizes growth of *V. parahaemolyticus* and *V. vulnificus*. The time between refrigeration and reaching a temperature that does not support growth of *V. parahaemolyticus* and *V. vulnificus* should be minimized when the temperature of the bivalve molluscs exceeds the minimum growth temperature for pathogenic vibrios, and the time between harvest and raw consumption should be limited appropriately or the product should undergo additional treatment to reduce pathogenic *Vibrio* levels. Special attention should be paid to maintaining the characteristics of bivalve molluscs to be consumed live following Section 7.3 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).
- It may be useful to periodically survey levels of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs at various points in the distribution chain to verify effectiveness of recommended control measures.
- Anyone involved in the handling, storage or transport of bivalve molluscs should be educated in the relationship between temperature control and growth of *V. parahaemolyticus* and *V. vulnificus* and trained in proper handling, storage and transport.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

19. Refer to Section IV of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section IV of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

20. Refer to Section 5.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

21. The control measures described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* typically requires the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

22. Any control measures or practice selected to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs (e.g. freezing, high pressure and mild heating), should be adequately validated to ensure that the control measure is effective. They should also be approved by the competent authority. Such validated control measures/practices should be implemented under the HACCP system. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

23. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). Temperature control to reduce the temperature to the point that *V. parahaemolyticus* and *V. vulnificus* do not grow should be used and maintained during processing operation and subsequently until consumption.

5.2.2 Specific process steps

24. Bivalve molluscs destined to be consumed live or untreated raw should be distributed separately from those destined for post-harvest processing or other treatment.

5.2.3. Microbiological cross contamination

25 bis. Control measures should be in place to avoid cross contamination between bivalve molluscs destined to be consumed live or untreated raw and those destined for post-harvest processing or other treatment.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

25. Refer to Section VI of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

26. Refer to Section VII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VII of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VIII – TRANSPORTATION

27. Refer to Section VIII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

28. Refer to Section IX of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

29. In addition, programs for consumer information should be directed at consumers with increased susceptibility to contracting vibriosis (see para. 100 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*) to help consumers make informed choices about purchase, storage, shelf-life labelling and appropriate consumption of live and raw bivalve molluscs, taking into consideration the specific regional conditions and consumption habits.

9.3 LABELLING

30. Refer to Section 9.3 (Labelling) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood* and Section I-7 and II-7 of the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008).

9.4 CONSUMER EDUCATION

31. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

32. Programs for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risks associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

SECTION X - TRAINING

33. Refer to Section X of the *Recommended International Code of Practice-General Principles of Food Hygiene*, (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products*, (CAC/RCP 52-2003) and Section X of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

PART II. BIVALVE MOLLUSCS CONSUMED IN PARTIALLY TREATED STATE⁷

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

34. Refer to Section 3.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

35. The controls described in Section III (Primary production) of Part I should be implemented. The combination of measures of the treatment and those described in Section III of this part should achieve at least an equivalent level of protection to the level of protection provided for raw or live bivalve molluscs in Section III of Part I.

36. If data on log reduction achieved by partial treatment is available, predictive tools in Part I could be applicable.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

37. Refer to Section 3.2 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.2 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

- The control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw despite the fact that these bivalve molluscs are to be consumed after partial treatment.

3.3 HANDLING, STORAGE AND TRANSPORT

38. Refer to Section 3.3 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 3.3 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

⁷ Part II applies only to products which are partially treated, excluding post-harvest processing. For products in thoroughly treated state, refer to relevant parts of the Good Hygienic Practices as specified in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Practice for fish and fishery products* (CAC/RCP 52-2003) and other applicable Codex documents as those are generally suitable to control *V. parahaemolyticus* and *V. vulnificus* in fully cooked bivalve molluscs.

