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 09/32/13**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX ALIMENTARIUS COMMISSION**

***Thirty second Session***

***Rome, Italy, 29 June – 4 July 2009***

# REPORT OF THE FORTIETH SESSION OF THE

# CODEX COMMITTEE ON FOOD HYGIENE

***Guatemala City, Guatemala, 1 - 5 December 2008***

**NOTE:** *This report includes Codex Circular Letter CL 2009/1-FH*

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**CX 4/20.2** **CL 2009/1 - FH**

**TO:** Codex Contact Points
Interested International Organizations

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

**SUBJECT:** **Distribution of the report of the Fortieth Session of the Codex Committee on Food Hygiene (ALINORM 09/32/13)**

The report of the Fortieth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty second Session of the Codex Alimentarius Commission, (Rome, Italy, 29 June – 4 July 2009).

## A. MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

**1. Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) at Step 5/8 (ALINORM 09/32/13 paras 45-47 and Appendix III);**

**2. Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods at Step 5/8 (ALINORM 09/32/13 para. 69 and Appendix II)**

Governments and interested international organizations are invited to comment on the above texts and should do so in writing, preferably by e-mail to Secretary, 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 1 April 2009**.

## B. REQUEST FOR COMMENTS AND INFORMATION

**1. Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (ALINORM 09/32/13, paras 71 – 92)**

The Committee had considered the above Proposed Draft Guidelines (for details of consideration see paras 71 - 92). The Committee agreed to request additional information, as outlined in paragraph 85 of this ALINORM.

Governments and interested international organizations are invited to provide this additional information as outlined in paragraph 84 and should do so in writing, preferably by e-mail to: **Dr Sarah CAHILL,** JEMRA Secretariat, Nutrition and Consumer Protection Division, Food and Agriculture Organization, of the United

Nations, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax: 39-06-5705-4593, email: jemra@fao.org with copies to: **Ms Judi Lee**, Principal Advisor (Risk Management), New Zealand Food Safety Authority, South Tower, 86 Jervois Quay, P O Box 2835 Wellington 6001, New Zealand, email: judi.lee@nzfsa.govt.nz or fax: +64 4 894 2643 and **Mr Lars Plym Forshell**, Assistant Chief Veterinary Officer, National Food Administration, Box 622, SE-751 26 Uppsala, Sweden, email: iapl@siv.se or fax: +46 18 10 58 48, and to the Secretary, 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 27 February 2009.**

**2. Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) (ALINORM 09/32/13, paras 93 – 103)**

The Committee had considered the above proposed draft Annex (for details of consideration see paras 93-103). The Committee agreed to request additional information on large and small-scale operations, as outlined in paragraph 101 of this ALINORM.

Governments and interested international organizations are invited to provide this additional information as outlined in paragraph 100 and should do so in writing, preferably by e-mail to: **Ms Amy GREEN,** Policy Analyst, FDA/CFSAN, 1500 Paint Branch Parkway, College Park, MD, 20740, Fax: 301 436 2651, email: amy.green@fda.hhs.gov with a copy to Secretary, 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 27 February 2009.**

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## SUMMARY AND CONCLUSIONS

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

**MATTERS FOR ADOPTION BY THE 32ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION:**

**The Committee:**

- agreed to forward Annex on the Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special medical Purposes to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) for adoption at Step 5/8 (see ALINORM 09/32/13 paras 45 - 47 and Appendix III);

- agreed to forward the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods for adoption at Step 5/8 (see ALINORM 09/32/13 para. 70 and Appendix II);

**MATTERS FOR ACTION BY THE COMMISSION**

**The Committee:**

- agreed to inform the Commission that it had considered the hygiene provisions in the light of the clarification provided by the 29th Session of the Codex Committee on Fish and Fishery Products to the questions on the hygiene provisions in the Standards for Raw and Live Bivalve Molluscs which had been adopted by the 31st Session of the Commission. The Committee noted that the CCFFP had addressed the concerns expressed by the 39th Session of the CCFH and that there was no need for further discussions on the Section of Hygiene in the above standard. The Committee agreed to inform the 32nd Session of the Commission of this decision (ALINORM 09/32/13, para. 14);

**NEW WORK**

- agreed to take up new work on the proposed Draft Code of Hygienic Practice for Control of Viruses in Food (see ALINORM 09/32/13, para. 139 and Appendix V).

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

- The 30th Session of the Commission, while approving new work on the Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. for Broiler Chicken (ALINORM 07/30/REP, paras 110-112), agreed to the recommendation of the Executive Committee[1] that the scope of the new work be expanded to cover chicken meat in general, thereby deleting reference to "broiler (young bird)" in the title. The 39th Session of the CCFH, following the decision of the Commission, re-scoped the Proposed Draft Guidelines, however the 40th Session of the CCFH, recognizing the lack of data in several areas such as for birds other than broilers, free-range and organic production systems agreed that the work should initially focus on broilers and that annexes to address these additional issues be developed when more information becomes available and to inform the Commission about this decision (ALINORM 09/32/13, para. 76);

- The Committee agreed to request JEMRA to implement an expert meeting to facilitate elaboration of Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. for Broiler Chicken with the Terms of Reference as outlined in para. 88 of this ALINORM.

[1] ALINORM 07/30/3 paras 43-45.

- agreed to request JEMRA to develop the web-based risk management decision support tool as a basis for the Section on risk based controls to be developed within the Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. for Broiler Chicken (ALINORM 09/32/13, para. 82);

- in response to the request of the 31st Session of the Commission to consider giving a higher priority to the revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985), the Committee agreed to establish an electronic working group led by Switzerland, open to all interested parties and working in English only, to consider this matter in order to make a more informed decision on this matter at the next session (ALINORM 09/32/13, paras 142-143);

- agreed to the proposal to develop an annex on control measures for *V. parahaemolyticus* and *V. vulnificus* in molluscan shellfish to the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* species in Seafood (ALINORM 09/32/13, para. 146).

**MATTERS OF INTEREST TO OTHER COMMITTEES**

**Committee on Fish and Fishery Products**

Endorsement of Hygiene Provisions in the Standard for Raw and Live Bivalve Molluscs

The Committee considered the hygiene provisions in the light of the clarification provided by the 29th Session of the Codex Committee on Fish and Fishery Products to the questions on the hygiene provisions in the Standards for Raw and Live Bivalve Molluscs posed by the 38th Session of the Committee. The Committee noted that the CCFFP had addressed the concerns expressed by the 39th Session of the CCFH and that there was no need for further discussions on the Section of Hygiene in the above standard. The Committee agreed to inform the 32nd Session of the Commission of this decision (ALINORM 09/32/13, para. 14).

**Committee on General Principles**

Noting the decision of the CAC regarding Activity 2.1 of the Codex Strategic Plan 2008-2013 (Review of consistency of risk analysis principles elaborated by the relevant Codex Committees)[2] and the decision of the previous session of CCFH on the work to elaborate a risk analysis policy document to guide CCFH work[3], the Committee encouraged the Delegation of India to proceed with this work in order to consider the above document at its next session (ALINORM 09/32/13, para. 15).

[2] ALINORM 08/31/REP para. 133; CRD 6 (Referral from the 30th Session of the CCNFSDU).
[3] ALINORM 08/31/13 para.162.

## LIST OF ABBREVIATIONS

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|---|---|
| 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 |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| GHP | Good Hygienic Practice |
| GIFSA | Global Initiative for Food-Related Scientific Advice |
| HACCP | Hazard Analysis and Critical Control Point System |
| IACFO | International Association of Consumer Food Organizations |
| IBFAN | International Baby Food Action Network |
| ICMSF | International Commission for Microbiological Specifications for Foods |
| IDF | International Dairy Federation |
| 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 |
| WHA | World Health Assembly |
| WHO | World Health Organization |

## INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Fortieth Session in Guatemala City, Guatemala, from 1 to 5 December 2008, at the kind invitation of the Government of Guatemala. Dr Emilio Esteban, Science Advisor for Laboratory Services and Research Coordination, United States Department of Agriculture, Food Safety and Inspection Service (FSIS), Office of Public Health Science, chaired the meeting. Dr Antonio Ferraté de la Riva, Guatemalan Codex Coordinator, Ministry of Agriculture, Government of Guatemala served as Co-Chairperson. The Session was attended by 139 delegates representing 58 member countries, one member organization and 15 international organizations. A complete list of participants, including the Secretariat, is attached as Appendix I.

## OPENING OF THE SESSION

2. The Session was welcomed by:

- Lic. Julio César Recinos Salas, Minister of Agriculture, Livestock and Food, Government of Guatemala;
- Ms Elizabeth Johnson, Under-Secretary for Food Safety, United States Department of Agriculture (USDA), Government of United States of America;
- Mr Alfred Almanza, USDA, FSIS Administrator, Government of United States of America;
- Ing Guilhermina Teixeira, FAO Representative, Guatemala;
- Dr Peter Ben Embarek, World Health Organization;
- Mr Álvaro Arzú Irigoyen, Mayor (Alcalde), Guatemala City.

### Division of Competence

3. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 2 on the division of competence between the European Community (EC) and its Member States and noted that 16 member States of the EC were present at the current session.

## ADOPTION OF THE AGENDA (Agenda Item 1)[1]

4. To the proposal of the Delegation of Indonesia to discuss melamine tolerance in foodstuffs under Agenda Item 9, the Committee noted this was not within its terms of reference and could possibly be discussed in another Codex subsidiary body, such as the Committee on Contaminants in Foods.

5. The Committee accepted the proposal of the Delegation of Japan to establish an intra-session physical Working Group open to all interested parties, working in English, French and Spanish and chaired by Japan to consider the comments received on the proposed draft Code of Hygienic Practice for *Vibrio* spp. in Seafood under Agenda Item 8 in order to facilitate the discussion at the Plenary.

6. The Committee accepted the recommendation of the Chairperson to postpone discussion on Item 4 after Agenda Item 8 in order to allow more time to study the report of the working group and with this modification adopted the Provisional Agenda.

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

7. The Committee noted that a number of matters arising from the 31st Session of the Codex Alimentarius Commission (CAC) were for information purposes only or would be discussed in more detailed under relevant agenda items.

8. The Committee noted that the request from the CAC regarding the revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters would be discussed under Agenda Item 9 (see paras 143-144).

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[1] CX/FH 08/40/1; CRD 2 (Division of competence between the European Community and its Member States, prepared by the EC).

2 CX/FH 08/40/2; CRD 6 (Maters referred from the 30th Session of CCNFSDU to the CCFH).

9. In addition, the Committee commented and made decisions on matters referred as follows:

Inconsistencies arising from amendments made to Codex standards and relevant texts

10. The Committee considered an inconsistency, as referred by the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses, that had been created in the section on food hygiene in the Guidelines on Formulated Supplementary Foods for Infants and Young Children (CAC/GL 08-1991). It was noted that the Guidelines contained a reference to the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979), which had been revoked when adopting the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. The Committee noted that the revoked Code contained end-product microbiological specifications of advisory nature for a number of products for infants and children.

11. The Committee confirmed that, when adopting the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children, it had been agreed to revoke the Recommended International Code of Hygienic Practice for Foods for Infants and Children (1979) as the Codes that had been developed by the CCFH since 1979, e.g. the Recommended International Code of Hygienic Practice-General Principles of Food Hygiene (CAC/RCP 1-1969) provided enough guidance for elaboration of products other than powdered infant formulae for infants and young children. The Committee also noted that this information had been made available to its 39th Session in CX/FH 07/39/4.

12. The Committee also considered how to deal with some other inconsistencies in texts elaborated by the Committee on Food Hygiene. For instance, in Section 5.2 on Cleaning and Disinfection – Washing up of the Recommended International Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering (CAC/RCP 39-1993) there was a reference to "old" Annex I of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) which contained practical guidance for cleaning. During the revision of this Code, Annex I had been deleted from Recommended International Code of Practice – General Principles of Food Hygiene, however the reference to it in the Recommended International Code of Hygienic Practice for Precooked and Cooked Foods in Mass Catering remained.

13. The Committee requested the Codex Secretariat to look at inconsistencies that might have arisen from previous revocations or amendments and to make proposals for consideration by the 32nd Session of the Commission.

Endorsement of hygiene provisions in the Standard for Raw and Live Bivalve Molluscs

14. The Committee considered the hygiene provisions in the light of the clarification provided by the 29th Session of the Codex Committee on Fish and Fishery Products to the questions on the hygiene provisions in the Standards for Raw and Live Bivalve Molluscs posed by the 38th Session of the Committee. The Committee noted that the CCFFP had addressed the concerns expressed by the 39th Session of the CCFH and that there was no need for further discussions on the Section of Hygiene in the above standard. The Committee agreed to inform the 32nd Session of the Commission of this decision.

Elaboration of a risk analysis policy document for CCFH

15. Noting the decision of the CAC regarding Activity 2.1 of the Codex Strategic Plan 2008-2013 (Review of consistency of risk analysis principles elaborated by the relevant Codex Committees)[3] and the decision of the previous session of CCFH on the work to elaborate a risk analysis policy document to guide CCFH work[4], the Committee encourages the Delegation of India to proceed with this work in order to consider the above document at its next session.

