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 08/31/13

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION
Thirty first Session
Geneva, Switzerland, 30 June - 5 July 2008

REPORT OF THE THIRTY-NINTH SESSION OF THE

CODEX COMMITTEE ON FOOD HYGIENE

New Delhi, India, 30 October - 4 November 2007

NOTE: *This report includes Codex Circular Letter CL 2007/41-FH*

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CX 4/20.2 **CL 2007/41 - 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 Thirty-ninth Session of the Codex Committee on Food Hygiene (ALINORM 08/31/13)**

The report of the Thirty-ninth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Thirty first Session of the Codex Alimentarius Commission, (Geneva, Switzerland, 30 June – 5 July 2008).

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

1. Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at Step 5/8 (ALINORM 08/31/13 para. 62 and Appendix II)

2. Proposed Draft Guidelines for the Validation of Food Safety Control Measures at Step 5/8 (ALINORM 08/31/13 para. 84 and Appendix III)

3. Proposed Draft Annex II on the Guidance on Microbilogical Risk Management Metrics to the Principles and Guidelines for the Conduct of Microbilogical Risk Management at Step 5/8 (ALINORM 08/31/13 para. 146 and Appendix IV)

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 2008**.

B. REQUEST FOR INFORMATION

4. Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (ALINORM 08/31/13, paras 98 – 100 and 114)

In view of the re-scoping of the proposed draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat, the delegations of New Zealand and Sweden noted that the extension of the scope

required additional scientific information through a Circular Letter that would help the working group develop an approach for a new annex on other chicken meat to be presented to the next session of the CCFH.

The Committee agreed to seek the following additional information regarding chicken other than broilers:

- For the purpose of risk profiling on *Salmonella* and *Campylobacter,* relevant information requested should include but not be limited to: incidence rates in flocks and in human salmonellosis and campylobacteriosis attributable to consumption of contaminated chicken meat other than broiler meat, prevalence of the two pathogens in this meat including seasonal variations, the outcomes of risk assessments, the results from risk management activities, the effect on trade, etc.
- Codes of practice or other generic documents that include "specific" GAPs, GHP, HACCP-based controls for the two pathogens. This information will help the WG establish the generic production-to-consumption hazard pathway flow chart (breeding flocks to final consumption of chicken meat other than broiler meat) and identify any specific control measures that might be effective in different countries.
- Scientific information that quantifies likely levels of reduction of either of the pathogens as a consequence of specific interventions at any step in the older bird food chain, and any critical limits (HACCP) that may have been established in these terms at the national level. Examples of information of interest are quantitative and qualitative changes in incidence of the pathogens in older bird flocks and changes in the concentration of the pathogens in older birds and meat resulting from specific interventions at various steps in the older bird food-chain;
- Any kind of scientific information from government, industry or academia, be it pertaining to a single step in the food-chain or to several steps, will be appreciated.

Governments and interested international organizations are invited to provide information as listed above and should do so in writing, preferably by e-mail 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: judi.lee@nzfsa.govt.nz or fax: +64 4 894 2643 and Mr Lars Forshell, Assistant Chief Veterinary Officer, National Food Administration, Box 622, SE-751 26 Uppsala, Sweden: iapl@siv.se or fax: +46 18 10 58 48, 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 1 March 2008**

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SUMMARY AND CONCLUSIONS

The Thirty-ninth Session of the Codex Committee on Food Hygiene reached the following conclusions:

MATTERS FOR FINAL ADOPTION BY THE 31ST SESSION OF THE CODEX ALIMENTARIUS COMMISSION:

The Committee:

- agreed to forward the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children to the Commission for adoption at Step 5/8 (see ALINORM 08/31/13 para. 62 and Appendix II);

- agreed to forward the Proposed Draft Guideline for the Validation of Food Safety Control Measures to the Commission for adoption at Step 5/8 (see ALINORM 08/31/13 para. 84 and Appendix III);

-agreed to forward the Proposed Draft Annex II: Guidance on Microbiological Risk Management Metrics (Annex to the Principles and Guidelines for the Conduct of Microbiological Risk Management) to the Commission for adoption at Step 5/8 (see ALINORM 08/31/13 para. 146 and Appendix IV).

MATTERS FOR ACTION BY THE COMMISSION

The Committee:

-agreed to inform the Commission that, as requested by its 30th Session with regard to the restriction of the use of the lactoperoxidase system in milk and milk products in international trade, the Committee had considered further new information, but could not reach consensus on the lifting of the restriction. However, the Committee noted the value of the system, particularly in developing countries and in those situations where technical, geographical, economical and/or practical reasons do not allow the use of refrigeration. Therefore, the Committee requested that the Commission should consider clarifying the statement regarding the restriction of the use of the LPS to explain that the restriction on the use of the LPS for milk in international trade in no way precluded the use of the system by countries at the national level (ALINORM 08/31/13, paras 173 – 180).

NEW WORK

- agreed to take up new work on commodity specific annexes for the Code of Hygienic Practice for Fresh Fruit and Vegetables and on a Code of Hygienic Practice for *Vibrio* spp. in seafood (see ALINORM 08/31/13, para156 and Appendices V and VI).

DISCONTINUATION OF WORK

- noted that since the structure of the microbiological risk management metrics annex had substantially changed there was no longer any need to develop an annex on liquid eggs and therefore agreed to remove work on the Annex on Application of Food Safety Metrics in Risk Management Decision Making-Pasteurized Liquid Whole Eggs from its agenda (paras 147-148);

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

The Committee:

- noted that assignments given by the Commission in relation to the implementation of the Strategic Plan 2008 – 2013 such as the review and development of Codex standards and related texts for food safety was ongoing work; or the development of committee-specific decision-making and priority setting criteria had

already been successfully completed and was used in practice by the CCFH and that Activity 2.2 Review of risk analysis principles would need to be completed by 2013. (para. 8);

- agreed to begin work on a risk analysis policy for CCFH (paras 161-162);

- agreed to re-scope the Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat to include all chicken meat, not only meat from broilers, but to continue work on broiler chicken meat as a priority and to address meat from birds other than broilers in a separate annex and requested scientific information from members of the Committee to assist the development of this annex (para. 100);

- agreed to request FAO/WHO to collate and review available data and to convene an expert meeting to address a number of specific questions to enable a working group led by Canada to further develop Annex II to the Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. It was confirmed that FAO/WHO would prepare a Circular Letter requesting the data necessary to address the questions posed by the Committee (paras 149-154).

LIST OF ABBREVIATIONS

ALA	Asociación Latinoamericana de Avicultura
ALOP	Appropriate Level of Protection
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CRD	Conference Room Document
CCEXEC	Executive Committee of the Codex Alimentarius Commission
FAO	Food and Agriculture Organization of the United Nations
FSO	Food Safety Objective
GAP	Good Agricultural Practice
GHP	Good Hygienic Practice
GISFA	Global Initiative for Food-related Scientific Advice
GLP	Good Laboratory Practice
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
LPS	Lactoperoxidase System
MRA	Microbiological Risk Assessment
OIE	Office international des epizooties (World Organization for Animal Health)
PC	Performance Criterion
PO	Performance Objective
QMRA	Quantitative Microbiological Risk Assessment
RTE	Ready-to-Eat
SARS	Severe Acute Respiratory Syndrome Virus
SQA	Supplier Quality Assurance
WHA	World Health Assembly
WHO	World Health Organization

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-ninth Session in New Delhi, India, from 30 October to 4 November 2007, at the kind invitation of the Government of India. Dr Karen Hulebak, Chief Scientist, Food Safety and Inspection Service, United States Department of Agriculture, chaired the meeting. Mr Debasish Panda, Joint Secretary, Ministry of Health and Family Welfare, Government of India served as Co-Chairperson. The Session was attended by 192 delegates representing 74 member countries, one member organization and 13 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:

- Mrs Panabaka Lakshmi, Union Minister of State for Health and Family Welfare, Government of India;
- Mr Naresh Dayal, Secretary, Ministry of Health and Family Welfare, Government of India
- Mr Debasish Panda, Joint Secretary, Ministry of Health and Family Welfare, Government of India;
- Mr Steven White, Deputy Chief of Mission, United States Embassy;

3. Dr Karen Hulebak, while welcoming the delegates to the 39th Session of the CCFH, encouraged them to complete the work on the revision of the proposed draft guidelines for the validation of food hygiene control measures and the guidance on microbiological risk management metrics. She also drew the attention of the Committee to the need to advance the work on the code of hygienic practice for powdered formula for infants and young children, on microbiological criteria for *Listeria monocytogenes* in ready-to- eat foods and to agree on new work proposals to be undertaken by the Committee.

4. Following Rule II.5 of the Rules of Procedure of the Codex Alimentarius Commission the Committee was informed about CRD 3 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]

5. The Committee accepted the recommendations of the Chairperson and agreed to move from Item 2 to Item 9 the referral from the 30th Session of the Commission on the consideration of the removal of the restriction on the use of Lactoperoxidase System for milk and milk products entering international trade, and with this modification adopted the Provisional Agenda as Agenda for the session.

6. The Committee accepted the proposal of the Delegation of the United States of America that it was necessary to have preliminary discussions on microbiological metrics (Agenda Item 8) regarding comments and concerns that might arise among member states, therefore agreed to establish an in-session physical Working Group opened to all interested parties and chaired by the United States of America in order to facilitate the finalizing of this work at the current session.

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

7. The Committee was informed about matters arising from the 30th Session of the Codex Alimentarius Commission (CAC) which were relevant to the Committee's work.

8. The Committee noted that most of the matters referred by the CAC were for information purposes while others would be discussed in more detail under relevant Agenda items. The Committee also noted that assignments given by the Commission in relation to the implementation of the Strategic Plan 2008-2013 of the Codex Alimentarius Commission such as the review and development of Codex standards and related texts for food safety was ongoing work; or the development of committee-specific decision making and priority setting criteria had already been successfully completed and was used in practice by the CCFH and that Activity 2.2 Review of risk analysis principles would need to be completed by 2013.

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[1] CX/FH 07/39/1; CRD 3 (Division of competence between the European Community and its Member States, prepared by the EC).

[2] CX/FH 07/39/2; CRD 14 (Comments from the EC).

9. The Committee agreed that the recommendation to develop a specific risk policy document would be discussed under Agenda Item 9 while considering proposals for new work.

Project documents

10. With regard to Project Documents for new work, the Committee noted that the 30th Session of the CAC was of the view that some project documents were not of sufficient quality, not addressing all criteria with sufficient explanation/justification and that the CAC had requested that in future all documents should be prepared in accordance with provisions set forth in the Codex Procedural Manual.