39. The control measures described in Section III (Primary production) of Part I should be implemented to achieve at least an equivalent level of protection for bivalve molluscs to be consumed live or raw despite the fact that these bivalve molluscs are to be consumed after partial treatment.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

40. Refer to Section IV of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

41. Refer to Section 5.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003), the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008) and Section 5.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*. Competent authorities should ensure that the food business operator is able to verify the delivery of any partial treatment and additional control measures necessary to assure the safety of the product.

42. The controls described in this section generally apply to post-harvest handling and processing. Control of *V. parahaemolyticus* and *V. vulnificus* will typically require the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

43. *V. parahaemolyticus* is generally more resistant than *V. vulnificus* to any given treatment. Therefore, a process that is effective for *V. vulnificus* may not be as effective for *V. parahaemolyticus*. Any measure or practice to significantly reduce or limit but not necessarily completely eliminate *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs should be adequately validated to assure that the control measures are effective and such validated control measures as practiced should be implemented under an HACCP system.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

44. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The partial heat treatment of bivalve molluscs should ensure that the internal temperature of the bivalve molluscs reaches the temperature to ensure a reduction of *V. parahaemolyticus* and *V. vulnificus*. Achievement of the validated time and temperature treatment should be ensured. After partial heat treatment, growth of *V. parahaemolyticus* and *V. vulnificus* should be controlled.

5.2.2 Specific process steps

45. The partial treatment of bivalve molluscs by means other than heat should be validated to ensure the intended reduction of *V. parahaemolyticus* and *V. vulnificus*. The parameters (e.g. target pH, salt concentration, water activity) should be controlled, monitored and verified.

5.2.3 Microbiological cross contamination

46. Control measures should be in place to avoid cross contamination between bivalve molluscs before partial treatment and after partial treatment.

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

47. Refer to Section VI of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VI of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

48. Refer to Section VII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VII of *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION VIII – TRANSPORTATION

49. Refer to Section VIII of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section VIII of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

50. Refer to Section 9.1 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section 9.1 of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

9.1 LABELLING

51. Refer to the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) and Section II-7 Labelling in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

52. In addition, where appropriate, labelling for bivalve molluscs should include advice on specific safe handling practices (e.g. time, temperature) and consumption.

9.2 CONSUMER EDUCATION

53. Refer to Section 9.4 (Consumer education) of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

54. Programs for consumer education should inform consumers of safe consumption practice and handling and preparation of bivalve molluscs aimed at avoiding food safety risk associated with *V. parahaemolyticus* and *V. vulnificus* in bivalve molluscs.

SECTION X - TRAINING

55. Refer to Section X of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969), Section 7 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003) and Section X of the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Pathogenic Vibrio Species in Seafood*.

Appendix V**PROJECT DOCUMENT FOR NEW WORK ON THE REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS (CAC/RCP 33-1985)****1. PURPOSE AND SCOPE OF THE NEW WORK**

The purpose of the proposed new work is to revise the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985). This guidance will be supplemental to the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).

The scope of the new work will be the revision of the Code in order to take into account the latest developments in food safety and food hygiene, such as HACCP principles, which have been adopted since the Code's adoption in 1985. In particular, the revised Code should comply with the requirements of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969). Furthermore, it should be ensured that the structure of the current Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) CAC/RCP 48-2001 forms the basis for the revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985). The microbiological criteria in the revised Code of Hygienic Practice for Natural Mineral Waters should further be aligned with the microbiological criteria found in the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997) and the Codex Standard for Natural Mineral Waters (CODEX STAN 108-1981).

2. RELEVANCE AND TIMELINESS

The Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) was adopted in 1985. Since then important Codex texts in the fields of food safety and food hygiene have been adopted by the Codex Alimentarius Commission thereby rendering obsolete several provisions in the Code. The foreseen revision is necessary in order to bring the Code of Hygienic Practice for Natural Mineral Waters in line with the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) based on the structure of the Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) (CAC/RCP 48-2001).