[3] ALINORM 08/31/REP para. 133; CRD 6 (Referral from the 30th Session of the CCNFSDU).
[4] ALINORM 08/31/13 para.162.

## MATTERS ARISING FROM THE WORK OF FAO, WHO AND OTHER INTERNATIONAL ORGANIZATIOS[5]:

## PROGRESS REPORTS ON THE JOINT FAO/WHO EXPERT MEETINGS ON MICROBIOLOGICAL RISK ASSESSMENT (JEMRA) AND RELATED MATTERS (Agenda Item 3 (a))[6]

16. The Representative of FAO presented this item and provided an overview of the work of JEMRA relevant to the work of the Committee.

17. Referring to the requests of the 39th session of the CCFH, the Representative summarized the work that had been undertaken in the last year noting the implementation of two expert meetings by FAO and WHO and indicated that the first of these, was an expert meeting on microbiological hazards in fresh produce implemented to contribute to the development of the Annex to the Codex Code of Hygiene Practice for Fresh Fruits and Vegetables specifically addressing the risks associated with leafy vegetables and herbs. The said expert meeting was convened in Bangkok, Thailand in May 2008 and the report of this meeting made available to all Codex Members. Further information on this item was presented under Agenda item 7.

18. The second activity highlighted by the Representative was the implementation of an expert meeting on *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formula which was held in Washington DC, USA (July 2008) to provide scientific information to inform the decision-making process of the development of microbiological criteria for *E. sakazakii* (*Cronobacter* spp.) in powdered follow-up formulae for infants and young children. The report of that meeting was made available to all Codex Members in advance of the current session and further addressed under Agenda Item 4.

19. The Representative expressed appreciation for the financial support provided by the governments of the United States of America and Japan in support of the implementation of the above expert meetings. Appreciation was also extended to all members of Codex that provided data and information to support the work to provide scientific advice on microbiological hazards in fresh produce and *E. sakazakii* (*Cronobacter* spp.) in powdered follow-up formulae.

20. The Committee was informed of the publication of the report of the FAO/WHO expert meeting on viruses in response to the 38th session of the Committee and requested members to take note of this in light of the proposed new work on viruses in food (Agenda Item 9).

21. In addition, the Committee was informed of the implementation of the FAO/WHO expert meeting on the risks and benefits on the use of active chlorine in food production in May 2008 and that the report of that meeting was expected to be available in early 2009. Information on other recently published reports on critically important antimicrobials and the impact of animal feed on food safety as well as new work on nanotechnology was also provided.

22. Finally, the Representative of FAO highlighted the establishment of the Global Initiative for Food-related Scientific Advice (GIFSA) and encouraged countries to use this mechanism to strengthen the FAO/WHO program for the provision of scientific advice enabling them to continue to provide timely scientific advice to the Committee.

23. The Committee expressed appreciation to FAO and WHO for the provision of extensive scientific advice in a timely manner which greatly facilitated and contributed to the quality of the work of the Committee.

## INFORMATION FROM THE WORLD ORGANISATION FOR ANIMAL HEALTH (Agenda Item 3 (b))

24. The Observer of OIE, referring to its written information presented in CX/FH 08/40/3-Add.1, informed the Committee about the current and future OIE activities that are of interest to the CCFH and highlighted the importance of maintaining close collaboration between OIE and Codex in order to avoid duplication and inconsistencies of work in the area of food safety of products of animal origin.

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

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[5] CX/FH 08/40/3, CX/FH 08/40/3-Add.1, CRD 18 (Comments of European Community)

[6] CX/FH 07/40/3.

## MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN (ANNEX TO THE CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN AT STEP 2 (Agenda Item 4)[7]

26. The Committee recalled that at its last session it had agreed to return Annex II containing microbiological criteria for powdered follow-up formula and formulas for special medical purposes to Step 2 for revision by an electronic working group led by Canada with the understanding that the working group would utilize scientific advice provided by FAO/WHO to prepare proposals for consideration by the Committee.

27. The Delegation of Canada while introducing this matter reminded the Committee that this Annex had been previously circulated at Step 3 and considered by the previous session of the CCFH and that the main unresolved issue was whether to establish a microbiological criterion for *E. sakazakii (Cronobacter* spp) for powdered follow-up formulae. The Delegation explained that in light of the information presented in the FAO/WHO expert meeting report the electronic working group recommended not to establish a microbiological criterion for *E. sakazakii (Cronobacter* spp.) in follow-up formulae (FUF) at the present time with the understanding that the Annex could be revised by the CCFH in the future, if further epidemiological evidence became available. The Delegation pointed out that there was evidence that FUF is consumed by infants of less than 6 months of age; which indicated that the product was not used as per the label instructions and that the unintended use/misuse of the product should be addressed through clearer labelling and by education of caregivers and healthcare professionals, as to the appropriate uses of the product.

28. The Delegation indicated that the working group proposed a number of recommendations to member governments and to FAO/WHO that more specific training should be undertaken in developing countries to increase surveillance and improve data collection in foods and the environment, including the development of a guidance document and/or training manuals. A further recommendation was that FAO/WHO should consider the need to review the "Guidelines on Safe Preparation, Storage and Handling of Powdered Infant Formula"[8] to establish whether these guidelines sufficiently cover FUF, as well as information on the need to ensure that the products are used for their intended target populations.

29. The Delegation also informed the Committee that the physical working group, which had met immediately before this session of the Committee, was in agreement with these recommendations.

30. The Delegation pointed out that the physical working group agreed with the recommendation of the electronic working group not to establish a microbiological criterion for *E. sakazakii (Cronobacter* spp.) in follow-up formulae (FUF); however, in recognizing the need to provide flexibility to competent authorities in the application of control measures, including more stringent microbiological criteria, as appropriate, it was proposed to add an additional sentence in the Preamble in order to address this matter, however there was no final agreement on the wording. The Delegation indicated that the working group recognized that FUF were used for infants less than 6 months of age and that this misuse of the product should primarily be addressed through improved education and labeling, however some observer organizations did not agree with the proposal and recommended that a criterion should be established for *E. sakazakii* (*Cronobacte*r spp.) in follow-up formula.

31. The Delegation indicated that the physical working group considered the proposed draft Annex section by section and that in addition to editorial amendments, proposed a number of changes for the consideration by the Plenary as presented in CRD 21. The Delegation indicated that the working group recommended that this Annex could be forwarded to the next Session of the Commission for final adoption.

32. The Committee considered Annex II as presented in CRD 21 and in addition to editorial amendments made the following comments and changes.

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[7] CX/FH 08/40/4; CRD 3 (comments from Ghana); CRD 9 (comments from Thailand); CRD 10 (comments from Indonesia); CRD 21 (Report of the Working group); CRD 35 (comments from ICMSF); CRD 38 (Proposed wording for Section 2).

[8] FAO/WHO. 2007. Safe preparation, storage and handling of powdered infant formula: guidelines.

**General comments**

33. The Delegation of Indonesia pointed out that education programs on appropriate preparation, handling and storage of powdered formulae were needed in order to increase the awareness of caregivers and health care professionals and consumers about the safety of follow-up formula and formulas for special medical purposes for young children and that better surveillance and reporting systems of *E. sakazakii (Cronobacter* spp.) infections were necessary. The Delegation emphasized that specific training to increase surveillance and improve data collection in foods and the environment should be undertaken by FAO and WHO in developing countries including the development of a guidance document and/or training manuals and supported the establishment of a microbiological criterion for *E. sakazakii (Cronobacter* spp.). The Delegation also pointed out that availability of testing methods was essential for developing countries.

34. The Delegation of Nigeria highlighted the high level of infant mortality in its country, despite the implementation of various programs including the promotion of exclusive breast feeding of infants for the first six months and therefore was of the opinion that more stringent measures for follow-up formula were necessary.

**Preamble**

35. The Committee had a discussion on the proposed new wording in CRD 38 for the second paragraph of the Preamble. The Delegation of the European Community proposed to amend this wording to make it clearer that the risk associated with *E. sakazakii (Cronobacter* spp.) should be assessed by competent authorities on the basis of scientific evidence and that depending on these findings, strengthening control measures including establishment of an appropriate microbiological criterion for this pathogen may be considered. This view was supported by a number of delegations.

36. Observers from ILCA, IBFAN and IACFO opposed an inclusion of the reference to "scientific evidence" as developing countries lacked appropriate capacity of laboratories and surveillance systems to collect such data. In addition, they were of the view that additional factors such as anaemia, malnutrition and HIV/AIDS were contributing to the increased susceptibility of infants and young children to *E. sakazakii (Cronobacter* spp.). The observers stressed that the failure to set a microbiological criterion for this pathogen in follow-up formula would expose these vulnerable populations to a greater risk and that there was no basis for setting 6 month as the age at which risk of infection from *E. sakazakii (Cronobacter* spp.) decreases. Therefore they considered that it was essential to apply precaution on this important issue and to establish the same microbiological criterion for follow-up formula as exists for powdered infant formula. This view was supported by the Delegations of Mali and Indonesia.

37. After some discussion, the Committee agreed, that, as expressed by the Delegation of China and supported by several other delegations, a microbiological criterion for *E. sakazakii (Cronobacter* spp.) in FUF should not be established at the present time, in view of the limited scientific evidence available. The Committee also noted that a possible need for a microbiological criterion for *E. sakazakii (Cronobacter* spp.) should be reviewed when new information becomes available and agreed to maintain the wording for the second paragraph as proposed in CRD 38 with modifications proposed by the European Community. The Delegations of Indonesia, Nigeria and Mali expressed their opposition to this decision.

**Tables 1 and 2 and footnotes**

38. The Committee amended "m" in the 2- and 3-class sampling plans in both tables to make clear that microbiological limit refers to a separation of "acceptable lots from unacceptable lots" rather that "good quality from defective quality".

39. The Committee noted that more technically accurate information was available on the performance of the sampling plan and agreed to amend the footnote "*" as proposed in CRD 35.

40. The Committee also agreed to request the 32nd Session of the CAC to make the above consequential changes in relevant parts of the tables in Annex I of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008).

41. To be consistent with Annex I, the Committee agreed to clarify the 4th paragraph related to typical actions to be taken when there is a failure to meet proposed microbiological criteria by inserting a second action that if already released, the product should be recalled..

**Criteria for process hygiene**

42. The Committee agreed to wording proposed by the physical working group in paragraphs 3 and 4 of this Section.

**Labelling and education**

43. The Observer from IACFO, supported by the observer from ILCA proposed to add an additional sentence to this section to stress that labeling should clearly indicate that follow-up formula should only be given to healthy full-term children over 6 months of age. The Committee however noted that the definition of follow-up formula covered the age of introduction of this product and that there might be cases when a child is sick with common illnesses such as influenza and that this should not prevent the feeding with FUF. It was also noted that the main body of the Code addressed labelling and education and that it was not necessary to expand the wording on labeling and education in this Annex. The Committee therefore agreed to the wording for this Section as proposed by the working group.

44. The Committee noted that formulae for special medical purposes are given to targeted populations under very strict supervision therefore their misuse was not considered to be a problem.

**Final considerations**

45. The Committee noted that due to the late arrival of this document it was unable to solicit comments at Step 3, and that the Annex was therefore considered at Step 2 by the physical working group and the Committee and that an agreement had been reached on all provisions of this Annex.

46. The Committee also noted that the Codex Procedural Manual does not address how to deal with moving a document from Step 2 for final adoption and was of the view that the Commission could make the most appropriate decision on the final status of this document.

**Status of the proposed draft Annex II - Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical purposes for Young Children**

47. The Committee therefore agreed to forward the proposed draft Annex II - Microbiological Criteria for Powdered Formulae and Formulae for Special Medical purposes for Young Children to the 32nd Session of the Commission for final adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix III).

## PROPOSED DRAFT MICROBIOLOGICAL CRITERIA FOR LISTERIA MONOCYTOGENES IN READY-TO-EAT FOODS AT STEP 4 (Agenda Item 5)[9]

48. The Committee recalled that its 39th Session had agreed to return the Annex on the Proposed Draft Microbiological Criteria in Ready-to-Eat Foods to Step 2 for further elaboration by a physical working group led by Germany, circulation for comments at Step 3 and consideration by this session of the Committee.

49. The Delegation of Germany introduced the document and highlighted the main points considered by the working group in their revision of the Annex and explained the outline of the document. The Delegation indicated that Annex II was intended to be used within the context of the main document and was specifically linked to Section 5.2.3 *Microbiological and Other Specifications* of 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) and that a new Annex III had been created from portions of earlier drafts of Annex II to provide further recommendations to competent authorities for the use of environmental microbiological testing and process control verification for *Listeria monocytogenes*.

50. The Delegation stressed that both Annexes II and III should be considered as a package along with Annex I, and the main guideline document, *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) for the control of *Listeria monocytogenes*.