Duration of meetings

11. The Committee accepted the proposal of the Chairperson and agreed that, if the Committee retains five substantial items on its agenda, to hold five day meetings instead of six.

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

12. The Representatives of FAO and WHO presented this item and provided an overview of the work of JEMRA relevant to the work of the Committee.

13. In noting the recent developments with regard to the provision of scientific advice on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula the Representative of WHO highlighted the completion by FAO and WHO of a user-friendly risk assessment tool and the availability of risk based guidance for the safe preparation, handling and use of powdered infant formula. Together, such tools provide countries with both the information and flexibility to develop their own risk management strategies. Noting that WHO would be reporting to the next session of the WHA on the progress of the Committee on the revision of the code of hygienic practice for powdered infant formula, he emphasized the importance and value of demonstrating to the WHA that the Committee could work in an efficient and effective manner.

14. Representatives of both WHO and FAO also summarized the work that had been undertaken in the areas of foodborne viruses, microbiological hazards in fresh produce and *Vibrio parahaemolyticus* in bivalve molluscs in response to the specific requests of the 38th session of the Committee. In doing so FAO and WHO expressed their appreciation to all those countries (Ireland, Japan, the Netherlands, United States of America) who had provided resources, both financial and in-kind, to facilitate the expeditious development of scientific advice and urged the Committee and countries to continue to build partnerships and provide support to FAO and WHO to facilitate the provision of scientific advice in support of the work of the Committee.

15. The Representative of FAO highlighted the success of the request for data via Circular Letter to support the work to provide scientific advice on fresh produce and thanked the 22 member countries, 1 member organization and observers to the Committee that submitted data in response to the Circular Letter. It was noted that the success of this approach might serve as a model for the future.

16. The Representative of FAO also informed the Committee of the publication of the framework for the provision of scientific advice which aims to provide transparency on the approaches that FAO and WHO take to provide scientific advice. In addition, the Representative noted the recent establishment of the Global Initiative for Food-related Scientific Advice (GIFSA) and encouraged countries to use this mechanism to strengthen the FAO/WHO programme for the provision of scientific advice to Codex.

17. Several delegations expressed their appreciation to FAO and WHO for the work undertaken on the provision of scientific advice and their efforts to provide this advice in a timely manner.

18. Taking into consideration the scientific advice provided by FAO and WHO on *Vibrio parahaemolyticus* in shellfish the Delegation of Japan expressed its appreciation for the scientific advice and noted that it was both important and timely that the Committee take up work on this issue. In responding to a request from that Delegation, the FAO Representative noted the delay in the publication of risk assessment guidelines but indicated that the exposure assessment guidelines would be available at the end of 2007 with the risk characterization guidelines becoming available in early 2008.

[3] CX/FH 07/39/3; CRD 14 (comments of the EC).

19. The Delegation of the United States of America noted that the experience of the past year, particularly with regard to fresh produce, highlights the importance of advance planning in ensuring the provision of scientific advice in a timely manner and expediting the work to the Committee. The Delegation recommended that the Committee consider longer range planning of its work and specifically its needs for scientific advice to facilitate planning by FAO and WHO and ensure more efficient operation of the Committee.

20. The Delegation of Portugal, speaking on behalf of the Member States of the EC, expressed particular appreciation for the work on viruses and their regret that a procedural hindrance would prevent the Committee from immediately considering new work on this issue. In addition they noted the importance of the establishment of GIFSA and hoped that this would ensure the continuation of a strong FAO/WHO program for the provision of scientific advice.

21. Highlighting the problems associated with the safety of game and food harvested/caught in the wild the Delegation of Côte d'Ivoire requested FAO and WHO to consider providing scientific advice in this regard. The Representative of WHO acknowledged these concerns and noted that the work on viruses had already given some consideration to emerging viruses such as Nipah virus, highly pathogenic avian influenza and SARS coronavirus. In addition, he noted that given the high level of emerging pathogens and foodborne illnesses associated with game and food harvested from the wild, specific consideration of this issue was planned for the forthcoming biennium.

22. The Representative of FAO highlighted the importance of member countries being familiar with the procedures for the consideration of new work by the Committee in order to request any necessary scientific advice in a timely manner. She also supported the recommendation for longer term planning by the Committee noting that this would greatly facilitate FAO and WHO planning processes to provide scientific advice.

23. In concluding this item the Chairperson noted that there would be further opportunity to hold discussions on the scientific advice provided by FAO and WHO under the relevant agenda items and also highlighted the value of seeking data from member countries via Circular Letter as a basis for the provision of scientific advice. The Chairperson concluded that long term planning and the establishment of GIFSA may provide the Committee valuable tools to enhance and expedite the work of the Committee.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN (Agenda Item 4)[4]

24. The Committee recalled that at its last session it had agreed to return the proposed draft Code to Step 2 for redrafting by a physical Working Group led by Canada.

25. The Delegation of Canada introduced the document and explained that the working group had met in Ottawa in June 2007 to revise the Code according to guidance given by the last session of the Committee.

26. The Delegation explained that the Code had been reviewed to determine if specific hygienic practices needed to be identified or emphasized when considering the manufacturing conditions of the different products covered by the Code but that it had been concluded that there were no significant differences among the products therefore all hygienic practices had been included in the proposed draft Code.

27. The Delegation indicated that the Code was related to aspects of hygiene only, that it followed the format of the *Recommended International Code of Practice – General Principles of Food Hygiene,* and that issues such as emphasis on breast-milk feeding, were covered in a general manner.

28. The Delegation pointed out that the use of negative statements in Section 9 and the inclusion of follow-up formula up to 12 months in Annex I required further consideration.

29. The Committee considered the proposed draft Code section by section and in addition to editorial amendments, made the following observations and/or changes.

[4] CX/FH 07/39/4; CX/FH 07/39/4-Add.1 (comments from Brazil, Costa Rica, Islamic Republic of Iran, Mexico, Peru, Philippines, United States of America, International Baby Food Action Network (IBFAN), International Diary Federation (IDF), International Lactation Consultant Association (ILCA), International Special Dietary Foods Industries (ISDI); CRD 5 (comments from ICMSF); CRD 7 (comments from Argentina), CRD 9 (comments from Republic of Korea); CRD 10 (comments from India), CRD 11 (comments from Mali), CRD 12 (comments from Thailand), CRD 14 (comments from European Community), CRD 16 (comments from China), CRD 17 (comments from India).

Introduction

30. The Committee agreed to insert a reference to the *WHO Report on HIV and Infant Feeding: New Evidence and Programmatic Experience (Report of the Technical Consultation, Geneva, Switzerland, 25-27 October 200, held on behalf of the Interagency Task Team (IATT) on preventing HIV infection in pregnant women, mothers and their infants (2007)* in the last sentence of paragraph 8 so as to avoid confusion on feeding of HIV positive infants since mixed feeding could be risky to such infants.

31. In order to convey more directly the risks to neonates in intensive care settings, the Committee agreed to amend paragraph 13 as proposed by the Delegation of the United States in its written comments in CX/FH 07/30/4-Add.1.

32. The Committee agreed to include "infant care givers" at which prevention efforts also needed to be directed and made this insertion in all subsequent texts where appropriate.

Section II – Scope, Use and Definitions

2.1.2 Roles of Governments, Industry and Consumers

33. The Committee agreed to insert "packaging materials" in addition to ingredients in the second paragraph since manufacturers of these materials also needed to ensure that effective control measures were in place. This amendment was also made in all subsequent sections as appropriate. In addition, it was agreed to replace "assure the safety" with "minimize the risk" since absolute safety could not be ensured and to make it consistent with a following paragraph.

34. After a lengthy discussion, the Committee did not agree with the proposal to include in the bulleted section, GLP and SQA as aspects to which parties needed to pay specific attention, since these concepts were by implication covered by the application of HACCP referred to in this section.

35. Following a proposal to delete from bullet points 7 and 8 reference to handling and storage according to manufacturers instructions, it was agreed to retain the bullet points unchanged since it was necessary to clarify what was meant by proper handling and storage.

36. Concern was also raised about the reference in bullets 7 and 8 to the *WHO/FAO Guidelines on safe preparation, storage and handling of powdered infant formula,* which could restrict flexibility for national governments to set their own guidelines. However, it was clarified that the guidelines provided sufficient flexibility since they were generic in nature and allowed national governments to set their own guidelines for proper handling and storage.

2.3 Definitions

37. To more accurately reflect that the wet-mix process included several optional steps, the Committee agreed to amend the definition by stating that the process after handling in the liquid phase may involve homogenization, heat-treatment and/or concentration by evaporation before drying.

Section IV

4.1.2 Equipment

38. The Committee agreed to delete "whenever possible" in paragraph 2 with regard to equipment design in order to ensure that such design allowed for equipment to be properly cleaned and disinfected and noted that the term "should" still allowed for a certain degree of flexibility. The Committee further agreed to delete reference to "formation of harborage sites" since the section was of a general nature and that this was dealt with in more detail in a subsequent section.

4.2.1 Design and layout

39. It was agreed to replace "considered" with " maintained as" in the 2nd paragraph since dry processing areas were considered to be hygiene areas and needed to be maintained as such and to delete reference to "relevant" pathogens in the 4th paragraph since access to high hygiene areas needed to restrict all pathogens.

4.3.1 General

40. The Committee agreed to delete the last sentence of the 2nd paragraph as the approach was not practical and that harbourage sites should be avoided in all cases.

5.8 Recall Procedures

41. To a proposal by the Observer from IBFAN to develop specific recall procedures in future for the products covered by the Code because of their unique nature and the groups at risk, it was clarified that the current *Recommended International Code of Practice – General Principles of Food Hygiene* already covered this matter. The Committee agreed to include reference to the recently adopted *Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System (CAC/GL 60-2006)* as well as the *International Health Regulations* of the WHA (2005), which were of relevance to this document, but did not agree to insert "food aid" in addition to foods traded internationally because food aid was not covered in the documents being referred to in this section, but by the Code of Ethics for International Trade in Food (CAC/RCP 20-1979).

Section IX Product Information and Consumer Awareness

42. The Committee agreed to replace in paragraph 3, "small" with "certain" with respect to the number of servings that may contain pathogenic microorganisms to provide more accuracy to this statement and to also make reference to Annexes I and II for further clarification.