3. MAIN ASPECTS TO BE COVERED

The proposed revision will address the entire Code of Hygienic Practice for Natural Mineral Waters (CAC/RCP 33-1985), but in particular Sections 2 and 4 and Section 3 as appropriate. The revision will further focus on the review and update the microbiological criteria in the Code of Hygienic Practice for Natural Mineral Waters in order to standardise the microbiological criteria found in the Code of Hygienic Practice for Natural Mineral Waters (CAC/RCP 33-1985) and the Standard for Natural Mineral Waters (CODEX STAN 108-1981).

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES ()**4.1 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.

4.2 Criteria applicable to general subjects**(a) Diversification of national legislations and apparent resultant or potential impediments to international trade**

This new work will provide guidance to Codex members and stakeholders so that they can update their hygiene requirements for the collecting, processing and marketing of natural mineral waters based on the revised Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985). This work will assist in providing an internationally harmonised approach in the field.

(b) Scope of work and establishment of priorities between the various sections of the work

The scope of the new work will be the revision of the Code in order to take into account the latest developments in food safety and food hygiene, such as HACCP principles, which have been adopted since the Code's adoption in 1985. During the revision, particular attention will be paid to the requirements of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969). Furthermore, it should be ensured that the structure of the current Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) (CAC/RCP 48-2001) forms the basis for the revision of the Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985).

(c) Work already undertaken by other international organisations in this field and/or suggested by the relevant international intergovernmental body(ies).

This new work does not duplicate work undertaken by other international organisations.

5. RELEVANCE TO CODEX STRATEGIC GOALS**Goal 1: Promoting Sound Regulatory Frameworks**

The revised Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) will contribute to the development of sound food control and regulatory infrastructures. It will strive to reduce health risks along the food chain by taking into account the latest scientific and technological developments and thereby enhance food safety and consumer health protection.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis

The revised Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) will be updated in order to bring it in line with modern food hygiene concepts such as HACCP Principles and the requirements of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969). The revised Code will contain modern food hygiene principles which will enable members and stakeholders to respond effectively and expeditiously to new issues concerning the hygienic practice for collecting, processing and marketing of natural mineral waters.

Goal 4: Promoting Cooperation between Codex and Relevant International Organisations

This revision will take into account relevant Codex texts that have been developed by the Codex Committee on Natural Mineral Waters as well as other relevant information from FAO and WHO.

Goal 5: Promoting Maximum and Effective Participation of Members

The revision of the Code of Hygienic Practice for Natural Mineral Waters will enhance the participation of all stakeholders in Codex work and promote the participation of both developing and developed countries.

6. RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX TEXTS

The proposed revision will take into account the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969) as well as the Code of Hygienic Practice for Bottled/Packaged Drinking Waters (Other than Natural Mineral Waters) (CAC/RCP 48-2001). The microbiological criteria in the revised Code of Hygienic Practice for Natural Mineral Waters should further be aligned with the microbiological criteria found in the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997) and the Standard for Natural Mineral Waters (CODEX STAN 108-1981).

7. REQUIREMENT FOR AND AVAILABILITY OF EXPERT ADVICE

Although scientific expertise among Codex members and observers is currently available, it might be necessary to seek scientific advice at a later stage from the FAO/WHO (e.g. JEMRA) and ICMSF.

8. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

A period of three to four years is foreseen for the completion of this revision.

9. WORK TO BE LED BY

Switzerland

10. INCLUSION OF A RISK PROFILE

Developing a risk profile at this stage is not considered necessary. Existing guidelines and reports such as the WHO's Guidelines for drinking-water quality contain the necessary components of risk profiles.