[9] CX/FH 08/40/5; CX/FH 08/405-Add.1 (comments from Australia, Kenya, Philippines, the United States of America, CIAA, IACFO); CX/FH 08/40/5-Add.2 (comments from Brazil, Colombia, European Community, Japan, New Zealand), CRD 11 (comments from India); CRD 13 (comment from Thailand); CRD 20 (comments from New Zealand and the United States of America).

51. The Committee expressed its appreciation to the Delegation of Germany and the working group for their work and considered the draft proposed Annexes II and III section by section. In addition to editorial amendments, the following observations and/or changes were made.

**2. Scope**

52. The Committee agreed to delete reference to "performance objective" as an example in the second paragraph since establishment of a performance objective was difficult to achieve due to insufficient data and technical resources and therefore considered inappropriate for inclusion as a working example.

53. The Committee replaced "alternative" with "different" as more appropriate in the 3rd paragraph. It further agreed to replace "equivalent" with "acceptable" since equivalence had a more specific meaning within Codex and was not appropriate in the context of the Annex and to apply this change throughout the text where applicable.

**3. Use of Microbiological Criteria for *L. monocytogenes* in Ready-to-Eat Foods**

54. The Committee agreed to reorder this section to improve its flow and readability. It was further agreed to insert a new paragraph 4 in order to reinforce that the risk-based approach was desirable for the development of microbiological criteria, while still allowing for some flexibility for situations where no risk assessment data might be available.

**3.1 Ready-to-Eat Foods in which growth of *L. monocytogenes* will not occur**

55. The Committee did not agree to a proposal to include in paragraph 3 a reference to the population to which the food is targeted and it was clarified that this section related to the demonstration of whether *Listeria monocytogenes* would grow or not in a particular food and was therefore linked to the food substrate.

56. The example at the end of paragraph 4 was deleted since there was no scientific rationale for the use of the factor 1.3 when establishing the expected usage period of a food.

57. The Observer from the Industry Council for Development (ICD) was of the view that the example provided in the 4th paragraph for which testing may have limited utility could be misleading as past history of absence of *L. monocytogenes* did not protect against a future failure unless the processing was such that contamination, survival or growth of *L. monocytogenes* above detection limits is unlikely and proposed alternative wording to address this concern, however, the Committee did not support this proposal.

58. The Committee agreed to replace the fifth paragraph with more generic wording without reference to a specific temperature of refrigeration (8°C).

**Tables 1 and 2**

59. It was agreed to amend the Tables by deleting the column "M" as it was not applicable to a 2-class sampling plan; to insert a legend to explain "n", "c" and "m" for consistency with other similar texts; and to indicate that "m" was a microbiological limit to distinguish acceptable lots from unacceptable lots rather than to distinguish between good quality and defective quality.

60. Footnote "a" was amended to indicate that national governments could also "support the provision of guidance" from other sources other than national governments.

61. Footnote "c" was amended to improve transparency of the performance of the sampling plan.

62. The Committee agreed to insert an additional paragraph to clearly illustrate the action to be taken when the criteria were not met.

63. The Delegation of Mexico, supported by several other delegations from the Latin America region, questioned the criterion for *L. monocytogenes* in foods which did not support the growth of *L. monocytogenes* (Table.1). These Delegations were of the view that the level of 100cfu/g was unnecessary; that presence of *L. monocytogenes* in such foods could be addressed through alternative approaches; and that the criterion could pose a technical barrier to trade. It was however clarified that, even though certain foods may not support the growth of *L. monocytogenes*, that *L. monocytogenes* could still be present even in high numbers in these foods, either due to their presence before processing or through cross-contamination, and that the criterion was there to protect public health interest and was based on current risk assessments. After some discussion, the Committee agreed to retain this provision unchanged.

### 4.3 Alternative approach

64. The first paragraph was amended for consistency with the content of paragraph 3 of the Scope.

65. The Committee agreed to refer to "food business operator" rather than "business operator" for consistency with Section 3.1 and other Codex texts and to apply this throughout the document where applicable.

66. The Delegation of the United States of America, while referring to their written comments in CX/FH 08/40/5-Add.1, raised the issue of review of national public health experience to support this approach. This was supported by the observer from IACFO. The Committee decided that the Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/RCP 63-2007) document covered this issue.

### Annex III

### b) Process Control

67. The title was amended to read "Process Control Verification" in line with the title of the Annex.

68. Several changes were made to paragraphs 2 and 3 for clarification purposes.

69. The second sentence of the last paragraph was moved to the second paragraph for a better fit in the Annex.

## Status of the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods

70. The Committee agreed to forward the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (Annex II: Microbiological Criteria for *Listeria monocytogenes* in ready-to-Eat Foods and Annex III: Recommendations to for the Use of Microbiological Testing for Environmental Monitoring and Process Control Verification by Competent Authorities as Means of Verifying the Effectiveness of HACCP and Prerequisite Programs for Control of *Listeria monocytogenes* in Ready-to-Eat Foods) to the 32nd Session of the Commission for adoption at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix II).

## PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *CAMPYLOBACTER* AND *SALMONELLA* SPP. IN CHICKEN MEAT (Agenda Item 6)[10]

71. The Committee recalled that its 39th Session had agreed on the approach to be taken in the development of the proposed draft guidelines for the control of *Campylobacter* and *Salmonella* spp. in chicken meat, and in returning the document to step 2 for further elaboration had agreed to the establishment of a physical working group led by New Zealand and Sweden to undertake this work.

72. The Delegation of Sweden introduced the proposed draft guidelines as presented in CX/FH 08/40/6 and informed the Committee that the lack of data for birds other than broilers prevented the working group from effectively addressing the request to broaden the scope of the guidelines at the current time but that this could be addressed in the future, should the necessary information become available.

73. The Delegation of New Zealand reminded the Committee that the document was divided into three parts, the first on Good Hygiene Practices (GHPs), the second on hazard-based controls and the third on risk-based control measures and indicated that to date the work had focussed on the first two elements and that work on the third element was planned for the coming year and included the development of a web-based risk management decision support tool.

74. A number of Delegations noted their satisfaction with the extensive progress that had been made to date and highlighted the importance of continuing with this work. In particular, the guidance provided by the section on GHPs was considered to be very useful. Several Delegations made reference to their written comments and asked that they be specifically considered by the working group as it continues its work

75. Some Delegations expressed concern about trying to address *Salmonella* and *Campylobacter* in the same document; however the Delegation of Sweden noted that the work to date indicated that it made sense

[10] CX/FH 08/40/6; CX/FH 08/40/6-Add.1 (comments from Australia, Kenya, Philippines, United States); CRD 5 (Sweden); CRD 14 (Brazil); CRD 15 (Indonesia); CRD 16 (Japan); CRD 17 (Thailand); CRD 18 (EC); CRD 19 (ALA); CRD 24 (New Zealand)

to provide guidance on the management of both organisms together since many control measures applied to both *Salmonella* and *Campylobacter*. The Committee agreed to continue to address both organisms together to improve the readability of the document. The Delegation of Argentina suggested that only *Salmonella typhimurium*, and *Salmonella enteritidis* be addressed.

76. Recognizing the lack of data in several areas such as for birds other than broilers, free-range and organic production systems the Committee agreed that the work should initially focus on broilers and that annexes to address these additional issues be developed when more information becomes available and to inform the Commission about this decision.

77. There was general support for the development of a web-based risk management decision support tool as outlined in CRD 24 as a basis for the section on risk based-controls to be developed within the guidelines.

78. In response to a proposal of the Delegations of New Zealand and Sweden to request JEMRA to develop the web-based decision support tool, the Representatives of FAO and WHO indicated their willingness to provide it and pointed out that it was very important to receive a clear definition on the requirements of such a tool in order to ensure that it would meet the needs of the Committee.

79. A number of Delegations sought clarification on the relationship between the guidelines that were being developed and the web-based risk management decision support tool. It was noted that this web-based tool would ultimately be a JEMRA product and would be made available via the internet to all Codex members. The tool would also be used by the working group in the development of the risk-based controls section of the guidelines document.

80. Several Delegations noted the novel approach of this work and highlighted their interest in the development of the risk-based controls together with the web-based risk management decision support tool and the value of such a tool to regulators. Recognizing the data and other resources that would be required to develop such a tool some Delegations expressed concern that this might the delay the completion of the guidelines and noted that the GHPs and hazard-based controls already provided important guidance for countries and their completion should not be delayed by the development of the risk-based component.

81. The Delegation of New Zealand indicated that the development of all three parts of the document could continue in parallel but recognizing the aforementioned concerns indicated that, if necessary, the risk-based section could be decoupled from the other sections so as not to delay their finalisation and adoption.

82. In light of these clarifications the Committee agreed to request JEMRA to develop the web-based risk manament decision support tool as outlined in CRD 24.

83. The Delegation of Brazil, supported by several other delegations, referred to the work of OIE on the control of *Salmonella* in primary production, and highlighted the importance of ensuring harmonization between this work and that of OIE and encouraged their participation. The Delegations of New Zealand and Sweden indicated that in the work to date every effort had been made to ensure compatibility between these guidelines and the work of OIE and noted that OIE had been invited to participate in the working group.

84. The Delegation of New Zealand highlighted the importance of receiving additional data in order to be able to complete the sections on hazard-based and risk-based controls. The Committee agreed that the quantitative information that was needed should be primarily sourced from regulators and industry and that such information was critical to provide evidence of key interventions, many of which have been described in the scientific literature, that are being effectively applied in commercial settings.

85. In light of this, the Committee agreed that a Circular Letter should be issued by end of the year 2008 to request that the following additional information which should be sent to New Zealand, Sweden and JEMRA by the end of February 2009:

**a) Broiler chicken**

- Quantitative information on changes to levels (prevalence and/or concentration) of *Campylobacter* and or *Salmonella* as a consequence of a specific intervention at any step in the food chain, i.e.:
    - Primary production (elite flocks to broiler growing);
    - Processing (slaughter to chill/freeze)
    - Storage and distribution (transport through to consumer)

- More specifically, quantitative information on any changes to levels (prevalence and/or concentration) of *Campylobacter* and or *Salmonella* as a consequence of a specific intervention or interventions at the following steps are needed:
    - Depopulate and transport to slaughterhouse
    - Scalding, defeathering and evisceration
    - Washing and chilling
    - Storage, retail and consumer handling.
- Examples of possible interventions on which data are required are as follows:

*Primary Production*:

- Live Birds: Competitive exclusion (CE) and probiotics; feed and water additives (other than CE, probiotics and antibiotics); bacteriophages; genetics; vaccines; immunostimulators; antibiotics; housing conditions; litter treatment.
- Hatchery: Egg decontamination and air sanitation
- *Processing:* Handling of crates; pre-scalding; scalding; head pulling; decontamination; chilling; storage and freezing.
- *Transport-retail/wholesale-consumer:* Microwave cooking; kitchen practices
- Potential sources of this data could include:
    - Data from testing of the effectiveness of a control measure
    - Data used to establish critical limits at Critical Control Points
    - Verification data after a new intervention has been put in place.

**b) Birds other than broilers**

- Any of the above data relating to birds other than broilers.

**c) Monitoring**

- Countries are asked to provide examples of monitoring programmes (regulatory or industry driven) specific for *Campylobacter* and *Salmonella* that can be used to support development of this section of the draft Guidelines, e.g. at:
    - Primary production (elite flocks through to slaughter flocks)
    - Processing
    - Transport and distribution

86. In considering how such data should be analysed prior to the next session of the working group, the Delegation of Ireland recommended that FAO and WHO convene an expert meeting to review all the available data and that the report of such a meeting could contribute to the completion of the work on hazard-based controls as well as be a preliminary step in the development of the web-based decision support tool.

87. The Representative of FAO indicated the willingness of FAO and WHO to facilitate the work of the Committee to the extent possible and implement such a meeting in an expeditious manner. The Delegation of New Zealand, while in general agreement with this proposal, expressed concern that the implementation of the expert meeting could delay progress by the working group.

88. However, in noting that the output of such a meeting should ultimately contribute to the robustness of the guidelines the Committee agreed to request JEMRA to implement an expert meeting with the following Terms of Reference:

- To carry out an independent assessment and review of available scientific information (existing data as well as that provided in response to the CL) on control of *Campylobacter* and *Salmonella* at relevant steps throughout the broiler chain.

- To evaluate quantitative aspects of hazard reduction in terms of prevalence and concentration following specific interventions.
- To evaluate likely outcomes of specified interventions in terms of hazard reductions in the commercial setting.
- To assess suitability of the outputs of the Expert Meeting as a basis for the development of a risk management tool, as described in CRD 24.
- To identify any further data needs that may be required for the web-based risk management decision support tool to be developed by JEMRA.

89. The Committee agreed to re-establish a physical working group led by New Zealand and Sweden in order to complete the work on GHPs and hazard-based control measures and to begin elaborating in more detail the section on risk-based control measures in the guidelines document. The outputs of the working group would be considered by the next session of the Committee.