43. After considerable discussion about the negative nature and impact of reference that powdered infant formulae were not sterile and that such statements could lead to misinterpretation and encourage the use of other products without such warning, it was clarified that this was not a labelling requirement but, that such information needed to be conveyed to those responsible for the reconstitution, preparation, handling and feeding of such products. Therefore in order to better put in context the issue of the non-sterility of the product, it was agreed to modify paragraph 4 to explain that because formulae were not sterile that information should be provided to professionals and caregivers to ensure that GHP were in use during reconstitution, preparation and handling, but further agreed to delete reference to *E. sakazakii* and *Salmonella* since this statement applied to all pathogens including the latter two.

44. In order to better convey the findings of the report of the 2006 FAO/WHO expert meeting on *E. sakazakii* and *Salmonella*, the Committee agreed to the proposal of the Observer from the IDF as presented in their written comments (CX/FH 07/30/4-Add.1) with some modifications and to insert a footnote to clarify the meaning of "feeding time". The Committee did not agree to stipulate any specific refrigeration temperatures as proposed by some delegations since these were clearly dealt with in the FAO/WHO report and the WHO/FAO Guidelines for the Safe Preparation, Storage and Handling of Powdered Infant Formula (2007).

45. After some discussion on the use of the terms 'high confidence" in paragraph 5, it was agreed to retain the paragraph unchanged.

46. The Committee agreed to clarify which stakeholders need to be communicated with in regard to control measures citing examples of those stakeholders in paragraph 7.

9.3 Labelling

47. The Committee agreed to amend paragraph 3 to reflect that the label should carry clear graphic instructions illustrating the method of preparation to provide better clarity and to make the wording consistent with existing Codex texts.

48. The Committee agreed to delete paragraph 4 since this matter was already covered by section 2.2.

49. The Committee agreed to modify the last paragraph of Section 9.3 to indicate the need for cooperation between industry and national governments with regard to ensuring that messages are understood by all potential users rather than to ensure validation of labels as proposed by the Delegation of EC in its written comments as presented in CRD 14. In addition, a sequential amendment in line with an earlier agreement regarding "PF not being sterile" was made. In order to provide better clarification that consumers needed to be able to identify products to assist with a recall, the last part of the paragraph was modified to provide for this.

9.4 Education

50. Some delegations proposed to modify paragraph 4 to stress the potential risks associated with inappropriate preparation, handling and use of PF and to avoid the use of negative statements such as PF not being a sterile product. The Observers of IBFAN, IACFO AND ILCA were of the view that this paragraph be retained unchanged since it was important to provide such information to caregivers and since there was

no evidence that consumers when provided with such information, would not follow advice provided by manufacturers.

51. The Representative of WHO pointed out that the proposed modification would not provide information on how to reconstitute infant formulae, but rather on inappropriate use and therefore proposed to retain the paragraph unchanged. After some discussion, the Committee agreed with the modification as proposed by the Delegation of the United States of America in its written comments in CX/FH 07/30/4 Add.1.

52. The Committee agreed to modify sentences 6, 7 and 8 of paragraph 5 to highlight more specifically the details with regard to safe storage temperature for reconstituted PF without specifying the duration of feeding or refrigeration temperature of storage.

Section X - Training

53. The Committee agreed to modify the last paragraph to indicate that the *WHO/FAO Guidelines for the Safe Preparation, Storage and Handling of Powdered Infant Formula* would be used as a reference for training.

Annex I

54. The Committee had a lengthy discussion on the inclusion of follow-up formulae up to 12 months in this annex. Several delegations were of the opinion that follow-up formulae should be excluded since there was no scientific justification for criteria on *E. sakazakii* for this type of product. Some delegations were of the opinion that this product needed to be included because the criteria developed were based on the available scientific information and that it was important to take precaution in this instance. Other delegations supported the removal of follow-up formulae from Annex I, but inclusion in Annex II and were of the view that there was no need for further scientific advice. Several delegations also recalled that the original request of the Committee to the working group was for two separate annexes, one specifically for follow-up formulae.

55. The Representative of the WHO clarified that the current criteria were based on the most current scientific advice available and on recommendation of two expert meetings taking into account the situation in especially developing countries, where follow-up formulae were being used for infants under 6 months. The Representative further indicated that FAO/WHO were willing to provide further scientific advice provided that clear terms of reference was developed by the Committee for such advice and that member countries commit to providing data.

56. In order to proceed with the finalization of the document, the Committee agreed to remove follow-up formulae from Annex 1 and to consider follow-up formulae in Annex II. The Committee agreed to request further scientific advice from FAO/WHO regarding specifications of *E. sakazakii* in follow-up formulae for infants from 6 to 12 months and established an *ad hoc* working group to prepare draft questions to be addressed by FAO/WHO (see agenda item 9).

57. The Committee agreed to provide explanatory text for the terminology used for the different classes of sampling plans; to insert as an additional action, the recall of product if it had been released for human consumption when there was a failure to meet criteria for pathogenic microorganisms; and to provide information in the form of a footnote to clarify why the proposed 2-class plan for *Enterobacteriaceae* had been used.

Annex II

58. The Committee agreed to return Annex II to Step 2 for further elaboration when scientific advice from the FAO/WHO becomes available.

Annex III

Part I

59. To the proposal to delete the last sentence of the first paragraph since it appeared that there was no evidence to make the assumption that reduction in the levels of *Enterobacteriaceae* in the environment could lead to lower levels of *Enterobacteriaceae* in finished product, it was clarified that it conveyed the message that there was a relationship between levels in the environment and levels in the finished product even though there was no correlation and that this statement was necessary to provide the rationale for the criteria. Therefore the Committee agreed to retain the paragraph with slight amendments to improve clarity.

60. The Committee modified the second bullet point in paragraph 5 for clarification purposes by indicating that *E. sakazakii* was currently more frequently found in dry processing areas rather than being the normal part of its flora and that monitoring programmes should be to assess whether control measures were effective to prevent growth of *E. sakazakii* rather than to prevent its entry in these areas.

61. The first paragraph of (a) Type of product and process/operation was modified to clarify that the need and extent of a sampling programme should also be defined by the age and health status of the consumer.

Status of the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

62. In view of the considerable progress made on the Code, the Committee agreed to forward the proposed draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children including Annexes I and III for final adoption by the Commission at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix II).

63. The Committee also agreed to return Annex II to Step 2 for further revision by an electronic working group working in English only, open to all interested parties and led by Canada with the understanding that the working group would utilize scientific advice provided by FAO/WHO and that a physical working group would meet the day before the next Session to consider the comments received at Step 3 on the proposed draft Annex II and to prepare proposals for consideration by the Committee.

PROPOSED DRAFT GUIDELINE FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES (Agenda Item 5)[5]

64. The Committee recalled that its 38th Session had agreed to return the proposed draft guideline for the validation of food safety control measures to Step 2 and to establish a physical working group, led by the United States of America to revise the document[6].

65. The Delegation of the United States of America introduced the proposed draft guideline and informed the Committee that following the decision of the 38th Session, the scope of the document was clarified to be control measures (or combinations/sets of control measures forming a food safety control system) at any point in the food chain, and that the proposed draft guidelines addressed both monitoring and verification in relation to validation with examples.

66. The Delegation highlighted the inclusion of a new Annex I containing six examples of approaches to validating control measures.

67. The Committee considered the proposed draft guidelines section by section and, in addition to editorial amendments, made the following observations and changes.

Introduction

68. In the third sentence of paragraph 2, the term "advice" was replaced by "guidance" for clarity and the term "should" was changed to "may" in order to provide more flexibility.

69. In paragraph 3, the text was amended to emphasize that the examples of validation scenarios in Annex I were for the purpose of illustration only and did not represent actual validation of control measures nor did they have global application.

III. Definition

70. The Committee agreed to delete the definitions of ALOP, FSO, PC and PO since these terms were either not used in the document or are included in the Codex Procedural Manual.

IV. Concept and nature of validation

71. At the end of the second sentence of the first paragraph, a phrase "in respect of a required level of hazard control" was added for clarity.

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[5] CX/FH 07/39/05, CX/FH 07/39/05 Add.1, CRD 7 (comments of Argentina), CRD 10 (comments of India), CRD12 (comments of Thailand), CRD 15 (comments of European Community), CRD 17 (comments of IACFO), CRD 19 (comments of ICD).

[6] ALINORM 07/30/13 para.183.

72. To improve the quality of the text in the box, the Committee agreed to amend the title as "interrelationships among validation, monitoring and verification" and to make necessary changes in the chapeau paragraph.

73. In the second dash point, the Committee agreed to delete the last part of the first sentence and the second sentence since it was not always the case for verification. For clarity, "an ongoing activity" was added in the first sentence.

74. In the last dash point, "periodic process control testing" was added to the first sentence, for clarity.

V. Task prior to validation of control measures

75. In the second paragraph, the wording "in the commodity and/or environment concerned" was added. A new sentence was added under point b to clarify that industry could set stricter food safety outcomes or targets than those set by the competent authority.

76. In point c, in the second bullet point, the first sentence was amended to improve the text. In the third bullet point, the first sentence was deleted since this was already covered in Section IV. In relation to adverse health effect, a sentence was also added to indicate that consideration should be given to the size of the population and the age/gender of the groups most a risk.

Resources

77. In relation to a case where resources were not available for the conduct of validation studies on control measures, the text was amended to clarify that assistance from national and international organizations to small and/or less-developed businesses could help to perform validation of food safety control measures.

Other factors/constraints

78. It was agreed to add a separate sub-sub bullet point on other factors/constraints to clarify that there could be certain control measures, such as hand washing, whose quantitative effect on a hazard would be difficult to determine and which were not always technically and scientifically possible to validate.

VI. The validation process

79. A new sentence was added in the second paragraph to clarify that approaches on validation described in Section VI were presented in no particular order. In the third bullet point, the first sentence was amended in order to clarify that data should be collected not only during normal operating conditions of the food operation, but also during specific periods of increased production. In the fifth bullet point, it was agreed to delete "representative" for consistency and to add a text to clarify that surveys can be used to validate control measures, as appropriate, in conjunction with other approaches to demonstrate the expected level of control of hazard.

VII. Need for re-validation

80. In the first bullet point, a sentence was added to clarify that system failure may also result from an inadequate hazard analysis and may require the need for re-validation of a control measure or combination of control measures.

Annex I

81. The Committee agreed to amend the second sentence of the introductory paragraph in order to highlight that all examples presented in Annex I were for the purposes of illustration of the general concept only and were not representing actual validation scenarios. In addition, it was agreed to delete the first sentence of the same paragraph since it was not describing the nature of this annex.