11. WORK PLAN FOR THE REVISION OF THE OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR COLLECTING, PROCESSING AND MARKETING OF NATURAL MINERAL WATERS

(CAC/RCP 33-1985) TIMETABLE	CODEX SESSION	PROGRESS
November 2009	41 st session, CCFH	Agree on the purpose and scope of the revision and on the request for new work.
July 2010	33rd Session, CAC	Approval of New Work
November 2010	42 nd session, CCFH	Consideration of the Proposed Draft Revised Code at Step 3 and advance to Step 5
July 2011	34 th session, CAC	Adoption of the Proposed Draft Revised Code at Step 5.
November 2011	43 rd session, CCFH	Consideration of the Draft Revised Code and advance to Step 8 for final adoption by the CAC.
July 2012	35 th session, CAC	Final adoption

Appendix VI**PROJECT DOCUMENT FOR NEW WORK ON THE REVISION OF THE “PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS” (CAC/GL 21-1997)****1. PURPOSE AND SCOPE OF THE NEW WORK**

The purpose of the new work is to update the existing general guidance document Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21–1997) in order to reflect several important elements as developed in the Principles and Guidelines for the Conduct of Microbiological Risk Management and its annex on Guidance on Microbiological Risk Management Metrics (CAC/GL 63-2007).

The scope of new work will involve:

- bringing the establishment and application of microbiological criteria for foods by governments and industry in line with the latest knowledge and practices.
- introducing the new risk management metrics (Food Safety Objective (FSO), Performance Objective (PO), and Performance Criterion (PC)) developed in the framework of microbiological risk management and other quantitative microbiological limits (e.g., process control based criteria, testing for HACCP verification) not currently dealt with in the general guidance document.
- providing guidance on the relationship between microbiological criteria, risk management metrics and other quantitative microbiological limits according to the latest knowledge and practice, including the application of microbiological criteria in the context of risk metrics and other quantitative microbiological limits.

2. RELEVANCE AND TIMELINESS

Testing against microbiological criteria in the form of microbiological standards, microbiological guidelines, and microbiological specifications is routinely used by competent authorities and business operators to evaluate the microbiological safety of foods. To foster consistency in the use of microbiological criteria, Codex Alimentarius introduced the general hygiene guidance document “Principles for the Establishment and Application of Microbiological Criteria for Foods” in 1997. Since that time, a number of key new concepts have been introduced globally to enhance consumer protection relative to food safety, quality and fair practices in food trade.

These new concepts are relevant to the establishment and application of microbiological criteria in foods. Of particular importance are the risk management metrics introduced in the general guidance document “Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)” (CAC/GL 63-2007), especially Annex II “Guidance on Microbiological Risk Management Metrics”, which specifically considers the FSO, PO, and PC.

Additionally, the use of microbiological testing against microbiological criteria has changed substantially by both competent authorities and industry since the 1997 Codex document was adopted. The current Codex document is based on the concept of lot-by-lot testing, whereas many current applications involve “cross-lot” testing for verification of process control or the periodic testing of individual lots for verification of HACCP programs. These applications, which are used extensively by both competent authorities and industry, have different requirements, protocols, assumptions, and interpretations that are not adequately covered by Codex guidance documents.

New work is proposed to reflect this information and experience and it is proposed to update the existing guidance document and bring it into alignment with current best practices.

3. MAIN ASPECTS TO BE COVERED

Guidance will be introduced in the document to reflect current best practice regarding the utility of microbiological criteria in the context of specific applications. The following aspects are required attention:

- the principles of establishing microbiological criteria for within-lot evaluation of food product acceptability,
- the principles for establishing microbiological criteria for between-lot evaluation of food product acceptability in relation to verification of process control, effectiveness of HACCP programs, and other trend analysis application,
- the appropriate roles of microbiological testing for verification of process control within the context of HACCP and validation of control measures,
- the establishment and interpretation of microbiological criteria related to hygiene indicator microorganisms,
- the principles and practices for relating the stringency of a microbiological criterion to required or recommended risk management outcomes; i.e., means for relating the performance of sampling plans for both within-lot and between-lot applications to food safety risk management metrics (e.g., FSO, PO, PC),
- actions to be taken in case of non-compliance to microbiological criteria and other risk management metrics (e.g., PO, PC),
- the role of microbiological testing to monitor environments in which foods are exposed and the establishment of performance criteria by competent authorities and industry to indicate an acceptable level of control.

4. ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

General criterion

This work is directed towards consumer protection from the point of view of food safety, quality and ensuring fair practices in food trade while taking into account the identified needs of developing countries: This new work will strengthen other guidance provided in general support of consumer protection in developing and developed countries. At a global scale, it will contribute to further prevention of human illnesses due to potential food-borne risks and simultaneously clarifies issue that impact the advancement of fair trading practices. This new work also supports the general goal of Codex Alimentarius to continually review and update its standards and guidance.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade: this new work aims to provide general best practice guidance and update on new scientific and technical developments that are relevant for all countries and enable them to further refine their own risk management strategies.

(b) Scope of work and establishment of priorities between the various sections of the work: the most important parts of the work may be the update on the utility of microbiological criteria and the relationship with microbiological risk management metrics as these have seen some key developments since the elaboration in 1997 of Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997).

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental bodies: This new work does not duplicate any ongoing work undertaken by other (inter)national governmental organizations. It builds on recommendations expressed by informal discussions between the co-requestors.

5. RELEVANCE TO CODEX STRATEGIC GOALS

The proposed work falls under all five goals of the Codex Strategic Plan 2008-2013.

Goal 1: Promoting Sound Regulatory Frameworks.

The results of this new work will further contribute to the development of sound food control and regulatory infrastructures and consequently will promote assurance of the safety of foods in general.

Goal 2: Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis.

The new work updates the existing general guidance document with the latest thinking on the application of scientific principles and risk analysis and thus is essential to meeting this objective.

Goal 3: Strengthening Codex work-management capabilities

The new work strengthens an important aspect of Codex regarding the risk-based approach to food safety management and makes links to operational practice that are key to implementing the risk-based approach in day-to-day food industry practice.

Goal 4: Promoting cooperation between Codex and other relevant international organizations.

This work requires a close coordination between FAO, WHO and Codex, as well as competent authorities in countries and scientific organisations such as ICMSF.

Goal 5: Promoting Maximum and effective Participation of members.

The new work affects all members of Codex and may trigger further participation of both developing and developed countries with general interests in global trade of food and food ingredients.

6. INFORMATION ON THE RELATION BETWEEN THE PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS

The proposed work concerns several general guidance documents (see above).

7. IDENTIFICATION OF ANY REQUIREMENT FOR AND AVAILABILITY OF EXPERT SCIENTIFIC ADVICE

The new work can be undertaken without a major effort related to scientific advice, despite the fact that some aspects will benefit in their development from targeted discussions in a physical or electronic working group.

8. IDENTIFICATION OF ANY NEED FOR TECHNICAL INPUT TO THE STANDARD FROM EXTERNAL BODIES SO THAT THIS CAN BE PLANNED FOR

None identified.

9. PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK

The following timeline is proposed for the completion of the work, preferably for final adoption in 2012. The timeline should not exceed five years (2013).

Timetable	Meeting	Progress
November 2009	41 th session CCFH	Agree on project documents and submit it to 33 rd CAC for approval of new work
July 2010	33 rd CAC	Approval of new work
November 2010	42 nd session CCFH	Consideration of the proposed Draft Revised Guidelines at Step 4 and advance to 34 th CAC for adoption at Step 5.
July 2011	34 th CAC	Adoption at Step 5
		Circulation for comments at Step 6
November 2011	43 rd session CCFH	Consideration of the proposed Draft Revised Guidelines and annexes at Step 7 and advance for adoption at Step 8.
July 2012	35 th CAC	Final adoption.

Appendix VII**PROPOSED DRAFT RISK ANALYSIS PRINCIPLES AND PROCEDURES APPLIED BY THE
CODEX COMMITTEE ON FOOD HYGIENE****(For inclusion in Section VI of the Procedural Manual)****I. SCOPE**

1. This document addresses the respective applications of risk analysis principles and procedures by the Codex Committee on Food Hygiene (CCFH) as the risk management body and the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) as the risk assessment body. This document should be read in conjunction with the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* to which these principles are supplemental.