90. The Delegation of Brazil confirmed its willingness to provide a venue for the physical working group in late August/early September 2009 and indicated that they would provide interpretation in English, French, Spanish and Portuguese, in order to facilitate greater participation of members in the working group.

91. The Committee noted that significant progress had been made on the development of document. However it was of the view that there was still a substantial amount of work to be undertaken on certain parts of the document and therefore the Committee agreed to request the physical working group to further elaborate the document taking into account comments received and comments provided by the Plenary.

**Status of the Proposed Draft Guideline for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat**

92. The Committee agreed to return the proposed draft guidelines to Step 2 for further elaboration by the above physical working group, circulation at step 3 for comments and consideration by the next session of the Committee.

## 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 7)[11]

93. The Committee recalled the decision of its 39th Session to start new work on an annex on leafy green vegetables including leafy herbs through an electronic working group led by the United States of America and that this work had been approved by the 31st Session of the Commission.

94. The Delegation of the United States introduced the document and recalled that when the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) was developed, it had been understood that the Code would be supplemented by annexes on specific commodities and that leafy green vegetables including fresh herbs had been identified as the commodity group of highest concern by an FAO/WHO Expert Meeting in September 2007. The Delegation further indicated that the proposed draft annex was based on guidance provided by an FAO/WHO Expert Consultation (May 2008) and pointed out that there were a few areas on which further guidance from the Committee was needed, i.e. on small-scale production and processing systems: wet systems used to produce leafy vegetables and herbs, including the production of watercress, herbs and other leafy greens in wet systems; and on production systems for fresh leafy vegetables: and on other than those used in producing lettuce, spinach and salad mixes which were well presented in the current document. The Delegation proposed that these areas should be addressed before proceeding with detailed consideration of the document and its advancement in the Codex step procedure.

95. The Representative of FAO speaking on behalf of the FAO and WHO gave a brief overview of the aforementioned two expert meetings, on microbiological hazards in fresh fruits and vegetables and on microbiological hazards on leafy greens, respectively, and the outcomes of those meetings.

96. The Committee had a general discussion on the document and made the following observations.

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[11] CX/FH 08/40/7; CX/FH 08/40/7-Add.1 (comments from Argentina and Australia); CRD 18 (comments from the European Community); CRD 23 (comments from Brazil); CRD 25(comments from Canada); CRD 26 (comments from IACFO); CRD 27 (comments from Indonesia); CRD 28 (comments from Mexico); CRD 34 (comments from Japan); CRD 37 (comments from Philippines); CRD 39 (proposal for Circular Letter prepared by the United States of America).

97. The Delegation of the European Community referring to its comments in CRD 18, supported by some other delegations, indicated that while good progress had been made, more specific recommendations could better address the particular risks linked to the products covered by the Annex that better articulation with the main code would facilitate the reading and use of the Annex; that some parts of the Annex were too prescriptive (such as the guidance provided in Sections 3.2.1 and 3.2.24); that more coherence, clarity and/or explanation as regards the approach to define the different sources and level of quality of water used at the different steps especially at farm level was needed; that consistent terminology should be used; and that temperature aspects should be more consistent and supported the recommendation to return the Annex for redrafting.

98. An observer was of the view that the document could be strengthened by making it a requirement for growers to develop comprehensive written foods safety plans that would outline the potential hazards and the steps to be taken to reduce microbial food safety risks that may result from those hazards or to provide a model of what a written plan should look like. Some delegations however cautioned against placing an additional administrative burden for primary producers through such a requirement.

99. A delegation indicated that the Annex needed to be more specific about the particular commodities to be covered to ensure that the guidance provided would be applicable and practicable, while another delegate indicated that the scope should be restricted to packaged leafy green vegetables. Another delegation indicated that instead of making references to other Codes of Hygienic Practice, the specific recommendations from those Codes be added to the Annex to make it more user-friendly.

100. The Committee noted that despite significant progress made on the elaboration of the document the above-raised issues should be addressed before proceeding with further elaboration. The Committee therefore agreed that a Circular Letter would be issued requesting information to provide further guidance in the development of the Annex on fresh leafy vegetables in order to ensure that this Annex is equally applicable to small and large scale operations and takes account of the challenges that small-scale operations face.

101. The following additional information on large and small-scale operations would be requested and mention should be made to whether the response applies to specific leafy vegetables (e.g. romaine lettuce); group of leafy vegetables (herbs) or leafy vegetables in general:

- The typical steps and processes, including handling, storage and transport, used in small scale production systems of fresh leafy vegetables and herbs from primary production through to marketing of the finished product.
- The typical steps and processes, including handling, storage and transport, used in wet production systems (e.g. production of watercress) from primary production through to marketing of the finished product.
- The application of existing Codex codes of practice or national/regional codes of practice, GAPs and the extent to which they address microbiological risks
- In particular, information on the following steps including any information on the microbiological risks associated with the steps, processes and practices and any interventions taken to mitigate these risks would be useful:
    - Size of production system
    - Location (e.g. proximity to urban areas, livestock production, sewage systems, waterways etc., prior land use)
    - Weather during growing season(s)
    - Inputs to production (e.g. source, quality and method of application of irrigation water, water used for other agricultural purposes such as in preparing fertilizers, for dust abatement, on roads, use and type of soil amendments and fertilizer etc.)
    - Packaged or unpackaged
    - Major pests and control measures used for production systems
    - Sanitation, Sanitary facilities

- Worker hygiene
  - Access to handwashing facilities and toilets
  - Child access to fields
- Equipment sanitation
  - Sanitation of equipment (e.g. knives, containers, mechanical harvest equipment)

- Harvesting practices and packing (e.g., is product field packed, packed in shed, is water used, how, what is the source and quality of water)
- Processing practices (is the product subject to any further processing such as washing, sanitizing, cutting packing, where does this take place – a specific facility, at markets)
- Marketing practices (e.g. where and how the produce is transported, and sold (export or domestic market, type of retail establishment))
- Application of the cold chain (e.g. use of ice, refrigeration during storage, transport retail, etc.)

102. The Committee agreed to reconvene the electronic working group led by the United States of America, open to all members and observers and working in English only, to further elaborate the Annex at Step 2 taking into account all written comments submitted, comments made during the Session and the information provided in response to the Circular Letter.

**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**

103. The Committee agreed to return the proposed draft Annex to Step 2 for further elaboration by the above working group, circulation for comments at Step 3 and consideration by the next session of the Committee.

**PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD (Agenda Item 8)[12]**

104. The Committee recalled that the 31st Session of the Commission had approved the new work proposal submitted by the 39th Session of the Committee to elaborate a Code of Hygienic Practice for Pathogenic *Vibrio* Species in Seafood. The Committee also recalled that at its 39th Session it had agreed to establish an inter-session physical working group led by Japan to prepare the proposed draft code for circulation for comments at Step 3 and consideration at Step 4 at the present session.

105. Following the previous decision by the Committee (see para. 4), the in-session physical working group[13], led by Japan, met to consider the proposed draft code presented in CX/CF/08/40/8 and prepared further proposed amendments that was presented in CRD 36.

106. The Delegation of Japan, as Chairperson of both the inter-session and the in-session physical working groups, referring to the above relevant two documents, highlighted that the proposed draft code of practice targeted pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleragenic *V. cholerae* and covered seafood including finfish and shellfish that are marketed in a live, raw, or partially or thoroughly treated state. The Delegation also explained that the in-session physical working group further proposed amendments to the text in particular in the sections on: temperature control; handling/storage and transport; labelling; and terminology of the scope of products. The physical working group recommended to develop an annex to this proposed draft code, which should focus on *Vibrio parahaemolyticus* and *V. vulnificus* in molluscan shellfish, and might be expanded to choleragenic *V. cholerae* as long as there were sufficient data for the

[12] CX/FH 08/40/8, CX/FH 08/40/8-Add.1 (comments from Australia, Canada, Costa Rica, Guatemala, Iran, Mexico, Philippines, United States and International Commission on Microbiological Specifications for Foods (ICMSF)), CRD 3 (comments of Ghana), CRD 18(comments of European Community), CRD 22 (comments of Japan) , CRD 29 (comments of Nicaragua), CRD 30 (comments of IACFO), CRD 31 (comments of Indonesia), CRD 32 (comments of Korea) , CRD 33 (comments of Mexico), CRD 36 (outcome of the in-session physical working group led by Japan) .

[13] Australia, Brazil, Canada, Costa Rica, Cuba, Denmark, Domenica Republic, El Salvador, European Community, France, Germany, Guatemala, Honduras, Japan, Mali, Mexico, Morocco, Mozambique, the Netherlands, New Zealand, Nicaragua, Nigeria, Norway, Peru, Philippines, Portugal, Serbia, Spain, Sweden, the United Kingdom, the United States of America, FAO,WHO, CIAA, ICD and ICMSF attended.

additional elaboration of the Annex. In addition, the working group recommended not to develop microbiological criteria for *Vibrio* spp. in reply to the request from the 29th session of the Committee on Fish and Fishery Products[14], based on the FAO/WHO risk assessment. It was clear that the risk reduction derived from a certain microbiological criterion was diverse among different parts of the world and that it was therefore difficult to set microbiological criteria, which were applicable worldwide.

107. The Committee considered the text presented in CRD 22, paragraph by paragraph. In addition to editorial amendments, the following observation and changes were made.

**Title**

108. The Committee considered to amend the title of the code in order to better reflect the contents of the document and to use a similar title as used in other recent CCFH documents, e.g. 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) for consistency. However no agreement was reached, therefore the two different titles were placed in square brackets for further consideration.

**Introduction**

Paragraph 7

109. The Committee agreed to add a sentence to provide more detail of the characteristic that specifies *Vibrio parahaemolyticus*.

Paragraph 11

110. The terms "undercooked" and "cooked" were replaced by "partially treated" and "thoroughly treated" respectively in order to better define the products covered by the code including those products that were cooked or treated through other processes. The same or similar amendments were made throughout the document including paragraph 23 of the scope. For the sake of clarity, a footnote was added to explain that "treated" meant any vibriocidal treatment, e.g. heat treatment, high pressure. The term "for example" was added in the first sentence to clarify that the number of seafood listed did not exclude other foods associated with illness caused by *V. parahaemolyticus*.

Paragraph 12

111. The reference "these choleragenic strains" and "patients" were deleted as unnecessary.

Paragraph 13

112. A text was added to better describe situations in which cholera outbreaks occurred with *V. cholerae.*

Paragraph 16

113. It was agreed to include "diabetes, haemochromatosis and HIV/AIDS" as further examples of chronic pre-existing health conditions in individuals which could make such individuals more susceptible to primary septicaemia following consumption of contaminated raw molluscan shellfish. Similar additions were also made in paragraph 108 for consistency.

Paragraph 19

114. For accuracy, it was agreed to indicate that *V. vulnificus* multiplied at temperatures higher than 13°C. It was also agreed to express salinities in both ppt and g/l.

Paragraphs 22-25

115. There was some discussion on which types of seafoods were covered in the code and whether ready-to-eat should be included as these were products that posed greater risk for which no further measures were taken for reduction of *Vibrio* spp.

116. After some discussion, amendments were made to indicate that the code covered seafood that were marketed in a live, raw, chilled/frozen, partially treated, or through treated, including ready-to-eat seafood.

117. These paragraphs 22-25 were restructured to eliminate any repetitions, redundancies and inconsistencies.

[14] ALINORM 08/31/18, para.76

Paragraph 26

118. The term "may" was added to allow some flexibility in the application of the code by national authorities, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp., water temperatures and salinity.

Paragraph 27

119. The Committee agreed to use the definition of *clean water /clean seawater* of the Code of Practice for Fish and Fishery Products since the definitions covered all types of water including seawater and consequently deleted the text with the understanding that in this code definitions available elsewhere in Codex were not repeated. It was noted that "health quality of fish" in the definition of *clean water /clean seawater* in the Code of Practice for Fish and Fishery Products covered issues that were related to human health. The definition of "partially treated" was added to clarify that this treatment was intended to reduce but not eliminate *Vibrio* spp.

Paragraph 36

120. A sentence was added to highlight that the delay between harvest and refrigeration should be as short as possible.

Paragraphs 39, 40 and 37

121. It was noted that clean water used for washing of seafood or for the storage of live seafood products was not necessarily limited to clean potable water but also covered clean seawater.

Paragraph 61

122. The term "plumbing" was replaced by "drainage" for consistency with the title of section 4.4.2.

Paragraph 67

123. The temperature "less than 10ºC" required for control of pathogenic *Vibrio* spp. was replaced by "10ºC or lower" for the sake of clarity and accuracy. And a footnote was inserted to indicate that the temperature of 10 ºC was used as a target to prevent or minimize *Vibrio* spp. growth and that a stricter temperature control closer to 0 ºC should also be considered to control other pathogens and that a different temperature control of *Vibrio* spp. in molluscan shellfish would be specified in the Annex. The same amendment was made in paragraph 7.