82. In relation to example one (validation of post-harvest dehydration to prevent aflatoxin contamination of tree nuts), the Committee recalled the ongoing discussion taking place in the Codex Committee on Contaminants in Foods regarding maximum levels of aflatoxin in tree nuts and therefore agreed to add a footnote to underline that the values indicated in example one were for illustration purposes only and shall not be considered as guidance in any way.

83. With regard to example two (meeting a performance objective for vero-toxin producing *Escherichia coli* (VTEC) in a hard raw milk cheese), it was proposed to replace the reference to VTEC by a more generic term (a pathogen) in order to avoid misunderstanding or misuse of this example, however, the Committee did

not accept this proposal, because some delegations continued to prefer to refer to a specific pathogen. The Committee recognised that no extrapolation could be made from the VTEC example to a real situation.

Status of the Proposed Draft Guideline for the Validation of Food Safety Control Measures

84. The Committee noted significant progress made on the document and agreed to forward the proposed draft guideline for the validation of food safety control measures for final adoption at Step 5/8 by the 31st Session of the Commission, 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 3 (Agenda Item 6)[7]

85. The Committee recalled that its 38th Session had finalized the "*Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods*" which subsequently had been adopted by the 30th Session of the Commission and that it had agreed to establish a physical working group led by Germany with the terms of reference to develop microbiological criteria on *Listeria monocytogenes* in ready-to-eat foods to be added as Annex II to the above guidelines.

86. The Delegation of Germany introduced the document and indicated that following the instructions of the 38th Session of the Committee the physical working group elaborated the draft Annex II which now consisted of four sections:

- Introduction;
- Scope;
- Use of microbiological criteria for *L. monocytogenes* in RTE-Foods; and
- Microbiological criteria for *L. monocytogenes* in RTE foods.

87. The Delegation pointed out that the proposed draft microbiological criteria in Annex II were developed on the basis of the FAO/WHO JEMRA and other risk assessments for this pathogen-commodity combination and that microbiological criteria for *L. monocytogenes* in RTE foods should complement other preventative control measures as laid down in the main document.

88. The Delegation indicated that, with regard to the risk of listeriosis, the working group identified that there were RTE foods for which no criteria were needed, and those for which criteria were appropriate. In the latter group two subgroups were identified: a) RTE foods in which growth of *L. monocytogenes* will not occur and b) RTE foods in which growth of *L. monocytogenes* can occur. The Delegation pointed out that the working group elaborated microbiological criteria for these two groups and that issues on which the working group did not reach agreement were left in square brackets.

89. In view of the numerous comments received, the Delegation suggested that rather than considering this document in detail at the present session, the Committee provide additional guidance for the working group on the approach taken including the proposed categorisation of RTE foods. The Delegation emphasized the need for further work on the criterion or criteria for RTE foods in which growth of *L. monocytogenes* can occur; the definition for the three RTE food categories, as well as the clarification of the point of application of the criteria in the food chain.

90. The Committee noted that further work on the document was needed and considered whether the original mandate was sufficient or whether it should be changed.

91. Several delegations were of the view that the original mandate was sufficient to cover further work on this document.

92. The Delegation of the United States was of the view that the mandate should be expanded to include elaboration of other appropriate risk management metrics.

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[7] CX/FH 07/39/6; CX/FH 07/39/6-Add.1 (comments from Brazil, Canada, Islamic Republic of Iran, Malaysia, Mexico, Peru, Philippines, United States of America, Eurocommerce and IDF); CRD 6 (comments from Guatemala); CRD 7 (comments from Argentina); CRD 9 (comments from People Republic of Korea); CRD 10 (comments from India); CRD 11 (comments from Mali); CRD 12 (comments from Thailand); CRD 15 (comments from the EC); CRD 17 (comments from IACFO).

93. After some discussion, the Committee agreed to confirm the original mandate given by the 38th Session of the Committee.

94. The Observer from IACFO highlighted the discrepancy in the point of application of the criteria between the FAO/WHO JEMRA risk assessment and the current draft Annex and suggested that more emphasis should be given on information on the impact of *L. monocytogenes* on public health.

95. The Committee noted the need to provide a more robust scientific basis for the proposed *L. monocytogenes* criteria and that the document should be applicable for food intended for both domestic and international trade.

96. It was pointed out that the scope of the document should clarify to whom this annex is addressed.

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

97. The Committee agreed to return the Annex on the Proposed Draft Microbiological Criteria in Ready-to-Eat Foods to Step 2 for further elaboration. The Committee agreed to establish a physical working group open to all interested parties and led by Germany[8] working in English language only, in Bonn (Bad Godesberg) Germany, from 27 – 29 May 2008. The Committee requested the working group to start working electronically and to consider all written comments submitted to the current session, and to prepare a revised version of the document to be circulated at Step 3 well in advance of the next session of the Committee.

DISCUSSION PAPER ON THE PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *CAMPYLOBACTER* AND *SALMONELLA* SPP. IN BROILER (YOUNG BIRD) CHICKEN MEAT (Agenda Item 7)[9]

98. The Committee recalled that at its last session it had agreed to submit the development of "Proposed Guidelines for Control of *Campylobacter* and *Salmonella* spp. in Broiler (young bird) Chicken Meat" to the 30th Session of the Commission for approval as new work.

99. The Committee noted that the 30th session of the Commission, while approving the new work, recommended to extend the scope of this work to cover chicken meat in general taking into account all relevant factors including the availability of risk assessments.

100. The Committee discussed re-scoping of the document. The delegations of New Zealand and Sweden noted that the extension of the scope to cover all chicken meat (*G. gallus*) required additional scientific information which might take some time to gather, and therefore proposed to continue with the work on broiler (young bird) chicken meat (*G.gallus*) as the main priority and to address meat from birds other than broilers in a separate annex. The delegations also proposed to issue a Circular Letter asking for scientific information from members of the Committee on birds other that broilers. This information would help the working group to develop an approach for a new annex on meat from birds other than broilers to be presented to the next session of the Committee.

101. After some discussion, the Committee agreed that the WG would extend the scope to address chicken meat of birds other than broilers of the species *G. gallus* in an Annex to the Guideline as proposed.

102. The Committee also confirmed that the Guideline should continue to focus on carcass meat and portions.

103. The Observer from ALA informed the Committee that OIE is also working on this subject at the primary production level in relation to the Americas region, The Committee was assured by the co-chairs of the working group that ongoing co-ordination between Codex and OIE would continue in the development of the on-farm component of the Guidelines.

104. The Representative of FAO informed the Committee about the availability of the document on "Good Practices for Poultry" and suggested that it should be considered in the development of the proposed Guidelines.

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[8] Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Denmark, European Community, Finland, France, India, Italy, Jamaica, Japan, Mali, Malaysia, New Zealand, Norway, Philippines, Republic of Korea, Switzerland, Thailand, United Kingdom, United States of America, IACFO, ICMSF, IDF, ISDI, FAO/WHO.

[9] CX/FH 07/39/7; CRD 8 (comments from Indonesia); CRD 13 (comments from Philippines); CRD 15 (comments from the European Community).

105. The Committee noted that the proposed Guidelines would be based on the Code of Hygienic Practice for Meat (CAC/RCP 58–2005) and where specific information on *Campylobacter* and *Salmonella* in birds other than broilers was lacking, the Annex would revert to the provisions on meat hygiene already elaborated within the above Code.

106. The Committee agreed with the proposed structure and approach of the Guidelines as presented in the Discussion Paper and requested the WG to develop the necessary text for the document to be circulated at Step 3 before the next session of the Committee.

107. Some delegations indicated that in several parts of the world most of the chicken meat consumed came from birds marketed as live birds or slaughtered through live bird markets and therefore suggested to cover the marketing of live birds in the scope of the Guidelines. The Committee noted that the marketing of live birds was important to meat hygiene, however the Committee was of the view that it was inappropriate to address this topic in the current proposed draft Guidelines.

108. The Delegation of Mexico stated that the flow diagram should reflect that offals could also be removed during Step 26. The working group informed the Committee that offals should be excluded from the scope of the work because there is not sufficient information.

109. The Committee was of the view that close liaison with JEMRA would occur throughout the development of the proposed Guidelines and that JEMRA would carry out the scientific advice work, if and when required by the Committee, with input from the WG as relevant. The Committee confirmed that Terms of Reference for the scientific advice requested from JEMRA would need to be agreed by the Committee.

110. Some delegations requested clarification on timelines of the originally proposed WG work plan. The Committee agreed that the original plan should be revised taking into account the extended scope of the proposed Guideline and that this would be presented to the next session of the Committee.

111. The Committee confirmed that the work of the WG to-date was in accordance with the risk management questions presented in the new work proposal (ALINORM 07/30/8) and requested these questions to be reproduced in the background information for the next session of the Committee.

112. Committee agreed to use the title as approved by the Commission to include chicken meat other than broiler (young bird) chicken.

113. The Committee had a lengthy discussion on the most appropriate ways to seek the additional data needed to support the development of the Guidelines with its new scope.

114. The Committee considered proposals presented by the Delegations of Sweden and New Zealand and after some discussion agreed to seek the following additional information regarding chicken other than broilers:

- For the purpose of risk profiling on *Salmonella* and *Campylobacter*, relevant information requested should include but not be limited to: incidence rates in flocks and in human salmonellosis and campylobacteriosis attributable to consumption of contaminated chicken meat other than broiler meat, prevalence of the two pathogens in this meat including seasonal variations, the outcomes of risk assessments, the results from risk management activities, the effects on trade, etc.
- Codes of practice or other generic documents that include "specific" GAPs, GHP, HACCP-based controls for the two pathogens. This information will help the WG establish the generic production–to–consumption hazard pathway flow chart (breeding flocks to final consumption of chicken meat other than broiler meat) and identify any specific control measures that might be effective in different countries.
- Scientific information that quantifies likely levels of reduction of either of the pathogens as a consequence of specific interventions at any step in the older bird food chain, and any critical limits (HACCP) that may have been established in these terms at the national level. Examples of information of interest are quantitative and qualitative changes in incidence of the pathogens in older bird flocks and changes in the concentration of the pathogens in older birds and meat resulting from specific interventions at various steps in the older bird food-chain.
- Any kind of scientific information from government, industry or academia, be it pertaining to a single step in the food-chain or to several steps, will be appreciated.

115. The draft risk profiles for *Salmonella* and *Campylobacter* in broiler (young bird) chicken would be available for information in English only from the following websites:

http://www.nzfsa.govt.nz/policy-law/codex/publications/cac-and-subsidiary-bodies/

ftp://ftp.fao.org/codex/ccfh40/fh40rpsl

ftp://ftp.fao.org/codex/ccfh40/fh40rpcb

116. Recognizing that information was likely to be provided in official languages other than English, the Committee had a discussion on the availability of interpretation during the working group meeting and on translation of information in the three official languages and whether the WG should provide translation or not.