II. PRELIMINARY RISK MANAGEMENT ACTIVITIES

2. The CCFH arranges to develop a risk profile for bringing forward newly proposed work. The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential microbiological risk management (MRM) options that have been identified by CCFH, if any, and the food safety policy context that will influence further possible actions. Scientific data may be commissioned from a range of sources so as to support a continuous science and risk based approach.
3. Members, who wish to make a request for inclusion of new item in the priority list of future work of CCFH, should prepare a project document in accordance with Part 2-1 of the Elaboration Procedure (Codex Procedural Manual) and provide a preliminary risk profile, based on the template in Annex 1 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)*. CCFH identifies the priority of all the new topics, submitted for its consideration, based on the *Criteria for the Establishment of Work Priorities (Codex Procedural Manual)*. The CCFH may also identify areas on which inputs from JEMRA are needed and make an appropriate request to JEMRA. Further details are provided in the Annex.
4. CCFH is responsible for developing the risk management questions to be addressed by JEMRA in its risk assessments and additionally has the responsibility for establishing the general risk assessment policy under which JEMRA will conduct its risk assessments for CCFH.
21. When referring pathogen-commodity combinations to JEMRA, the CCFH may also refer a range of MRM options, with a view to obtaining JEMRA's guidance on the attendant risks and the likely risk reductions associated with each option.

III. RISK ASSESSMENT

5. CCFH commissions JEMRA, through FAO/WHO, as the body primarily responsible for performing international risk assessments upon which CCFH and the Codex Alimentarius Commission (CAC) will base MRM options. For matters, which cannot be addressed by JEMRA, this document does not preclude the possible consideration of recommendations arising from other internationally recognized expert bodies, as approved by the Commission.
6. FAO/WHO will ensure that the selection of experts and other procedures follow the principles and procedures in the *FAO/WHO Framework for the Provision of Scientific Advice on Food Safety and Nutrition* and in accordance with the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)*.
7. JEMRA should:
 - strive to base its risk assessments, on relevant data from different parts of the world, including that from developing countries;
 - identify and communicate to CCFH in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-

populations and will, as far as possible, identify potential risks to populations of potentially enhanced vulnerability, e.g., infants, immuno-compromised population;

- communicate to CCFH the magnitude and source of uncertainties in its risk assessments. When communicating this information, JEMRA should provide CCFH with a description of the methodology and procedures by which JEMRA estimated any uncertainty in its risk assessment;
- communicate to CCFH the basis for all assumptions and the level of uncertainty in risk assessment outcomes as well as key factors contributing to uncertainty in its risk assessment.

IV. RISK MANAGEMENT

8. The MRM options recommended by the CCFH to the CAC should be based on the policies stated in the following paragraphs and shall take into account all relevant assumptions and uncertainties described by JEMRA.
9. Elaboration of 'Guidelines' or 'Codes of Hygienic Practices' could include Microbiological Criteria (MC) and/or provide enabling tools/procedures for countries to apply other MRM metrics (e.g., FSO, PO, PC), as outlined in Annex II of the MRM document (CAC/GL 63-2007), to address a food safety risk.
10. In cases where JEMRA has performed a risk assessment and CCFH or the CAC determines that additional scientific guidance is necessary, CCFH or CAC may make a specific request to JEMRA to provide further scientific guidance necessary for deciding on an appropriate MRM option.
11. CCFH decides, on a case-by-case basis, the need to elaborate 'Guidelines' or 'Codes of Hygienic Practices', and/or to establish an 'MC', or provide enabling tools/procedures for countries to apply other MRM metrics. In most cases, elaboration of a 'Guideline' or a 'Code of Hygienic Practices' is the preferred MRM option and should address food safety concerns in a diverse array of situations that prevail globally. It also provides the necessary flexibility to address/manage the risk to an acceptable level in the most efficient and appropriate manner. Also, for certain products that are intended for consumption by sensitive sub-populations (e.g., infant foods, foods specially meant for the elderly people, pregnant women, immuno-compromised persons, etc.), it may be necessary for the CCFH to establish MCs and/or provide enabling tools/procedures for countries to apply other MRM metrics.
12. Where appropriate, other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade, may also be considered by the CCFH, as described in the *Statement of Principles Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are Taken into Account* (Codex Procedural Manual). When establishing MRM options, CCFH shall clearly state when it applies any considerations based on other legitimate factors and specify its reasons for doing so.
13. Wherever possible, CCFH should consider establishing MCs for those pathogen – food combinations for which JEMRA is able to provide a quantitative microbiological risk assessment. Recommendations by CCFH should be based on the outcomes of the risk assessment taking into account differences in regional and national food consumption patterns and dietary exposure. The applicable guidance provided in the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) shall be utilized by the CCFH for establishment of MCs.
14. Where MCs are established, methods of analysis and sampling plans shall be provided, including validated reference methods.