Paragraph 73

124. A text was added to emphasize that temperature control and monitoring should be implemented at each step of the process.

Paragraph 74

125. "At low temperature" was added to emphasize that water used for washing and processing seafood should be at low temperature.

Paragraphs 75 and 77

126. The term "potable" was added to clarify that pathogen free water should be used to wash fish prepared for raw consumption or to cool foods after being cooked, in order to prevent any cross-contamination of pathogens noting that for such foods there was no additional measure on pathogen control afterward.

Paragraph 79

127. "Prevent the growth" was also added to clarify that the freezing procedure could reduce the level of pathogenic *Vibrio* spp. but did not always completely eliminate the pathogen.

Paragraph 80

128. Some delegations raised a concern regarding the wording in the second sentence of this paragraph which implied that member countries should adapt their control measures to the requirements of the country of retail sale and wondered if it were appropriate to have this text in the Codex document, and proposed to delete the text. It was clarified that this sentence described the reality in many countries in which their legislation either allowed or disallowed the use of certain inactivation technologies for pathogens including pathogenic *V. parahaemolyticus* and that the text was commonly used in other Codex documents. As there

was no agreement on this text, the Committee agreed that this text was bracketed for further consideration. It was also agreed to delete "gamma irradiation" as an example because this technology was not so commonly used.

Paragraph 83

129. Some delegations proposed to indicate the temperature of clean water and the ratio of crushed ice to water that were used to store seafood intended for raw consumption and other ready-to-eat food as the storage stage was crucial to control the level of *Vibrio* spp. or prevention of pathogen contamination. Noting that Section 9 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) contained detail of storage requirements that were also applicable to control of *Vibrio* spp in seafood, the Committee agreed to add a reference to this code. In addition, a text was added to stress the importance of the lowest temperature applied to the storage of live fish and shellfish. It was noted that clean water used at this storage stage sometimes include artificial seawaters or disinfected seawater that were treated not to constitute health hazards.

Paragraph 87

130. It was agreed to replace the term "cooked" with "ready-to-eat" so as to provide clear definition of the foods for which cross-contaminations was crucial. It was also agreed to delete the second sentence as this only provided factual information but not action to be taken.

Paragraph 92

131. The second sentence was amended to highlight that the use of coastal water should be avoided in the post harvest stage.

Paragraph 105

132. Recognizing the importance and effect of labelling as a risk management measure to protect the health of consumers associated with consumption of live/ raw seafood or treated products, it was agreed to improve the text of this paragraph to highlight that labelling of unpackaged live or raw seafood should be given consideration and that such labelling should alert at risk-consumers to avoid or cook raw seafood.

Paragraph 107

133. The Committee agreed to insert in the Consumer Education section a reference to "Five Keys to Safer Food (WHO)"[15] which could be applicable to control food pathogen contaminations at all stages of food chain in different countries and regions, as proposed by the observer from ICD. This would help address a number of issues on food safety constraints faced, in particular in developing countries, such as the use of clean water, prevention of potential contaminations by infected food handlers, control of food safety at street vendors, etc.

Paragraph 110

134. A text was proposed to allow special consideration be given to developing countries, taking into account the diverse nature of their fishing practices. Due to time constraints, the Committee did not discuss this text. The proposed text was bracketed for further consideration.

Paragraph 111

135. The term "primary production" was added to cover all personnel involved in the entire seafood chain.

**Status of the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* Species in Seafood**

136. Recognizing that substantial progress had been made to the text, it was noted that some important issues would need further consideration, therefore the Committee 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 the next session of the Committee (see Appendix IV). The Committee also agreed to establish a physical working group, led by Japan, that would meet immediately prior to the next session of the Committee to review comments submitted and prepare proposals for consideration by the next session.

[15] www.who.int/foodsafety/consumer/5keys/en/index.html

## OTHER BUSINESS AND FUTURE WORK: (a) DISCUSSION ON THE REPORT OF THE AD HOC WORKING GROUP FOR ESTABLISHMENT OF CCFH WORK PRIORITIES (Agenda Item 9)[16]

137. The Delegation of France, who chaired the *ad hoc* working group for establishment of CCFH work priorities, held immediately before the session introduced this item and provided the session with an overview of discussions and outcome of the working group as described in CRD 1.

### Viruses in food

138. Based on the recommendations of the working group the Committee agreed to start new work on viruses in food. The Committee agreed to ask the 32nd Session of the Commission to approve new work on the Code of Hygienic Practice for the Control of Viruses in Food. The project document is attached to the report as Appendix V.

139. To the question on whether it was possible to include the avian influenza virus in the scope of the document, it was clarified that following advice provided by the FAO/WHO Expert Meeting on Viruses in Foods there was currently no conclusive evidence of transmission of avian influenza virus through foods, therefore inclusion of this virus was premature at this stage.

140. The project document (Appendix V) will be submitted for approval as new work by the 62nd Session of the Executive Committee and the 32nd Session of the Commission.

141. The Committee agreed to establish a physical working group led by The Netherlands, open to all interested parties, working in English only, to meet in March 2009 to develop the Code of Hygienic Practice for Control of Viruses in Food for circulation at Step 3 for comments and consideration by the next session of the Committee. The committee requested that the working group should consider the most appropriate title and presentation of this work.

### Natural Mineral Waters

142. In response to the request of the 31st Session of the Commission to consider giving a higher priority to the revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985), the Committee agreed to establish an electronic working group led by Switzerland, open to all interested parties and working in English only, to consider this matter in order to make a more informed decision on this matter at the next session. The terms of reference of this electronic working group are as follows:

143. The Committee agreed that the electronic working group should:

- review the need for the revision of the *Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters* (CAC/RCP 33-1985):
    - In order to take into account the latest developments in food safety and food hygiene, such as HACCP principles, adopted since the Code's adoption in 1985;
    - To improve guidance provided to Codex members and bring its provisions in line with the microbiological requirements, which are obsolete, with the provisions in Section (Hygiene) of the *Codex Standard for Natural Mineral Waters* (CODEX STAN 108-1981). Work should be limited to the Code itself and should not include a revision of provisions in the *Codex Standard for Natural Mineral Waters*.
- prepare a discussion paper including, as appropriate, a draft project document, to be circulated for comments prior to the next session of the Committee and to be considered by the Committee in compliance with the current prioritization process.

[16] CX/FH 08/40/9; CRD 1 (Report of the CCFH working group for the establishment of CCFH work priorities), CRD 4 (proposal by United Kingdom), CRD 7 (comments from India); CRD 8 (comments from Thailand), CRD 18 (comments from the European Community).

**Possible Code of Hygienic Practice for Cocoa and Chocolate Production and Processing**

144. The Committee noted the widespread interest expressed during the working group to the suggestion by the United Kingdom to consider new work on a Code of Hygienic Practice for Cocoa and Chocolate Production and Processing and agreed that in order to allow an assessment on whether such a code was necessary, to issue a circular letter to collect comments and information on the following:

- Is the nature and relationship of chocolate and cocoa production and processing such as to justify a specific Code of Practice in this area, i.e. the General Principles of Food Hygiene and its annexes would be considered to be insufficient to meet Codex objectives;
- What products, processes and stages in the food chain would be the main areas to focus on?
- What issues associated with those points in the food chain would be the most important to address through any such Code?
- Information/data on human disease and contamination incidents with chocolate and chocolate products that would be relevant to a specific Code of Hygienic Practice in this area.

145. It was agreed that the United Kingdom would consider the information provided in response to the aforementioned Circular Letter and prepare a discussion paper on this matter for consideration by the next session of the Committee.

**Annex on Control Measures for *V. parahaemolyticus* and *V. vulnificus* in Molluscan Shellfish**

146. The Committee agreed with the proposal to develop an annex on control measures for *V. parahaemolyticus* and *V. vulnificus* in molluscan shellfish to the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* species in Seafood as discussed under Agenda Item 8. The Committee agreed to reconvene the physical working group led by Japan, open to all interested parties and working in English only to develop this Annex for circulation at Step 3 for comments and consideration by the next session of the Committee. The physical working group would meet in Kyoto, Japan most likely in May/June 2009.

**Other matters**

147. The Committee noted the observation by the observer from ICMSF, supported by the United States of America that consideration could be given to whether it was necessary to update the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) which was adopted more than 12 years ago in view of developments since then, e.g. the development of *Principles and Guidelines for the Conduct of Microbiological Risk Management* and its annex on *Guidance on Microbiological Risk Management Metrics* (CAC/GL 63-2007). It was noted that any other proposals for new work should be submitted in response to the usual circular letter calling for proposals for new work for consideration by the next meeting of the *ad hoc* working group for the establishment of CCFH work priorities.

148. The Delegation of Cameroon, while recognizing the fact that the Committee was having a good working example in decentralizing its session, appealed to chairs of other committees and working groups to associate with further developing countries in co-hoisting as a way of capacity building.

149. The Committee thanked the Delegation of France for their excellent work in chairing the *ad hoc* Working Group and accepted the offer of the Delegation of Guatemala to chair the next *ad hoc* working group for the establishment of CCFH work priorities which will meet the day before the next session of the Committee.

**DATE AND PLACE OF THE NEXT SESSION (Agenda Item 10)**

150. The Committee was informed that the 41st Session of the CCFH was scheduled from 16 to 20 November 2009 and that a tentative proposal had been received to hold this Session in Uganda, however 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 09/32/13 |
|---|---|---|---|
| Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods | 5/8 | Governments, 32nd CAC | para. 70 and Appendix II |
| Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) | 5/8 | Governments, 32nd CAC | paras 45 - 47 and Appendix III |
| Proposed Draft Guideline for the Control of *Campylobacter* and. *Salmonella* spp in Chicken Meat | 2/3 | WG led by New Zealand and Sweden, Governments, JEMRA, 41st CCFH | para. 92 |
| Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruit and Vegetables | 2/3 | WG led by the USA, governments, 41st CCFH | para. 103 |
| Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood | 3 | Governments, 41st CCFH | para. 136 and Appendix IV |
| Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shelfish to the Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood | 2/3 | PWG led by Japan, governments, 41st CCFH | para. 146 |
| Risk Analysis Policy of the CCFH | Proce-dure | WG led by India, governments, 41st CCFH | para. 15 |
| **Discussion papers** | | | |
| Possible Revision of the Recommended International Code of Hygienic Practice for Collecting, Processing and Marketing of Natural Mineral Waters (CAC/RCP 33-1985) | - | EWG led by Switzerland, 41st CCFH | paras 142-143 |
| Possible Elaboration of the Code of Hygienic Practice for Cocoa and Chocolate Production and Processing | - | United Kingdom | paras 144-145 |
| **New Work** | | | |
| Proposed Draft Code of Hygienic Practice for Control of Viruses in Food | 1/2/3 | 32nd CAC, WG led by the Netherlands, governments, 41st CCFH | paras 138-141, Appendix V |

**APPENDIX I**

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**APPENDIX II**

**PROPOSED DRAFTANNEX II: MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS**

**(At Step 5/8 of the Procedure)**

(ANNEX II OF 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))

## 1. INTRODUCTION

The microbiological criteria presented in this Annex are intended as advice to governments within a framework for control of *L. monocytogenes* in ready-to-eat foods with a view towards protecting the health of consumers and ensuring fair practices in food trade. They also provide information that may be of interest to industry.

This Annex references and takes into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997) and uses definitions, e.g. for microbiological criterion, as included in these principles. The provisions of this Annex should be used in conjunction with *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

The risk assessments referenced in the introduction to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Food* (CAC/GL 61-2007) have indicated that food can be categorized according to the likelihood of *Listeria monocytogenes* being present and its ability to grow in the food. Available risk assessments have been taken into account in the development of the microbiological criteria in this Annex. In addition, factors that might impact upon the ability of governments to implement these microbiological criteria such as methodological limitations, costs associated with different types of quantitative testing, and statistics-based sampling needs were taken into account.

## 2. SCOPE

These microbiological criteria apply to specific categories of ready-to-eat foods, as described herein. The competent authority should consider the intended use and how specific ready-to-eat foods are likely to be handled during marketing, catering, or by consumers to determine the appropriateness of applying the microbiological criteria. Governments may apply these criteria, where appropriate, to assess the acceptability of ready-to-eat foods in international trade for imported products, at end of manufacture (finished product) for domestic products, and at point of sale for at least the expected shelf life[1] under reasonably foreseeable conditions of distribution, storage and use.

The microbiological criteria may be used as the basis for the development of additional criteria (e.g. process criteria, product criteria) within a food safety control system[2] to ensure compliance with these guidelines.

Different criteria or other limits may be applied when the competent authority determines that the use of such an approach provides an acceptable level of public health or when the competent authority determines a more stringent criterion is necessary to protect public health.

[1] See definition in the Code of Hygienic Practice For Milk and Milk Products (CAC/RCP 57–2004).
[2] See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

## 3. USE OF MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

There are various applications for microbiological criteria. As described, microbiological testing by lot can be used as a direct control measure, i.e., sorting of acceptable and unacceptable lots[3]. In this instance, microbiological criteria are implemented for those products and/or points of the food chain when other more effective tools are not available and where the microbiological criteria would be expected to improve the degree of protection offered to the consumer.