117. The Delegations of Sweden and New Zealand informed the Committee that due to financial constraints they would not be able to provide interpretation during working group meetings and translation of information received in languages other than English.

118. The Secretariat clarified that following the Procedures of the Commission, all circular letters were issued in the three official languages and that all countries had the right to submit their comments in one of these official languages.

119. Some delegations, while understanding the financial difficulties faced by hosts of working groups, drew the attention of the Committee to the fact that limitation of languages might reduce the data input especially from developing countries which use languages other than English.

120. Some delegations were of the view that the situation with interpretation and translation was of a general nature and should be addressed across Codex. The Committee agreed to bring this issue to the attention of the Executive Committee.

121. Some delegations questioned why the scientific information should be directed to the working group and not to the FAO/WHO who normally provided scientific advice to the Committee and proposed that the FAO/WHO might help in translating and analyzing information.

122. The Representatives of FAO/WHO informed the Committee that they were not in a position to translate information collected by the WG. FAO/WHO, as part of the provision of scientific advice process, translate and analyze information received directly by the organizations in response to specific calls made by both organizations to address specific questions posed by the Committee. The Representatives indicated that in its current form, the information to be requested is of a general nature to facilitate the elaboration of the guidelines by the working group and not a specific request for scientific advice.

123. The Committee agreed to seek information needed by the WG through a circular letter.

124. The Committee further agreed to reconvene the physical working group[10] open to all interested parties, led by Sweden and New Zealand, to be held in Sweden, exact venue to be determined at a later stage, in May 2008. The Committee agreed that responses to the circular letter should be sent to the WG. The Committee encouraged member countries participating in the WG to help with translation of Spanish and French.

125. The Delegation of Brazil offered to host the WG meeting with interpretation facilities to be provided in all three languages. While expressing its appreciation to the Delegation of Brazil for this generous offer, the Delegations of Sweden and New Zealand informed the Committee that they would have to consult with their respective governments before being able to make a final decision on the venue for the WG.

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT: ANNEX II GUIDANCE ON MICROBIOLOGICAL RISK MANAGEMENT METRICS (Agenda Item 8)[11]

[10] Australia, Austria, Belgium, Brazil, Canada, China, Denmark, European Community, Finland, France, Germany, Ghana, Hungary, India, Italy, Jamaica, Japan, Kenya, Ireland, Netherlands, Peru, Thailand, Uganda, United Kingdom, United States, ALA, IACFO, ICMSF and FAO/ WHO.

[11] CX/FH 07/39/8; CRD 12 (comments from Thailand); CRD 15 (comments from EC); CRD 17 (comments from IACFO); Comments submitted by Intra-session Working Group Meeting.

126. The Committee recalled the decision taken at its 38th Session to hold this Annex at Step 4 and to establish a physical working group led by the United Sates of America to prepare proposals on how to proceed with this matter.

127. The Delegation of the United States of America introduced the document and reminded the Committee that this document formed part of the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 33-2007) and recalled the background to the development of this Annex.

128. The Delegation explained that the Annex focused on general principles and guidelines for the establishment of microbiological risk management metrics and that the included examples illustrated potential applications only due to the highly technical information required to adequately explore an example in detail.

129. The Delegation further outlined the structure of the document and what each section entailed.

130. The Committee had a general discussion on the document before considering further more specific comments.

General discussion

131. Some delegations indicated that the document was in good shape, flexible and that it provided practical guidance in the application of microbiological metrics.

132. Some delegations proposed that the document needed to include additional practical examples to more clearly illustrate the application of the new metrics.

133. Other delegations were of the opinion that application of these metrics needed to be applied firstly to high priority products due to the highly technical nature of the concepts.

134. The Committee agreed, after some discussion, that the document should be progressed without development of further examples acknowledging that provision of such examples would require gaining experience in the practical application which will take some time. The Committee requested the FAO/WHO to develop a practical manual on the implementation of metrics and to also reflect this request in the section on "Use of the document."

135. The Representative of FAO in recognizing the importance of developing such a manual however cautioned that it would take some years before the manual could be completed because there was a need to gain practical experience on the application of the metrics at national level.

Specific comments

136. The Committee proceeded to discuss the Annex section by section and in addition to editorial changes, made the following amendments and/or observations.

Introduction

137. The Committee agreed to replace "science-based, risk-based and transparent" in the first paragraph with "should be based on risk and determined using a scientific and transparent approach" for consistency of use with other Codex texts.

138. For clarification purposes, the Committee agreed to amend the second paragraph to reflect the linkages between food safety requirements and criteria to public health problems.

139. The Committee noted that in some instances in the document, the term microbiological risk assessments was incorrectly referred to as QMRA giving the impression that only quantitative microbiological risk assessments could be applied and agreed to correct this to read "MRA" where applicable.

Use of document

140. The Committee agreed to amend the end of the 1st paragraph to clarify that recourse to microbiological risk management metrics is not always the most appropriate approach and that alternatives existed. The sentence was further amended to also reflect that flexibility in implementation was needed.

141. The last paragraph was amended to reflect an earlier decision to request the development of a practical manual by FAO/WHO to facilitate implementation by countries having no experience in the implementation of MRM metrics.

Product criterion

142. It was agreed to replace "not support" with "limit" to more accurately reflect the purpose of product criteria.

Microbiological criterion

143. The Committee agreed to insert "or number of microorganisms" after "number of positives" for consistency with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

Integration of Microbiological Risk Management Metrics Within a Food Safety Control System

144. The Committee agreed to amend the last sentence of paragraph 2 by inserting "in the absence of an explicit PO the established" for clarification purposes.

An example of a Process for Establishing and Implementing Microbiological Risk Management Metrics

145. In order to improve the flow of this section, it was agreed to insert paragraph (g) between paragraphs (e) and (f). The Committee further agreed to insert a new paragraph (i) to better reflect that risk managers not only were responsible for establishing risk management metrics, but also their implementation in conjunction with industry.

Status of Annex II: Guidance on Microbiological Risk Management Metrics

146. The Committee agreed to advance the proposed draft Annex II for final adoption by the 31st Session of the Commission at Step 5/8 with the recommendation to omit Steps 6 and 7 (see Appendix IV). The annex should be inserted into the Principles and Guidelines for the Conduct of Microbiological Risk Management.

AGENDA ITEM 9: OTHER BUSINESS AND FUTURE WORK

Development of an Annex to the Code of Hygienic Practice for Egg and Egg Products

147. The Committee recalled the decision of the 38th session to postpone work on the development of an annex to the Code of Hygienic Practice for Egg and Egg Products on the establishment of performance objectives for liquid eggs pending the outcome of the work to develop an Annex to the Principles and Guidelines for the conduct of Microbiological Risk Management on microbiological risk management metrics.

148. The Committee noted the information by the Delegation of the United States of America that since the proposed guidance on microbiological risk management metrics was now complete the Committee should reconsider the need to develop an annex on performance objectives for liquid eggs as an example of the application of microbiological risk management metrics. The Committee noted that since the structure of the microbiological risk management metrics annex had substantially changed there was no longer any need to develop the proposed annex on liquid eggs and therefore agreed that this work be removed from the Committees agenda and to inform the Commission accordingly.

Request for scientific advice to facilitate decision making on the need to establish a microbiological criterion for *Enterobacter sakazakii* in follow-up formula.

149. After review and discussion of the draft revised code of hygienic practice for powdered formulae for infants and young children and the decision to return Annex 2 on microbiological criteria for follow-up formula to Step 2 for further elaboration, the Committee agreed to request additional information and scientific advice from FAO and WHO to enable it to further consider whether an *E. sakazakii* microbiological criterion was needed for follow-up formula for infants aged 6 – 12 months.

150. Following an extensive discussion the Committee requested FAO/WHO to collate and review available data and then to convene an expert meeting to address a number of specific questions as follows:

- What is the number and incidence rate of confirmed *E. sakazakii* infection in infants up to 12 months, presented by month as compared to the incidence rate in all other age groups, including young children (12 – 36 months), older children and adults?
- Critically review all documented cases of confirmed *E. sakazakii* infections in infants between 6 and 12 months of age and consider specifically i) the clinical history and outcomes as well as ii) the

strength of the descriptive, epidemiological and/or microbiological evidence concerning the origin or source of these infections?

- Estimate the relative risk of *E. sakazakii* infections in infants 6 – 12 months of age, associated with the consumption of follow-up formula, as well as any other sources as identified in the previous question?
- What is the number and incidence rate of immunocompromised infants up to 12 months, presented by month, as compared to the number and incidence rate of immunocompromised in all other age groups, including young children (12 – 36 months), older children and adults and does this vary regionally?
- Taking into consideration the information generated in the above four questions, and given the application of risk management options as advocated in the Code, what is the relative risk reduction achieved by the application of microbiological criteria, as proposed in Annex 1 of the Code, to follow-up formula?
- Identify and describe active and passive surveillance systems for *E. sakazakii* in countries.
- What is the proportion of infants less than 6 months of age that consume follow-up formula and does this vary regionally?

151. Several Delegations highlighted the types of data needed to address these questions.

152. While accepting the request for new work, the Representatives of FAO and WHO noted that substantial work on the relative risk reduction associated with the implementation of microbiological criteria had already been undertaken and in the absence of new data specifically pertaining to follow-up formula, no new modeling work could be undertaken.

153. It was confirmed that FAO and WHO would prepare a Circular Letter requesting the data necessary to address the questions posed by the Committee. This would be circulated by the Codex Secretariat and Members of the Committee were urged to respond and submit any relevant data to FAO/WHO by the end of March 2008, to facilitate the elaboration of scientific advice in adequate time to allow development of the annex in advance of the next session of the Committee.

154. The Delegation of Canada confirmed that they would convene an electronic working group to develop the Annex and that a physical working group would be convened immediately before the next session of the Committee.

DISCUSSION OF THE REPORT OF THE *AD HOC* WORKING GROUP FOR THE ESTABLISHMENT OF CCFH WORK PRIORITIES[12]

Consideration of new work proposals

155. The Delegation of India, 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 the discussions and outcome of the working group as described in CRD 1.

156. Based on the recommendations of the working group the Committee agreed to take up new work on commodity specific annexes for the Code of Hygienic Practice for Fresh Fruit and Vegetables and on a Code of Hygienic Practice for *Vibrio* spp. in seafood.