V. RISK COMMUNICATION

15. In accordance with the *Working Principles of Risk Analysis for Application in the Framework of the Codex Alimentarius*, the CCFH, in co-operation with JEMRA, should ensure that the risk analysis process is fully transparent and thoroughly documented and that the results are made available to the members in a timely manner. The CCFH recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. To this end, the CCFH and JEMRA should utilise the guidance on interaction provided in paras 18 through 23.
16. In order to ensure transparency of the risk assessment process in JEMRA, the CCFH may provide

comments on the guidelines related to assessment procedures being drafted or published by JEMRA.

VI. INTERACTION BETWEEN RISK MANAGER (CCFH) AND RISK ASSESSOR (JEMRA)

18. The CCFH recognizes that an iterative process between risk managers and risk assessors is essential for adequate undertaking of any microbiological risk assessment and development of MRM options. In particular, a dialogue between the CCFH and JEMRA is desirable to thoroughly assess the feasibility of the risk assessment, to assure that the risk assessment policy is clear, and to ensure that the risk management questions posed by the CCFH are appropriate.
17. In certain instances when the subject matter would benefit from additional interaction with other Codex Committees, other FAO/WHO expert consultations and/or other specialized international scientific bodies, these should be included into the iterative process.
19. It is essential that communications between CCFH and JEMRA are timely and effective.
20. CCFH is likely to receive questions from JEMRA relating to the requested microbiological risk assessment(s). The questions may include those needed to clarify the scope and application of the risk assessment, the nature of the MRM options to be considered and key assumptions to be made regarding the risk assessment. Likewise, the CCFH may pose questions to JEMRA to clarify, expand, or adjust the risk assessment to better address the risk management questions posed or to develop the MRM options.
22. CCFH may recommend to the CAC to discontinue or modify work on an MRM option if the iterative process demonstrates that: (a) completion of an adequate risk assessment is not feasible; or (b) it is not possible to provide appropriate MRM options.
23. CCFH and JEMRA should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members.

Annex**PROCESS BY WHICH THE CODEX COMMITTEE ON FOOD HYGIENE WILL UNDERTAKE ITS WORK****Purpose**

1. The following guidelines are established to assist the CCFH to:
 - Identify, prioritize and efficiently carry out its work; and
 - Interact with FAO/WHO and their scientific bodies as the need arises.