A microbiological criterion defines the acceptability of a product or food lot based on the absence or presence or number of microorganisms in the product. Testing for compliance with a microbiological criterion may be conducted on a lot by lot basis when there is little information about the conditions under which the product has been produced. Where there is information about the conditions of production, testing of lots for verification purposes may be conducted less frequently.

In addition, the application of the Hazard Analysis and Critical Control Point (HACCP) System describes how microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system[4]. Typically, such applications involve testing on less than a lot by lot basis and may be formalized into a system of process control verification testing (see Annex III).

Where possible and practicable, the risk-based approach to development of microbiological criteria as described in the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63-2007) can be used to assure or contribute to the assurance, that a food control system will achieve the required level of consumer protection.

The competent authority should use a risk-based approach to sampling for *L. monocytogenes* such as that found in the Codex General Guidelines on Sampling (CAC/GL 50 – 2004). It may consider modifying the frequency of testing for process control verification based on additional consideration of the likelihood of contamination, characteristics of the food, product history, conditions of production and other relevant information. For example, testing against microbiological criteria may have limited utility immediately following certain processing steps or if the level of *L. monocytogenes* in a ready-to-eat food is consistently well below the limit of detection taking into account practical limits for sample sizes.

In particular, testing against microbiological criteria for *L. monocytogenes* may not be useful for:

(a) products that receive a listericidal treatment after being sealed in final packaging that ensures prevention of recontamination until opened by the consumer or otherwise compromised,

(b) foods that are aseptically processed and packaged[5] , and

(c) products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain > 5 % ethanol)

Competent authorities may define other categories of products for which testing against microbiological criteria are not useful.

Different types of food present different risks from *L. monocytogenes*, hence different microbiological criteria could apply for the following categories of foods:

(a) ready-to-eat foods in which growth of *L. monocytogenes* will not occur, and

(b) ready-to-eat foods in which growth of *L. monocytogenes* can occur.

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[3] See: Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).
[4] See: Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).
[5] See: Code of Hygienic Practice For Aseptically Processed And Packaged Low-Acid Foods (CAC/RCP 40-1993).

### 3.1 Ready-To-Eat foods in which growth of *L. monocytogenes* will not occur

Ready-to-eat foods in which growth of *L. monocytogenes* will not occur would be determined based on scientific justification[6], including the inherent variability of factors controlling *L. monocytogenes* in the product. Factors such as pH, $a_w$, are useful in preventing growth. For example, *L. monocytogenes* growth can be controlled in foods that have

- a pH below 4.4,
- an $a_w < 0.92$,
- a combination of factors (pH, $a_w$ ,), e.g. the combination of pH < 5.0 with $a_w < 0.94$,

and by freezing (during that period when the product remains frozen).

In addition, inhibitors can control the growth of *L. monocytogenes* and synergy may be obtained with other extrinsic and intrinsic factors that would result in no growth.

Demonstration that *L. monocytogenes* will not grow in a ready-to-eat food can be based upon, for example, food characteristics, the study of naturally contaminated food, challenge tests, predictive modelling, information from the scientific literature and risk assessments, historic records or combinations of these. Such studies would generally be conducted by food business operators (or by the appropriate product board, sector organizations or contract laboratories) and must be appropriately designed to validate that *L. monocytogenes* will not grow in a food [7].

The demonstration that *L. monocytogenes* will not grow in a ready-to-eat food should take into account the measurement error of the quantification method. Therefore, for example, for practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log CFU/g[8] for at least the expected shelf life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use, including a safety margin.

For foods intended to be refrigerated, studies to assess whether or not growth of *L. monocytogenes* will occur should be conducted under reasonably foreseeable conditions of distribution, storage and use.

National governments should provide guidance on the specific protocols that should be employed to validate the studies demonstrating that growth of *L. monocytogenes* will not occur in a food during the expected shelf life.

If information is lacking to demonstrate that *L. monocytogenes* will not grow in a ready-to-eat food during its expected shelf life, the food should be treated as a ready-to-eat food in which growth of *L. monocytogenes* can occur.

### 3.2 Ready-to-eat foods in which growth of *L. monocytogenes* can occur

A ready-to-eat food in which there is greater than an average of 0.5 log CFU/g[8] increase in *L. monocytogenes* levels for at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use is considered a food in which growth of *L. monocytogenes* can occur.

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[6] References that have been addressed for identifying properties of ready-to-eat foods which will categorize them as foods in which growth of *L. monocytogenes* will not occur, or as foods in which growth of the pathogen can occur, include *Microorganisms in Foods 5 – Characteristics of Microbial Pathogens* (ICMSF, 1996) and *Microbiological Risk Assessment Series 4 and 5: Risk assessment of Listeria monocytogenes in ready to eat foods: Interpretative Summary and Technical Report* (FAO/WHO, 2004).

[7] See: Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

[8] 0.5 log is two times the estimated standard deviation (i.e. 0.25 log) associated the experimental enumeration viable counting/plate counts.

## 4. MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

Microbiological criteria for *L. monocytogenes* in ready-to-eat foods are described.

Another procedure for establishing microbiological criteria for *L. monocytogenes* other than the criteria at specified points in the food chain that are described below, would be through the application of risk-based metrics (e.g., Food Safety Objective (FSO), Performance Objective (PO)) according to the general principles established in the *Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

### 4.1 Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

The criterion in Table 1 is intended for foods in which *L. monocytogenes* growth will not occur under the conditions of storage and use that have been established for the product (see Section 3.1).

This criterion is based on the product being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control and validation that the product meets the requirements of a food in which growth of *L. monocytogenes* will not occur (see Section 3.1).

If the factors that prevent growth cannot be demonstrated, the product should be evaluated based on criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur (see Section 4.2).

Another approach can also be used (see Section 4.3).

**Table 1:**

**Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur**

| Point of application | Microorganism | n | c | m | Class Plan |
|---|---|---|---|---|---|
| Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale | *Listeria monocytogenes* | 5 [a] | 0 | 100 cfu/g [b] | 2 [c] |

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan;. m=a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 93.3 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected based on any of the five samples exceeding 100 cfu/g *L. monocytogenes.* Such a lot may consist of 55% of the samples being below 100 cfu/g and up to 45% of the samples being above 100 cfu/g, whereas 0.002% of all the samples from this lot could be above 1000 cfu/g. The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

**4.2 Microbiological criteria for ready-to-eat foods in which growth of *L.monocytogenes* can occur**

The criterion in Table 2 is intended for foods in which *L. monocytogenes* growth can occur under the conditions of storage and use that have been established for the product (see Section 3.2).

This criterion is based on the product being produced under application of general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods with appropriate evaluation of the production environment and process control (see Annex III).

The purpose of this criterion is to provide a specified degree of confidence that *L. monocytogenes* will not be present in foods at levels that represent a risk to consumers.

Another approach can also be used (see Section 4.3).

**Table 2:**

**Microbiological criteria for ready-to-eat foods in which growth of *L.monocytogenes* can occur**

| Point of application | Microorganism | n | c | m | Class Plan |
|---|---|---|---|---|---|
| Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale | *Listeria monocytogenes* | 5 [a] | 0 | Absence in 25 g (< 0.04 cfu/g) [b] | 2 [c] |

[a] National governments should provide or support the provision of guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] Assuming a log normal distribution, this sampling plan would provide 95% confidence that a lot of food containing a geometric mean concentration of 0.023 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes.* Such a lot may consist of 55% of the 25g samples being negative and up to 45% of the 25 g samples being positive. 0.5 % of this lot could harbour concentrations above 0.1 cfu/g.

The typical actions to be taken where there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption, (2) recall the product if it has been released for human consumption, and/or (3) determine and correct the root cause of the failure.

**4.3 Alternative approach**

Further to the approaches described in sections 4.1 and 4.2 competent authorities may choose to establish and implement other validated limits for the *L. monocytogenes* concentration at the point of consumption or at other points that provide an acceptable level of consumer protection for foods in which *L. monocytogenes* will not grow as well as foods in which *L. monocytogenes* growth can occur.

Due to the large diversity among ready-to-eat food products in which growth of *L. monocytogenes* can occur, this approach would primarily be applied for specific categories or subcategories of ready-to-eat foods being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods and that have a limited potential of growth over a specified shelf life.

In establishing such limits for *L. monocytogenes*, the competent authority needs to clearly articulate the types of information required of food business operators to ensure that the hazard is controlled and to verify that

these limits are achieved in practice. Information needed by competent authorities should be obtained through validation studies or other sources, and may include

- specification for physicochemical characteristics of the products, such as pH, $a_w$, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf life[9] including a safety margin, and

- consultations of available scientific literature and research data regarding the growth and survival characteristics of *L. monocytogenes*.

When appropriate on the basis of the above mentioned studies, additional studies should be conducted, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for *L. monocytogenes* in the product,

- challenge tests and durability studies to evaluate the growth or survival of *L. monocytogenes* that may be present in the product during the shelf life under reasonably foreseeable conditions of distribution, storage and use including seasonal and regional variations.

[9] See footnote 2 : Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57–2004).

# ANNEX III: RECOMMENDATIONS FOR THE USE OF MICROBIOLOGICAL TESTING FOR ENVIRONMENTAL MONITORING AND PROCESS CONTROL VERIFICATION BY COMPETENT AUTHORITIES AS A MEANS OF VERIFYING THE EFFECTIVENESS OF HACCP AND PREREQUISITE PROGRAMS FOR CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

## Introduction

These recommendations are for use by competent authorities if they intend to include environmental monitoring and/or process control testing as part of their regulatory activities. It is also anticipated that the annex will provide guidance that the competent authority can provide to industry. The recommendations provide an elaboration of the concepts in Sections 5 and 6 of the main text of this Code.

Guidance within Codex regarding microbiological testing is often restricted to the testing of end products using traditional lot-by-lot testing. However, the guidance provided in the main text of this Code emphasizes the criticality of enhanced control of sanitation, including the appropriate use of environmental monitoring. This is further elaborated in Annex I: *Recommendations for an Environmental Monitoring Program for Listeria monocytogenes in Processing Areas,* which provides recommendations to industry on implementation of environmental monitoring programs. The *Recommended International Code of Practice General Principles of Food Hygiene* (CAC/RCP 1-1969) emphasizes the need to apply control measures in a systematic manner using HACCP or other food safety control systems, including the testing of in-line or finished product samples for process control verification. This annex provides general recommendations on how competent authorities can use microbiological testing to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

The two types of microbiological testing programs described below can be an important part of the ability of competent authorities to verify the effectiveness of *L. monocytogenes* control programs over time (see Section 5.9). In developing these recommendations, no attempt is made to establish specific decision criteria for the two types of microbiological testing or the specific actions that should be taken to re-establish control. Establishment of such specific criteria and actions is more appropriately the responsibility of competent authorities due to the diversity in products and manufacturing technologies.

## a) Environmental Monitoring

In certain instances, competent authorities may incorporate the testing of the environment (food contact and/or non-food contact surfaces) for *L. monocytogenes* (or an appropriate surrogate microorganism (e.g., *Listeria* spp.)), as part of their regulatory requirements or activities. This can include sampling by a competent authority as part of its inspection activities or sampling performed by the individual food business operator that the competent authority can review as part of its verification of the business operator's controls (see Section 5.9). The aim of conducting and/or reviewing environmental testing programs by a competent authority is to verify, for example, that a manufacturer has successfully identified and controlled niches and harbourage sites for *L. monocytogenes* in the food plant and to verify that sanitation programs have been appropriately designed and implemented to control contamination by *L. monocytogenes*.

In developing environmental testing programs and the decision criteria for actions to be taken based on the results obtained, competent authorities should clearly distinguish between sampling of food contact surfaces and non-food contact surfaces. For example, sampling locations for competent authorities may be similar to those used by food business operators (See Annex I). In evaluating facilities that produce multiple products where at least one can support growth of *L. monocytogenes*, competent authorities should consider the importance of environmental sampling as a means of verifying that there is no cross contamination between the products (see Section 5.2.4). In the design of an environmental verification program, the competent authority should articulate the testing and sampling techniques that would be employed, including size, method and frequency of sampling, analytical method to be employed, locations where samples should be

taken, decision criteria, and actions to be taken if a decision criterion is exceeded (similar to recommendations in Annex I).

The competent authority should establish decision criteria that include specific conditions (e.g., specific number of positive samples) that will initiate follow-up actions (including additional testing) when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp. The competent authority should also establish actions that the food business operator should anticipate if the criteria are exceeded. Detection of positive environmental samples by the competent authority exceeding the decision criteria should lead to an investigation by the food business operator and/or the competent authority to identify the source of contamination and action that should be taken by the food business operator to correct the problem. In reporting results of their analyses to food business operators, competent authorities should provide advice on the possible inferences the data provide in order to assist the food business operator in finding and correcting the source of contamination. For example, the competent authority could point out that the repetitive isolation of a specific subtype of *L. monocytogenes* is indicative of a harbourage site that current sanitation activities are insufficient to control.