157. The Committee noted the proposal of the United States to initiate development of two commodity-specific annexes to the code of hygienic practice for fresh fruit and vegetables, namely leafy green vegetables and tomatoes. However, several Delegations presented their concerns with starting work on two annexes noting the following: as this was a new approach, work should initially focus on one commodity; the

[12] CX/FH 07/39/9; CX/FH 07/39/9-Add.1 (comments from Costa Rica, Islamic Republic of Iran, Mexico. Peru, the Philippines); CRD 1 (Report of the CCFH working group for the establishment of CCFH work priorities), CRD 4 (proposal for new work on viruses in food from the Netherlands), CRD 7(comments from Argentina), CRD 15 (comments from the European Community), CRD 20 (project document for proposal of new work – Elaboration of a code of hygienic practice for *Vibrio* species in seafood prepared by Japan and United States of America), CRD 21 (Project document – Commodity-specific annexes to the code of hygienic practices for fresh fruits and vegetables, prepared by the United States of America).

FAO/WHO expert meeting[13] had clearly identified leafy green vegetables including the leafy green herbs as the commodity group of highest priority from a global perspective; the Committee had several other work items to be considered in the coming year including viruses in food and the development of a risk analysis policy document for the Committee. The Committee, therefore, agreed that only one new commodity annex addressing leafy green vegetables including leafy green herbs should be taken on as new work.

158. The Committee agreed that the Delegation of the United States of America would lead this new work and further agreed to establish an electronic working group[14], led by United States of America open to all interested parties, to develop the Annex for circulation for comments at Step 3 and consideration by the next session of the Committee. The Delegation of the United States of America indicated that every effort would be made to make documents available in the three working languages of the Committee. However, the Delegation could not confirm at this stage if it would also be possible to have the electronic working group interaction in three languages.

159. The Secretariat advised the Committee that based on the Committee's decision, the Secretariat would delete reference to tomatoes before submitting the project document (Appendix V) for approval as new work by the 60th Session of the Executive Committee and the 31st Session of the Commission.

160. The Delegation of Japan agreed to lead the new work on a Code of Hygienic Practice for *Vibrio* spp in seafood. The Committee agreed to establish a physical working group open to all interested parties, led by Japan[15] to develop the proposed draft Code for circulation at Step 3 for comments and consideration by the next session of the Committee pending the decision of the Commission. The working group would meet in Japan most likely in May/June, 2008 and will operate in English only. The project proposal (Appendix VI) will be submitted for approval as new work by the 60th Session of the Executive Committee and the 31st Session of the Commission.

161. The Secretariat recalled the request from the Commission for the Committee to develop a Risk Analysis Policy document to guide its work as part of the Codex Strategic Plan. Although the deadline for review of such work by the Executive Committee was 2013, the Secretariat suggested to the Committee to begin this work as soon as possible so as to ensure there was adequate time for development of the document.

162. The Committee accepted the offer of the Delegation of India to lead the work on the development of the Risk Analysis Policy of the CCFH and agreed that the work would proceed via electronic working group[16] in future.

163. The Chairperson, recalling the discussions of the *ad hoc* working group on the proposal for new work on foodborne viruses presented by the Netherlands, noted a potential procedural barrier in the procedures for the prioritization of the work of the Committee whereby there appeared to be a lack of clarification on the procedure to be followed when, prior to agreeing to a new work proposal, the Committee requested scientific advice from FAO/WHO.

164. The Delegation of India suggested that a form of wording could be added to the Committees procedures to address this as follows: "In situations where holding an expert consultation or the availability of its report prevents submission of a new work proposal before the deadline specified in the circular letter inviting new proposals, the *ad hoc* Working Group may consider proposals for new work provided these are otherwise complete, in compliance with the prioritization criteria and are submitted at least three months in advance of the *ad hoc* Working Group meeting."

165. The Delegation of the United States considered that the procedures were already sufficiently flexible, although since they were relatively new, Delegations were still learning how to apply them. The Delegation

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[13] Microbiological hazards in fresh fruits and vegetables: meeting report. FAO/WHO (in press).

[14] Argentina, Angola, Australia, Brazil, Canada, China, Cuba, Denmark, Dominican Republic, the European Commission, Finland, France, Ghana, Hungary, Ireland, India, Italy, Japan, Kenya, Malaysia, the Netherlands, New Zealand, the Philippines, Spain, Sweden, Switzerland, Thailand, Uganda, United Kingdom, Zimbabwe, IACFO, ICMSF, FAO, WHO.

[15] Angola, Australia, Brazil, Canada, China, Denmark, Ecuador, the European Commission, Germany, India, Italy, Malaysia, New Zealand, Norway, Sri Lanka, the Philippines, Thailand, United States of America, IACFO, ICMSF, FAO, WHO.

[16] Australia, Brazil, Canada, the European Commission, France, Finland, Germany, Japan, Peru, the Philippines, Thailand, United States of America, FAO and WHO.

of the United Kingdom expressed the need to ensure that the situation that had occurred this year should not happen again, but cautioned against making quick changes to the procedures.

166. The Committee, therefore, agreed to take some time to further consider the proposal of the Delegation of India and whether or not the procedures actually needed to be modified. The Committee agreed to postpone a decision on the revision of the procedures to the next session of the Committee.

167. The Delegation of the Netherlands noted, with regret, the situation in which they found themselves this year with regard to the proposal for new work on viruses in food. However, the Delegation indicated that, considering the strong support expressed by Delegations, during both the *ad hoc* working group and in the Committee for work on foodborne viruses, they would prepare a project proposal for consideration by the *ad hoc* working group and the Committee in 2008[17]. They indicated that they would be proposing the development of a general guidance document for the control of foodborne viruses with a series of annexes to address specific virus-commodity pairs as prioritized by the FAO/WHO expert meeting on viruses in food[18].

168. The Committee accepted the offer of the Delegation of France 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 Committee.

Priorities for Scientific Advice

169. With regard to the priorities for scientific advice the Committee confirmed the priorities as:

- Provision of scientific advice to facilitate the decision on whether or not to establish a microbiological criterion for *E. sakazakii* in follow-up formula in response to the questions listed in para 149.
- Provision of scientific advice on the microbiological hazards on leafy green vegetables including leafy green herbs in accordance with the terms of reference and time frame provided by the 38th session of the Committee.

170. The Delegation of New Zealand informed the Committee that the next working group on *Salmonella* and *Campylobacter* in poultry would identify its needs for scientific advice and would present them for consideration at the next session of the Committee. However, to facilitate the advancement of the work, the Delegation requested FAO and WHO to consider this request in their planning for 2009.

171. The Representatives of FAO and WHO indicated their willingness to address the requests for scientific advice and noted with appreciation the support provided by Japan and the USA, which would allow them to address the request for scientific advice on leafy greens vegetables. However, the Representative noted that the request for additional scientific advice for *E sakazakii* was unanticipated and encouraged Members of the Committee to consider providing support for this new work.

172. The Chairperson thanked the Delegation of India for their excellent work in chairing the *ad hoc* Working Group and commended the Committee and its working groups on the progress made in the increased use of an electronic modus operandi and languages other than English in the working groups.

THE USE OF THE LACTOPEROXIDASE SYSTEM FOR MILK AND MILK PRODUCTS IN INTERNATIONAL TRADE[19]

173. The Committee recalled the decision of the 30th Session of the Commission to refer the matter on the recommendation to lift the restriction of the use of the lactoperoxidase system in milk and milk products in the international trade back to the Committee for further consideration taking into account the recommendations of the FAO/WHO Report on the Benefits and Potential Risks of the Lactoperoxidase System (LPS) of Raw milk Preservation and all other information provided in response to Circular Letter 2007/31-FH.

174. The Committee held a general discussion on the views of the countries present on the use of the LPS for products in international trade with a focus on the new information received.

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[17] With assistance from Australia, Denmark, France, Hungary, Italy, Japan, Norway, Panama, the United Kingdom and the United States of America.

[18] Viruses in foods: Meeting report. FAO/WHO Microbiological Risk Assessment Series (in press).

[19] CX/FH 07/39/2; CX/FH 07/39/2-Add.1 (comments from Cuba, Canada, United States of America, Argentina); CRD 2 (comments from Costa Rica, Peru); CRD 8 (comments from Indonesia), CRD 10 (comments from India), CRD 14 (comments from European Community), CRD 18 (comments from Uganda).

175. The Delegation of Cuba, referring to the information provided in CX/FH 07/39/2-Add.1, informed the Committee that all current scientific information indicated that the use of the LPS posed neither a toxicological nor microbiological risk to consumers if used in accordance with the Guidelines for the Preservation of Raw Milk by Use of the Lactoperoxidase System (CAC/GL 13-1991). The Delegation noted that articles submitted by some member countries showing adverse effects from a health perspective or on lactose-fermenting bacteria were based on exposure to higher levels of thiocyanate and/or hydrogen peroxide than those in LPS treated milk when the system is applied in accordance with these Guidelines.

176. In view of the lack of scientific evidence to justify the continued restriction on the use of the LPS in milk in international trade and noting the usefulness of the application of this system especially to developing countries, the Delegation reiterated its position that the Committee should support the recommendation of the FAO/WHO Expert Meeting to recommend to the Commission to lift its restriction on LPS treated milk entering international trade.

177. The Delegation of Canada was of the opinion that some toxicological concerns still remained. While recognizing the potential value of the use of the system in some countries, the Delegation emphasized that refrigeration was the preferred method for milk preservation and pointed out that, since it was the Commission that had taken the decision to place a restriction on use in international trade, any modification to this restriction should also be made by the Commission. Further, the Delegation questioned whether this Committee was the only appropriate one to consider this issue, which required consideration of toxicological and nutritional as well as microbiological aspects.

178. Several other Delegations, while acknowledging the usefulness of the system, highlighted the importance of training to ensure the appropriate use of the system and noted the challenges that are faced by countries in ensuring its use according to the guidelines. While some Delegations were of the opinion that the LPS had limited value for milk in international trade, they noted that it should be up to each country to decide whether or not to use the system within their country.

179. The Committee agreed to inform the Commission that, as requested by its 30th Session, the Committee had considered further new information, but could not reach consensus on the lifting of the restriction. However, the Committee noted the value of the system, particularly in developing countries and in those situations where technical, geographical, economical and/or practical reasons do not allow the use of refrigeration. Therefore, the Committee requested that the Commission should consider clarifying the statement regarding the restriction of the use of the LPS to explain that the restriction on the use of the LPS for milk in international trade in no way precluded the use of the system by countries at the national level.