Scope

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

Process for Considering Proposals for New Work

3. To facilitate the process of managing the work of the Committee, CCFH may establish an *ad hoc* Working Group for the Establishment of CCFH Work Priorities (“*ad hoc* Working Group”) at each Session, in accordance with the Guidelines on Physical Working Groups.
4. The Codex Committee on Food Hygiene will, normally, employ the following process for undertaking new work.
 - i. A request for proposals for new work and/or revision of an existing standard will be issued in the form of a Codex Circular Letter, if required.
 - ii. Proposals for new work received in response to the Codex Circular Letter will be transmitted to the Host of the *ad hoc* Working Group as well as the CCFH Host government and Codex Secretariats.
 - iii. The Host of the *ad hoc* Working Group will collate the proposals for new work in a document that will be distributed by the Codex Secretariat to Codex members and observers for review and comment within a specified time frame.
 - iv. The *ad hoc* Working Group will meet as decided by the Committee, normally on the day prior to the plenary session of CCFH to develop recommendations for consideration by the Committee during the CCFH session. The *ad hoc* Working Group will review the proposals for new work along with comments submitted. It will verify the completeness and compliance with the prioritization criteria of the proposals for new work and make recommendations to the Committee on whether the proposals for new work should be accepted, denied, or returned for additional information.
 - v. If accepted, a recommendation will be provided on the priority of the proposal for new work compared to pre-established priorities. The priority of the proposals for new work will be established using the guidelines outlined below, taking into account the ‘Criteria for the Establishment of Work Priorities’¹. Proposals for new work of lower priority may be delayed if resources are limiting. Proposals for new work of lower priority not recommended may be reconsidered at the next CCFH session. If the *ad hoc* Working Group recommends that a proposal for new work be “denied” or “returned for revision,” a justification for this recommendation will be provided.
 - vi. At the CCFH session, the *ad hoc* Working Group Chair will introduce the recommendations of the *ad hoc* Working Group to the Committee. The CCFH will decide whether a proposal for new work and/or revision of an existing standard is accepted, returned for revision, or denied. If accepted, a

¹ Codex Alimentarius Commission, *Procedural Manual*

project document², which may include amendments agreed upon by the Committee, will be prepared by the CCFH and submitted to the Codex Alimentarius Commission (CAC) with a request for approval of the proposed new work..

Proposals for New Work

5. In addition to the provisions applying to proposals for new work in the Procedural Manual, the proposals for new work should include a Risk Profile³, as appropriate. The proposals for new work should indicate the specific nature or outcome of the new work being proposed (e.g., new or revised code of hygienic practice, risk management guidance document).

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

7. The proposal for new work may also:

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

Prioritization of Proposals for New Work

8. The Committee will prioritize its proposals for new work at each CCFH meeting, if required. This will be carried out by the Committee after consideration of the recommendations from the *ad hoc* Working Group. The *ad hoc* Working Group will consider the priority of proposals for new work taking into account the current workload of the Committee, and in accordance with the “Criteria for the Establishment of Work Priorities” and if necessary, additional criteria to be prepared by the Committee. If CCFH resources are limited, proposals for new work or existing work may need to be delayed in order to advance higher priority work. A higher priority should be given to proposals for new work needed to control an urgent public health problem.

Obtaining Scientific Advice

9. There are instances where progress on the work of the Committee will require an international risk assessment or other expert scientific advice. This advice will be typically be sought through FAO/WHO (e.g. through JEMRA, *ad hoc* expert consultations), though in certain instances such advice may be requested from other specialized international scientific bodies (e.g. ICMSF). When undertaking such work, the Committee should follow the structured approach given in the *Codex Principles and Guidelines for the Conduct of Microbiological Risk Management* (under development and the *Codex Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*⁴).

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

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

² The elements of a project document are described in the Codex Alimentarius Commission, *Procedural Manual*,

³ Definition of a risk profile is “the description of the food safety problem and its context” (Codex Alimentarius Commission, *Procedural Manual*). The elements of a risk profile are provided in the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

⁴ Codex Alimentarius Commission, *Procedural Manual*.

- ii. There is a reasonable expectation that a risk assessment will provide results that can assist in reaching risk management decisions related to control of the microbiological hazard without unduly delaying the adoption of the needed microbiological risk management guidance.
- iii. Risk assessments performed at the regional, national and multinational levels that can facilitate the conduct of an international risk assessment are available.

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

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

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

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