Overall, sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated. Methods used should be appropriately validated for the recovery of *L. monocytogenes* from environmental samples.

**b) Process Control Verification**

Business operators ensure the effectiveness of HACCP and other programs for the control of *L. monocytogenes* in their operating facilities. Further, business operators validate the food safety control systems they have in place. Competent authorities verify that the controls are validated and being implemented as designed, through activities such as monitoring of records and activities of production personnel.

For a well-designed food safety control system, a competent authority may consider establishing microbiological process control testing and decision criteria for products to identify trends that can be corrected before decision criteria are exceeded. When undesirable trends occur or decision criteria are exceeded, the food business operator will investigate the food safety control system to determine the cause and take corrective action(s). The competent authority verifies that appropriate actions are taken when criteria are exceeded. For example, the decision criteria for process control testing could be the frequency of contamination that would be indicative of a process no longer in control and likely to produce ready-to-eat foods that do not meet the microbiological criteria established in Annex II.

In addition to verifying that the process controls within the food safety control system are validated and operating as designed, process control testing of finished product (sometimes referred to as cross-lot or between-lot testing) has been used by business operators and/or competent authorities to detect changing patterns of contamination, which allows distinction between occasional ‘in control’ positive samples and an emerging loss of control. Process control testing of finished product contributes to the assessment of the continuing performance of a food safety control system and helps to ensure that corrective actions are implemented before microbiological criteria are exceeded. The competent authority verifies that the food safety control system remains ‘in control’ or ensures that the food business operator has taken corrective actions to prevent loss of control, which could include immediate corrections or changes to the food safety control system itself. The presence of *L. monocytogenes* in finished product can also indicate the lack of control of *L. monocytogenes* in the processing environment.

In certain instances, competent authorities may find it useful to establish an industry-wide process control-based criterion for *L. monocytogenes* for the purpose of ensuring that specific ready-to-eat foods undergo a consistent approach for verification of HACCP or other food safety control systems. This can include sampling by competent authorities as part of their inspection activities or sampling performed by the business operator that the competent authority can review as part of its verification of the food business operator’s records.

As with other forms of verification via microbiological testing, the use of process control testing involves the establishment of decision criteria, specification of analytical methods, specification of a sampling plan, and actions to be taken in case of a loss of control. Details of process control testing principles and guidelines are beyond the scope of this annex, but are available through standard references.

**APPENDIX III**

## PROPOSED DRAFT ANNEX II - MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULAE AND FORMULAE FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN

**(At Step 5/8 of the Procedure)**

Microbiological criteria should be established in the context of available risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-97). Two sets of criteria are provided below, one for a pathogen and a second for process hygiene indicators.

Where a Competent Authority assesses that there is scientific evidence of a risk in relation to *E. sakazakii* (*Cronobacter* spp.) from consumption of follow-up formulae in the national population, under current manufacturing conditions and control measures, it may consider strengthening the combination of available control measures, including consideration of an appropriate microbiological criterion.

Criteria for pathogenic microorganisms

| **Microorganisms** | **n** | **c** | **m** | **Class Plan** |
|---|---|---|---|---|
| *Salmonella** | 60 | 0 | 0/25 g | 2 |

Where n = number of samples that must conform to the criterion: c = the maximum allowable number of defective sample units in a 2-class plan. m= a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots.

* The mean concentration detected is 1 cfu in 2034g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 577g ( (if the assumed standard deviation is 0.5 and probability of detection is 99%).[1]

This criterion is to be applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary package is opened.

The method to be employed for *Salmonella* should be the most recent edition of ISO 6579 or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

The criterion above is applied with the underlying assumption that the history of the lot is unknown, and the criterion is being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g., the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible. The typical action to be taken when there is a failure to meet the above criterion would be to (1) prevent the affected lot from being released for human consumption; (2) recall the product if it has been released for human consumption and (3) determine and correct the root cause of the failure.

Criteria for process hygiene

These criteria are to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of the verification.

[1] International Commission on Microbiological Specifications for Foods, 2002, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, Kluwer Academic/Plenum Publishers NY. ISBN 0-306-47262-7. Relating Microbiological Criteria to Food Safety Objectives and Performance Objectives by M. van Schothorst; M. H. Zwietering; Ross; R. L. Buchanan; M. B Cole & International Commission on Microbiological Specifications for Foods, J. Food Control.

The safe production of these products is dependent on maintaining a high level of hygienic control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these tests are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs.

| **Microorganisms** | **n** | **c** | **m** | **M** | **Class Plan** |
|---|---|---|---|---|---|
| Mesophilic Aerobic Bacteria* | 5 | 2 | 500/g | 5000/g | 3 |
| Enterobacteriaceae** | 10 | 2[2] | 0/10 g | Not Applicable | 2 |

Where n = number of samples that must conform to the criterion; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates acceptable lots from unacceptable lots , or in a 3-class plan, separates acceptable lots from marginally acceptable lots; M = a microbiological limit which, in a 3-class plan, separates marginally acceptable lots from unacceptable lots.

* The proposed criteria for mesophilic aerobic bacteria are reflective of Good Manufacturing Practices and do not include microorganisms that may be intentionally added such as probiotics. Mesophilic aerobic bacteria counts provide useful indications on the hygienic status of wet processing steps. Increases beyond the recommended limits are indicative of the build-up of bacteria in equipment such as evaporators or contamination due to leaks in plate-heat exchangers (refer to Annex III).

** The mean concentration detected is 1 cfu in 16g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 10g (if the assumed standard deviation is 0.5 and probability of detection is 99%).

The methods to be employed for Mesophilic Aerobic Bacteria and Enterobacteriaceae (EB) should be the most recent editions of ISO 4833 and ISO 21528-1/21528-2, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc. The criteria above are intended to assist in verifying a facility's microbiological hygiene programs. Such indicator tests are most effective when the stringency of the criteria allows deviations to be detected and corrective actions to be taken before limits are exceeded. The typical action to be taken when there is a failure to meet the above criteria would be to determine and correct the root cause of the failure and, as appropriate, review monitoring procedures,

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[2] This 2- class plan is used because a 3- class plan with equivalent performance would not be practical analytically, given the low levels of Enterobacteriaceae (EB) typically occurring when stringent hygiene conditions are maintained.

It may seem that peak contaminations in up to 2 samples are tolerated in this microbiological criterion (MC). However, it is assumed that the product is sufficiently homogeneous that high level contaminations will fail the MC. It is further assumed that, in practice, under sufficiently strict hygienic operation, the manufacturer will normally not find positives and that if, occasionally, positives are found the manufacturer will take appropriate actions.

Finding 1 or 2 positives should indicate to the manufacturer a trend toward potential loss of process control and appropriate actions would include further microbial evaluation of the implicated end product (i.e. re-evaluation of the EB content; when EB MC fails, evaluation of product safety using the proposed MC for *Salmonella* before its release as well as evaluation of the hygiene programme to confirm it is suitable to maintain ongoing hygiene control or to amend the programme such that is suitable to do so).

Finding 3 or more positives should signal to the manufacturer loss of process control and appropriate actions should be the evaluation of product safety using the proposed MC for *Salmonella* before release of the implicated product as well as evaluation of the hygiene programme to amend the programme such that it is suitable to maintain high hygiene control on an ongoing basis before production is resumed.

The rationale for using 2- class plans for hygiene indicators in particular situations is explained in Book 7 of the International Commission on Microbiological Specifications for Foods, 2002. *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management,* Kluwer Academic/Plenum, Publishers NY. ISBN 0-306-47262-7.

including environmental monitoring (Annex III), and review prerequisite programs in particular the hygienic conditions from the drying step up to the packaging step (Enterobacteriaceae) and the process conditions during wet processing (mesophilic aerobic bacteria). Continued failures should be accompanied by increased sampling of the product for *Salmonella* and potential re-validation of the control measures.

While these tests were originally developed for lot-by-lot applications where the history of the lot was unknown, their usefulness is much greater when there is a full understanding of the product and the processes used in its manufacture, in which case this can provide a means of verifying correct implementation of specific hygiene measures. Such indicator tests are particularly amenable to alternative process control sampling plans and statistics.

**Labelling and Education**

Follow-up formulae should only be used for the target population for which they are intended. There should be increased emphasis on the education of caregivers and healthcare professionals as to the appropriate uses of follow-up formulae, in addition to the training and education on the safe preparation, handling and storage (as recommended in Section IX of this Code of Practice ) and effective labelling[3] with respect to the intended consumer.

[3] Guideline for the Validation of Food Safety Control Measures (CAC/GL 69-2008).

**APPENDIX IV**

**[PROPOSED DRAFT GUIDELINES ON THE CONTROL OF PATHOGENIC *VIBRIO* SPP. IN SEAFOOD]**

**[PROPOSED DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF PATHOGENIC *VIBRIO* SPP. IN SEAFOOD]**

**(At Step 3 of the Procedure)**

## INTRODUCTION

1. During the last several 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*, choleragenic *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 seldom associated with high-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. Proper cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. Hygienic approaches 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 the 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 at 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 feces 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 treated[2] 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 feces 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 choleragenic *V.cholerae* into foods. The concentration of free-living choleragenic *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 choleragenic strains of *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 choleragenic strains of *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.

15. Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including molluscan shellfish, 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 choleragenic *V.*

[2] "treated" means any vibriocidal treatment (e.g. heat treatment, high pressure.)

*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 molluscan shellfish. This is a serious, often fatal, disease with the highest fatality rate 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 was isolated from oysters, other molluscan shellfish, 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 choleragenic *Vibrio cholerae* O1 and O139 in warm water shrimp in international trade have been published (2005)[3,4]. Additional risk assessments on *Vibrio parahaemolyticus* in raw oysters, in raw and undercooked finfish and in *Anadera granosa* (bloody clams) have been completed and are in press [5,6,7]. These risk assessments constitute the basis of this Code.

**SECTION I – OBJECTIVES**

21. This Code 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 this Code 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. This Code 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. This Code covers seafoodthat is marketed in a live, raw, chilled/frozen, partially treated, , or thoroughly treated state, which could include ready-to-eat seafood. . It is applicable to the whole food chain from primary production to final consumption.

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[3] FAO and WHO, 2005. Risk assessment of *Vibrio Vulnificus* in raw oysters. Microbiological Risk Assessment Series, No.8.

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

[5] FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in raw oysters. Microbiological Risk Assessment Series, No.XX (In press).

[6] FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in raw and undercooked finfish. Microbiological Risk Assessment Series, No.XX (In press).

[7] FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in *Anadara granosa* (bloody clams). 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 this Code are pathogenic *V. parahaemolyticus, V. vulnificus* and choleragenic *V. cholerae.* The control measures described in this Code may be applicable to other pathogenic *Vibrio* spp.

**2.2 USE OF THE DOCUMENT**

24. This Code 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) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The application of this Code 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 DEFINITIONS**

25. For the purpose of this Code, 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 reduce but not eliminate *Vibrio* spp. in seafood.

**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 molluscan shellfish 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. Monitoring of molluscan shellfish at harvest for the levels of pathogenic *Vibrio* spp. should be conducted to determine the regional and seasonal risk of these microorganisms for the application of appropriate controls.

30. When testing/monitoring criteria, established by a risk assessment, are exceeded, closing the harvesting area or issuing a public warning, restricting the time to refrigeration, diverting product into cooking or post-harvest processing should be considered.

31. Where predictive models are used to indicate the concentration of pathogenic *Vibrio* spp. in seawater and/or molluscan shellfish based on water temperatures and/or salinity, the predictive ability can be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.

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

**3.2 HYGIENIC PRODUCTION OF SEAFOOD SOURCES**

33. 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**

34. For the storage and handling of seafood aboard fishing vessels, the use of seawater taken near the seashore or from the region near the mouth of drain or river contaminated with sewage should be avoided. In

particular, clean water should be used for seafood intended to be eaten raw, and for preparing ice for such use. 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.

35. 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.

36. For the storage of live seafood products, clean water should be used to minimise initial cross-contamination from the water.

37. When the product is required to be washed whether onboard the boat or at port, clean water should be used.

38. 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 selling. 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 with faecal material.

### 3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

39. Refer to Section 3.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

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

## SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

### Objectives

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

### 4.1 LOCATION

42. 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

43. 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

44. 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

45. Refer to Section 4.2.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

46. The following practices should be followed, if possible, for live or raw ready-to-eat and cooked ready-to-eat seafood.

47. Whenever feasible, premises and rooms should be designed to separate processing and 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.

48. 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**

49. 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**

50. 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**

51. 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**

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

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

**4.3.3 Containers for waste and inedible substances**

54. 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**

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

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

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

**4.4.1 Water supply**

58. An adequate supply of clean 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**

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

60. 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.

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

**4.4.3 Cleaning**

62. 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**

63. 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**

64. 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).