180. The Delegation of Cuba informed the Committee that they were working on a guideline to improve the use of LPS and that the Delegation may submit a proposal for new work to the Committee in the future.

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

181. The Committee was informed that the 40th Session of the CCFH, was currently scheduled in the United States of America from 1 to 5 December 2008, exact venue to be determined by the host Government and the Codex Secretariat.

182. To the offer of the Delegation of Guatemala to co-host the 40th Session of the Committee in this country, the Chairperson clarified that the Delegation should communicate its willingness to the United States Codex Secretariat.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 08/31/13
Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (N10-2004)	5/8	Governments, 31st CAC	para. 62 and Appendix II
Proposed Draft Guideline for the Validation of Food Safety Control Measures	5/8	Governments, 31st CAC	para. 84 and Appendix III
Annex II: Guidance on Microbiological Risk management Metrics to the Principles and Guidelines for the Conduct of Microbiological Risk Management	5/8	Governments, 31st CAC	para. 146 and Appendix IV
Annex II: Microbiological Criteria for Powdered Follow-up Formula and Formula for Special Medical Purposes for Young Children (Annex to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children)	2/3	FAO/WHO, WG led by Canada, Governments, 40th CCFH	para. 63
Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods	2/3	WG led by Germany, governments, 40th CCFH	para. 97
Proposed Draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat (N08-2007)	2/3	WG led by New Zealand and Sweden, Governments, 40th CCFH	paras 98-125
New Work			
Proposed Draft Annex on Leafy Green Vegetables Including Leafy Herbs to the Code of Hygienic Practice for Fresh Fruit and Vegetables	1/2/3	61st CCEXEC, 31st CAC, WG led by the US, governments, 40th CCFH	paras 156-158 and Appendix V
Proposed Draft Code of Hygienic Practice for *Vibrio* spp. in Seafood	1/2/3	61st CCEXEC, 31st CAC, WG led Japan, governments, 40th CCFH	paras 156-160 and Appendix VI
Risk Analysis Policy of the CCFH	Procedure	WG led by India	paras 161-162
Discontinuation of work			
Annex: Application of Food Safety Metrics in Risk Management Decision Making – Pasteurized Liquid Whole Eggs to the Code of Hygienic Practice for Egg and Egg products		Governments, 31st CAC	paras 147- 148

Appendix I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairperson : Dr Karen HULEBAK
Président : Chief Scientist
Presidente : Food Safety & Inspection Service
Department of Agriculture
14th & Independence Ave, SW
Washington, DC 20250
U.S.A.
Tel: 202-720-5735
Fax: 202-690-2980
Email: karen.hulebak@fsis.usda.gov

Co Chairperson: Mr Debasish PANDA
Joint Secretary
Ministry of Health and Family Welfare
Government of India
Nirman Bhavan
New Delhi-110011
Tel/Fax: +91-11-23061447
Email: debasish.panda@nic.in

Assistant to the Chairperson : Dr Jose Emilio ESTEBAN
Laboratory Director
Food Safety & Inspection Service
United States Department of Agriculture
620 Central Ave
Alameda, California
94501
Tel : 510-337-5030
Fax : 510-337-5036
Email : Emilio.Esteban@fsis.usda.gov

ALBANIA

Dr Eljan KASA
Food Expert
Ministry of Agriculture, Food and Consumers Protection
Skenderbej, Square No.2
Tirana
ALBANIA
Tel : +355224503/163
Fax : +3554230867
Email : kasaelian@hotmail.com

ANGOLA

Ms Maria Antonia SANAZENGE
Coordinator Of Food Hygiene
Ministry of Health In Angola
National Institute Of Public Health
3665 Luanda
Angola
Tel : 244923653695
Email : sanazenge@hotmail.com

Ms Maria PEDRO SOBRINHO
Dra, Coordenadora de Comité
Luanda- Angola
Codex –Angola
Comite do Codex Angola
Tel : 923520950
Email : mpgaspar2002@yahoo.com

Dr Maria Linda ALFREDO
Chefe de Crimes Contra Saude Publica
Direccao Nacional de Jnspeccao Das Actividades Economicas/
Ministerio Do Interjor/CGPN
Largo do Kinaxixi
No 14 5th Andar
Luanda, Angola
Tel : 244 912454209/924370050
Email: lialfredo12@yahoo.com.br

ARGENTINA/ARGENTINE

Dr Luis Eduardo ECHANIZ
Responsible de los Asuntos Multilaterales
Cordinacion de Relaciones Internacionales e Institucionales
Servicio Nacional de Sanidad y Calidad Agroalimentaria
1063- Paseo Colon 439 -5 Piso
Ciudad de Buenos Aires
Argentina
Tel : 54-11-4121-5334
Fax : 54-11-4121-5360
Email : eechaniz@senasa.gov.ar

AUSTRALIA / AUSTRALIE

Ms Amanda HILL
Manager
Food Safety Section
Food Standards Australia New Zealand
P.O. Box 7186
Canberra BC ACT 2610
Australia
Tel : +61 2 6271 2632
Fax : +61 2 6271 2278
Email : amanda.hill@foodstandards.gov.au

Usha Sriram-PRASAD
Manager, Food Regulation and Safety
Australian Government Department of riculture Fisheries and Forestry
GPO Box 858 Canberra ACT
Australia 2601
Tel : +61 2 6272 3547
Fax: +61 2 6272 4367
Email : usha.sp@daff.gov.au

Mr Deon MAHONEY
General Manager, Risk Assessment Branch
Food Standards Australia New Zealand
P.O. Box 7186
Canberra BC ACT 2610
Australia
Tel : +61 2 6271 2695
Fax : +61 2 6271 2278
Email : deon.mahoney@foodstandards.gov.au

Ms Elizabeth DEAN
Assistant Manager
Food Safety Section
Food Standards Australia New Zealand
P.O. Box 7186
Canberra BC ACT 2610
Australia
Tel : +61 2 6271 2627
Fax : +61 2 6271 2278
Email : elizabeth.dean@foodstandards.gov.au

Dr Patricia DESMARCHELIER
Director, Research
Food Science Australia
Cnr Creek and Wynnum Roads
Cannon Hill 4170
Queensland Australia
Tel : + 61 7 3214 2032
Fax : + 61 7 3214 2150
Email : Patricia.Desmarchelier@csiro.au

Ms Carol BATE
Regulatory Manager Australia
Fonterra Australia Pty Ltd
327 Ferntree Gully Road
Mt Waverly Victoria
Australia 3149
Tel: +61 3 8541 1519
Fax: +61 3 8541 1462
Email: carol.bate@fonterra.com

AUSTRIA / AUTRICHE

Mr Dieter JENEWEIN
Federal Ministry of Health, Family and Youth
Radetzkystiasse 2
A-1030 Vienna
Tel: 0664/839 80 30
Email: dieter.jenewein@ages.at

BELGIUM / BELGIQUE / BÉLGICA

Mr Benoit HORION
Engineer – Expert
Federal Public Service of Health ,
Safety of the Food Chain and Environment Service
Food, Feed and other consumption Products
Place Victor Horta, 40 Box 10 – Bloc II – 7th floor
1060 Bruxelles
Tel : 32-2-5247360
Fax: 32-2-5247399
Email: benoit.horion@health.fgov.be

Dr Karen VEREECKEN
Ingenieur
Agence federale pour la securite de la chaine alimentaire
Avenue Simon Bolivar 30
B-1000 Brussel
Tel: 32(0)2 208 47 99
Fax: 32(0)2 208 47 43
Email: karen.vereecken@favv.be

BHUTAN/BHOUTAN

Dr Chador WANGDI
Regulatory and Quarantine Officer
Bhutan Agriculture and Food Regulatory Authority (BAFRA)
Ministry of Agriculture
Thimphu
Tel: 975-2-327031
Fax: 975-2-327032
Email: chador465@yahoo.com

BRAZIL / BRÉSIL / BRASIL

Dr Marcelo BONNET
Head, Official Laboratory Network
Ministry of Agriculture
Livestock and Food Supply
Esplanada dos Ministérios,
Bloco D Anexo B, Sala 337
Brasília, DF – Brazil
CEP 70043-900
Tel : 55 61 3218 2227
Fax : 55 61 3218 2697
Email : mbonnet@agricultura.gov.br

Ms Andrea SILVA
Expert on Regulation and Health Surveillance
National Health Surveillance Agency
SEPN 511, Bloco A, Ed. Bittar II, 2° andar
CEP 70750-541, Brasília/DF
BRAZIL
Tel : 55 61 3448 6277
Fax : 55 61 3448 6274
Email : andrea.oliveira@anvisa.gov.br

Dr Elenita ALBUQUERQUE
Chief, Poultry Meat and Egg Inspection Division-DIPOA
Ministry of Agriculture
Livestock and Food Supply
Esplanada dos Ministérios,
Bloco D Anexo A, Sala 430
Brasília, DF – Brazil
CEP 70043-900
Tel : 55 61 3218 2558
Fax : 55 61 3226 9850
Email : elenita@agricultura.gov.br

Mr Alexandre PONTES
Codex Coordinator –MAPA
Ministry of Agriculture, Livestock and Supply (MAPA)
Esplanada dos Ministérios, bloco D-sala 347
Brasilia/DF-Brazil
CEP : 70.043-900
Tel : 55 61 3218 2416
Fax : 55 61 3225 4738
Email : apontes@agricultura.gov.br

Ms Denise RESENDE
Food General Manager
Anvisa- National Health Surveillance Agency
SEPN 511, Bloco A, Ed. Bittar II, 2°andar
Brasilia /DF- Brazil
CEP: 70750-541
Tel: 55-61-3448-6091
Fax: 55-61-3448-6274
Email: denise.resende@anvisa.gov.br

BURUNDI

Mr Olivier SUGURU
Directeur
Huilene de Palme du Burundi Membre/ Codex Burundi
De l'Huile De Palme Du Burundi
Quartier Industriel
Chaussée d'Uvira
BP 1107 – Bujumbura
BURUNDI
Tel : 25722222337
Fax : 25722228058
Email : sugoly@yahoo.fr

CAMEROON / CAMEROUN / CAMERUN

Mr Charles BOOTO
Directeur de la Normalisation
BP 5674
Yaounde Nlongkak
Tel: 00(237) 99 93 76 21
Fax: 00 (237) 22 22 64 96
Email: bootogon@yahoo.fr