65. The *Code of Practice for Fish and Fishery Products* indicates maintaining the product at temperature as close as possible to 0ºC. For pathogenic *Vibrio* spp., a temperature of 10ºC or lower is adequate. 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 10ºC or lower[8].

**4.4.6 Air quality and ventilation**

66. 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**

67. 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**

68. 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**

69. This section should be applicable from harvest through to retails/food service/catering businesses. Control of pathogenic *Vibrio* spp. 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 pathogenic *Vibrio* spp. in seafood.

70. The factors and attributes described below are components of Good Hygienic Practice programs that will typically require increased attention to control pathogenic *Vibrio* spp. and may be used as critical control points in HACCP programs where pathogenic *Vibrio* spp. are identified as a hazard of concern.

**5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS**

**5.2.1 Time and temperature control**

71. 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**

72. Clean water at low temperature should be used for washing and processing seafood at processing establishments.

73. The eviscerated cavity of fish intended for raw consumption (*e.g.* preparation of *sashimi*) should be thoroughly washed with clean, potable running water.

**5.2.2.2 Cooking**

74. Time and temperature should be determined for each cooking operation to ensure the inactivation

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[8] In this Code, 10ºC is used as the target temperature to prevent/minimize growth of *Vibrio* spp. However, pathogenic bacteria 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 as possible 0ºC, should be implemented. In the case of molluscan shellfish, a different temperature control specified in the Annex would be required.

of pathogenic *Vibrio* spp.

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

**5.2.2.3 Food processing practices**

76. Food processing practices (*e.g.* acidification to pH below 4.8, salting to a sodium chloride concentration of more than 8-10% for *V. parahaemolyticus*, food preservatives (as established by the CCFA), water activity less than 0.94) can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.

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

78. For pathogenic *V. parahaemolyticus*, several possible inactivation technologies have been reported such as high pressure and mild heating. [The use of these technologies should be done in accordance with the legislation of the country of retail sale.]

79. Any practice selected to reduce/inactivate pathogenic *Vibrio* spp. in seafood or control/minimize their growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective.

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

**5.2.2.4 Storage**

81. Seafood intended for raw consumption, as well as other ready-to-eat seafood, should be stored in shallow layers and surrounded by sufficient finely crushed ice or with a mixture of ice and clean water before preparation. 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).

82. Seafood should be stored so as to avoid over-stacking or over-filling of containers so that cold air can adequately circulate.

**5.2.3 Microbiological and other specifications**

83. 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**

84. 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).

85. For all seafood, particularly those that are ready-to-eat, microbiological cross-contamination should be avoided in any foods with respect to pathogenic *Vibrio* spp., especially *V. parahaemolyticus.*

**5.2.5 Physical and chemical contamination**

86. 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**

87. 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**

88. 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**

89. 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.

90. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, the use of these waters should be avoided in the post-harvest stage.

**5.5.2 As an ingredient**

91. 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**

92. 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**

93. 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**

94. 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**

95. 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**

96. 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**

97. 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**

98. 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).

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

**SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS**

**9.1 LOT IDENTIFICATION**

100. 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**

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

**9.3 LABELLING**

102. 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.

103. 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, labelling should alert at-risk consumers to avoid or cook those products. Any treatment (*e.g.* heat treatment), that is applied to the product should be mentioned on the label (if present) if consumers would be misled by its omission.

**9.4 CONSUMER EDUCATION**

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

105. 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 other ready-to-eat foods, where appropriate.

- to help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafoods 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**

106. 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[9]. Subpopulations with increased susceptibility should follow the advice below:

- avoid the consumption of raw or partially treated seafood; and
- . heat seafood thoroughly before consumption.

**SECTION X – TRAINING**

**10.1 AWARENESS AND RESPONSIBILITIES**

107. 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).

108. [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 and consumers *etc.* for the control of pathogenic *Vibrio* spp. Special consideration shall be given to developing countries, taking into consideration their fishing

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

techniques, including small fisherfolks.]

**10.2 TRAINING PROGRAMMES**

109. 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,* choleragenic *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**

110. 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**

111. 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 V**

# PROJECT DOCUMENT FOR NEW WORK ON CODE OF HYGIENIC PRACTICE FOR CONTROL OF VIRUSES IN FOOD

## PURPOSE AND SCOPE OF THE NEW WORK

The purpose of the proposed new work is to provide guidance on the control of viruses in food. This guidance will be supplemental to the *Recommended International Code of Practice – General principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).

The scope of the new work will include the development of a general guidance document for the control of foodborne viruses with a series of annexes to address the specific virus-commodity combinations as prioritized by the FAO/WHO Expert Meeting on viruses in food. Based on the current knowledge, these include:

- Noroviruses (NoV) and hepatitis A virus (HAV) in fresh produce – transmission mainly by irrigation water and manure;
- NoV and HAV in molluscan shelfish– transmission by faecal contaminated water in growing areas;
- NoV and HAV in prepared ready-to-eat (RTE) foods - contamination by food handlers.

Depending on the emergence of other viruses or other transmissions routes having a serious public health impact the development of additional annexes may be considered in the future, subject to the approval by the Codex Alimentarius Commission.

## RELEVANCE AND TIMELINESS

Foodborne viral infections are increasingly recognized as causes of illness in humans. Reasons for this increase are most likely the improved diagnostic assays that have enhanced detection of some virus groups, and changes in food processing and consumption patterns that lead to worldwide availability of high-risk food. Implicated foods tend to be those that are minimally processed before consumption such as molluscan shelfish and fresh produce. These are typically contaminated with viruses in the primary production environment. In addition, many of the documented outbreaks of foodborne viral illness have been linked to contamination of prepared RTE food by an infected food handler. Control measures should be targeted at prevention of contamination (e.g. preventive measures at source or in food handling), rather than through food processes, as for the commodities of concern there is currently a lack of post harvest decontamination options. Intervention strategies should be focussed on the priority virus-commodity combinations. Where possible these combinations should be reviewed for specific regions.

While contaminated food has been clearly implicated in viral infections in humans, the proportion of infections that can be attributed to the consumption of contaminated food is not known.

## MAIN ASPECTS TO BE COVERED

The proposed new work will focus on hygienic practices and components of food safety systems that would be needed to control viruses in food.

Besides general guidelines for the control of foodborne viruses, specific guidance will be included concerning the control of NoV and HAV in fresh produce, molluscan shelfish and RTE foods.

## ASSESSMENT AGAINST THE CRITERIA FOR THE ESTABLISHMENT OF WORK PRIORITIES

***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: *This new work will contribute to the prevention of human foodborne viral infections at global scale by providing guidance to prevent these infections.*

***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 which will enable countries to develop their own risk management strategies for the control of viruses in food. This work will assist in providing an internationally harmonized approach for the control of viruses in food.*

*(b)* Scope of work and establishment of priorities between the various sections of the work: *The scope of the new work will include the development of a general guidance document for the control of foodborne viruses with a series of annexes to address specific virus- commodity combinations. These virus-commodity combinations include NoV and HAV in fresh produce, molluscan shelfish and RTE foods. Work on the general guidelines and on the three annexes will be done in parallel without a specific priority.*

*(c)* Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): *This new work does not duplicate work undertaken by other international organizations. It builds on recommendations expressed by the FAO/WHO Expert Meeting on viruses in food, the Consultation on Norovirus Prevention and Control by the European Centre for Disease Prevention and Control (ECDC), fact sheets made available by Centres for Disease Control and Prevention (CDC) and other relevant sources of information.*

*Criteria applicable to commodities*

(a) Volume of production and consumption in individual countries and volume of and pattern of trade between countries: *Fresh produce is a main food component in nearly all countries of the worlds. Fresh produce has a wide and complex distribution pattern being for the biggest part domestically, but also contributes significantly to the volume and value in international trade. Molluscan shelfish are popular as food in many countries, but mostly on a rather small scale. There is a substantial international trade in these products. Ready-to-Eat (RTE) foods are increasingly produced locally and regionally. A limited volume of these foods is involved in international trade. The persistence of some of the foodborne viruses in the environment and in foods results in survival during international trade. This means that the risk associated with foodborne viruses may lead to international outbreaks of illness and/or high economic losses. Trade in commodities known to be linked to virus hazards may be affected whenever there are reported cases, even from other sources.*

(b) Diversifications of national legislations and apparent resultant or potential impediments to international trade: *This new work will provide guidance which will enable countries to develop their own risk management strategies for the control of foodborne viruses in general and for specific commodities in particular. This may assist in providing an internationally harmonized approach for the control of viruses in food and specific commodities.*

(c) International or regional market potential: *An increase in the international trade in fresh produce, molluscan shelfishand RTE foods in the near future can be expected.*

(d) Amenability of the commodity to standardisation: *Fresh produce, molluscan shelfish and RTE foods constitute a wide variety of different products that are not easy to standardize.*

*(e)* Coverage of the main consumer protection and trade issues by existing or proposed general standards: *Current food hygiene guidelines, most of which have been optimised for the prevention of bacterial infections, may be only partially effective against viruses.*

(f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed: *In the first instance separate guidelines will be established for the commodities fresh produce, molluscan shelfish and RTE foods.*

(g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies): *This new work does not duplicate work undertaken by other international organizations.*

**RELEVANCE TO CODEX STRATEGIC GOALS**

*Goal 1: Promoting Sound Regulatory Frameworks*

The results of this new work will contribute to the development of sound food control and regulatory infrastructures and consequently will promote the safety of foods, especially in relation to the risks of virus contamination.

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

Because of the lack of sufficient appropriate data a complete risk analysis of viruses in food is not possible at the moment. However, the new work will include the identification and analysis of hazards associated with agricultural, manufacturing and hygienic practices in the production of fresh produce, and RTE foods. This information will be valuable for future international risk assessments for viruses in foods.

*Goal 3: Promoting Cooperation between Codex and Relevant International Organizations*

This work is based on a close coordination between FAO, WHO and Codex. For the annex on molluscan shelfish close cooperation with CCFFP will be sought.

*Goal 4: Enhance Capacity to Respond Effectively and Expeditiously to New Issues, Concerns and Developments in the Food Sector*

The results of this work will enhance the capacity of Codex and will enable Codex to respond more effectively on new food safety concerns related to viruses in specific commodities or by specific transmission routes.

*Goal 5: Promoting Maximum and Effective Participation of Members*

The development of annexes on specific virus-commodity combinations will promote the participation of both developing and developed countries with specific interests.

**RELATION BETWEEN PROPOSAL AND OTHER EXISTING CODEX DOCUMENTS**

As the Terms of Reference of the CCFH include the drafting of basic provisions on food hygiene, problems related to foodborne viruses should be part of the work program of CCFH. The proposed work is related and will be additional to the Codex General Principles of Food Hygiene. The development of commodity-specific annexes needs coordination with existing Codex documents such as the Code of Hygienic Practice for Fresh Fruits and Vegetables and the Code of Practice for Fish and Fishery Products.

**REQUIREMENT FOR AND AVAILABILITY OF EXPERT ADVICE**

Substantial scientific advice from the FAO/WHO expert meeting on "Viruses in Food", which took place in May 2007 in the Netherlands, is available. Further expert advise may be necessary when specific questions to be identified during the process of developing the document.

**PROPOSED TIMELINE FOR COMPLETION OF THE NEW WORK**

A period of four-five years is proposed for the completion of the general guidelines and the three proposed annexes, according to the attached work plan.

**WORK TO BE LEAD BY**

The Netherlands

**INCLUSION OF A RISK PROFILE**

Developing a risk profile for the general guidelines is not appropriate, but individual risk profiles for the different virus-commodity combinations would be useful. A first risk profile has been prepared for NoV in molluscan shellfish (CX/FH/06/38/10, Attachment 6). The report of FAO/WHO Expert Meeting on Viruses in Food also contains many components of risk profiles for the priority virus-commodity combinations. Further developing of risk profiles will be part of the preparation of the annexes.

**Work plan for the development of guidelines to control viruses in food including specific annexes**

| Timetable | Meeting | Progress |
|---|---|---|
| December 2008 | 40th session CCFH | Agree on purpose and scope and request |

| | | |
|---|---|---|
| | | permission for new work |
| March 2009 | Intersession – Physical Working Group (Netherlands) | Development of proposed Draft Code and annexes. Preparation of a detailed work plan. Discussion on the need of subgroups for the annexes |
| July 2009 | 32nd CAC, | approval as new work |
| December 2009 | 41st session CCFH | Present proposed Draft Code and annexes. Agree on the main structure of the document at Step 3. |
| March 2010 | Intersession – Physical or Electronic Working Group | Work by the Working Group on proposed Draft Code and annexes. |
| December 2010 | 42nd session of CCFH | Consider proposed Draft Code and annexes at Step 3 and advance for adoption at Step 5. |
| December 2011 | 43rd session of CCFH | Physical Working Group held immediately before the 43th Session in order to help review comments and finalize the document for adoption at Step 8. |
| July 2012 | CAC | Adoption of Code of Hygienic Practice to control viruses in food, including three specific annexes. |