CANADA / CANADÁ

Ms Hélène COUTURE
Head of Delegation
Head, Policy Development and Methodology Section
Evaluation Division, Bureau of Microbial Hazards, Food Directorate
Health Canada
251 Sir Frederick Banting Driveway
4th Floor, Locator (2204A1)
Tunney's Pasture
Ottawa, Ontario K1A OL2
Tel : 613-957-1742
Fax: 613-952-6400
Email: Helene_Couture@hc-sc.gc.ca

Dr Anna LAMMERDING
Chief, Microbial Food Safety Risk Assessment
Public Health Agency of Canada
160 Research Lane, Unit 206
Guelph, Ontario
N1G 5B2
Tel: (519) 826-2371
Fax : (519) 826-2367
Email: anna_lammerding@phac-aspc.gc.ca

Dr Reem BARAKAT
International Senior Policy Analyst,
Intergovernmental & International
Food Safety Directorate
Canadian Food Inspection Agency
49 CAMELOT DRIVE
Ottawa, ON, KIA OY9,
Tel: (613) 221-1345
Fax: (613) 221-7295
Email: barakatr@inspection.gc.ca

Dr Rejean BOUCHARD
Assistant Director, Policy and Dairy Production
Dairy Farmers of Canada
1101-75 Albert Street
Ottawa, Ontario
K1P 5E7
Tel: (613) 236-9997
Fax: (613) 236-0905
Email: rejeanb@dfc-plc.ca

Dr Jeffrey M. FARBER
Director,
Health Canada
Bureau of Microbial Hazards
3rd Floor Centre
251 Sir Frederick Banting Drivewsy
Address Locator 2203G3
Ottawa, ON Canada
K1A0L2
Tel: 613-957-0880
Fax: 613-954-1198
Email: Jeff_Farber@hc-sc.gc.ca

CAPE VERDE /RÉPUBLIQUE DU CAP VERT

Dr Íris Vasconcelos MATOS
ARFA – Agência de Regulação e Supervisão dos rodutos Farmacêuticos e Alimentares (Food and rug Agency)
Achada de Santo António
B.P. 296-A, Praia
Cap Vert
Tel: +238 262 64 10/
Fax: +238 262 49 70
Email: iris.vascocelos@govcv.gov.cv

CHINA / CHINE

Dr Xiumei LIU
Chief Scientist on Food Safety
National Institute of Nutrition and Food Safety
China CDC
No.7 Panjiayuan Nanli, Chaoyang District
Beijing 100021, China
Tel: 86-10-67770158
Fax: 86-10-67711813
Email: xmliu01@yahoo.com.cn

Ms Yang XIE
Ministry of Health
No. 1 Xizhimenwai Nanlu,
Beijing, 100044, China
Tel: 86-10-68792384
Fax: 86-10-68792387
Email: wsjdjc@126.com

Ms Jing TIAN
National Institute of Nutrition and Food Safety
China CDC
No.7 Panjiayuan Nanli, Chaoyang District
Beijing 100021, China
Tel: 86-10-67791259
Fax: 86-10-67711813
Email: tianjing960928@126.com

Ms Yuen- Sheung LEUNG
Superintendent (Import / Export)
Centre for Food Safety, FEHD HKSAR
43/F, Queens Way Government Offices
66 Queens Way, Hong Kong
Tel: (852) 28675532
Fax: (852) 25214784
Email: ysleung@fehd.gov.hk

Ms Ka Ming MA
Scientific Officer
Centre for Food Safety, FEHD HKSAR
43/F, Queens Way Government Offices
66 Queens Way, Hong Kong
Tel: 852- 28675147
Email: jkmma@fehd.gov.hk

CUBA

Dr Pastor Ponce CEBALLO
Investigador Titular
Director Laboratorio CENLAC
Centro Nacional de Sanidad Agropecuaria, CENSA
Carretera de Tapaste y 8 Vias. San Jose de las Lajas, La Habana, Cuba . Apdo Postal 10
Tel: 53-47863145
Fax: 53-47861104
Email: pponce@informed.sld.cu

Ms María Victoria Luna MARTÍNEZ
Presidenta del Comité Técnico de Normalización de Higiene de los Alimentos. J´ Dpto. Registro, Control y Calidad Sanitaria
Instituto de Nutrición e Higiene de los Alimentos.
Ministerio de Salud
Pública
Infanta No. 1158 e/ Clavel y Llinas. Ciudad Habana. Cuba.CP10300
Tel: (537) 8794165
Fax: (537) 8708947
Email: marvic@informed.sld.cu

DENMARK / DANEMARK / DINAMARCA

Ms Charlotte SPORON-FIEDLER
Veterinary Officer
Ministry of Family and Consumer Affairs
Danish Veterinary and Food Administration
Division for Microbiological Food Safety, Hygiene and Zoonoses Control
Morkhoj Bygade 19
DK-2860 Soborg
Tel: +45 33956121/ +45 33 95 60 00
Fax: +45 33956121
Email: **csf@fvst.dk**

Mr Jens Kirk ANDERSEN
Senior Adviser
Department of Microbiology and Assessment
National Food Institute
Technical University of Denmark
Morkhoj Bygade 19
DK-2860 Soborg
Tel: +45 72 34 6000
Email: jka@food.dtu.dk

DOMINICAN REPUBLIC / DOMINICANA REPUBBLICA / REPUBLIQUE DOMICICAINE

Prof. Ramon F. OZORIA
Coordinador de la Comisión de Investigación
Facultad de Ciencias de la UASD
Universidad Autónoma de Santo Domingo,UASD
Ciudad Universitaria, Santo Domingo, D. N
Tel**:** 809-763-5003
Fax: fax: 809-535-5221
Email: ozoria2000@hotmail.com.

ECUADOR/EQUATEUR

Dr Edison Fabian AYALA DE LA CUEVA
Tecnico de la Direccion de Vigilancia y Control Sanitario
Coordinador Alterno del subcomite del Codex Alimentarius sobre Higiene de los Alimentos
Ministerio de Salud Publica
Juan Larrea N-1447
Entre Checa y Riofrio Quito-Ecuador
Tel: 593-2-2972900/2771
Fax: 593-2-2541851
Email: eayala@msp.gov.ec

EUROPEAN COMMUNITY (MEMBER ORGANIZATION) / COMMUNAUTÉ EUROPÉENNE (ORGANISATION MEMBRE) / COMUNIDAD EUROPEA (ORGANIZACIÓN MIEMBRO)

Dr Jérôme LEPEINTRE
Head of Delegation
European Commission
Health and Consumer Protection Directorate
-General (SANCO)
B-1049 Brussels
Tel: +32-2-299 37 01
Fax: +32 2 299 85 66
Email: jerome.lepeintre@ec.europa.eu

Dr Ari HORMAN
European Commission
Directorate- General SANCO E2
B232 04/010
BE -1040 Brussels
Tel: +3222988543
Fax: +3222969062
Email: ari.horman@ec.europa.eu

FIJI

Mr Waisele DELAI
Chief Health Inspector
Ministry of Health, Fiji Government
P.O. Box 2223
Government Buildings
Suva, FIJI
Phone: (679)3306177
Fax: (679)3221434/3306163
Email: wdelai@health.gov.fj

FINLAND / FINLANDE / FINLANDIA

Dr Sebastian HIELM
Senior Health Officer
Ministry of Social Affairs and Health
P.O. Box 33
Government
FI-00023
Tel: 358-9-16074121
Fax: 358-9-16074120
Email: sebastian.hielm@stm.fi

FRANCE / FRANCIA

Dr Paul MENNECIER
Ministère de l'Agriculture et de la Pêche DGAl-SDSSA
251, rue de Vaugirard
F.75732 PARIS CEDEX 15
Tel : 331 49 55 84 18
Fax : +33 1 49 55 56 80
Email : paul.mennecier@agriculture.gouv.fr

Mr Pascal AUDEBERT
Point de Contact du Codex alimentarius en France
Premier Ministre Secretariat Auxa Affaires européennes (SGAE)
2, boulevard Diderot
F.75572 PARIS cedex 12
Tel : 33 1 44 87 16 03
Fax : 33 1 44 87 16 04
Email : sgae-codex-fr@sgae.gouv.fr

Dr Fransoise Thierry- BLED
Ministere de 1 Economie,
des Finances et de 1'' Emploi
Direction Generale de la Concurrence,
de la Consommation et de la Repression des Fraudes
Bureau C2-Securite et reseaux d alerte
59 Boulevard Vincent Auriol
F.75703 Paris Cedex 13
Tel: +33 1 44 97 32 07
Fax: +33 1 44 97 24 86
Email: francoise.thierry-bled@dgccrf.finances.gouv.fr

Ms Dominique BUREL
CNIEL
42, rue de Châteaudun
75314 PARIS CEDEX 09
France
Tel: 33 1 49 70 71 15
Fax: 33 1 42 80 63 45
Email: filfrance-alf@cniel.com

Dr Fabrice PELADAN
Docteur es Sciences
Responsible du groupe Risques Biologiques
Centre de Securite des Aliments
R.D. 128-91767
Palaiseau Cedex-France
Tel : 33(0)1 69 35 74 71
Fax :33(0)1 69 35 76 97
Email: fabrice.pealadan@danone.com

GERMANY / ALLEMAGNE / ALEMANIA

Dr Petra LUBER
Wiss. Referentin
Bundesamt fur Verbraucherschutz und Lebensmittelsicherheit (BVL)
Mauerstr 39-42
D-10117 Berlin
Germany
Tel: +49 30 18444 10618
Fax: +49 30 18444 10699
Email: petra.luber@bvl.bund.de

Dr Edda BARTELT
Veterinardirektorin
Niedersächsisches Landesamt für
Verbraucherschutz
und Lebensmittelsicherheit
Institut für Fischkunde Cuxhaven
Schleusenstraße 1
D-27472 Cuxhaven
Tel.: +49(0)4721-698913
Fax: +49(0)4712-698916
EMail: edda.bartelt@laves.niedersachsen.de

Dr Walter H. HEESCHEN
PROFESSOR, CONSULTANT
Verband der Deutschen Milchwirtschaft
e. V
German Dairy Association
Dielsweg 9 24105 KIEL
Germany
Tel: +49(0)431-34106
Fax: +49(0)431-338973
Email: heeschen@t-online.de

GHANA

Mr John ODAME-DARKWAH
Head Food Inspectorate
Food & Drug Board
PO Box CT 2783
Cantonment –Accra
Ghana
Tel: 233-21-673090
Fax: 233-21-779525
Email: jodamedarkwa@yahoo.co.uk

Dr Nicole AFFRIFAH
Regulatory Affairs Manager
Nestle Ghana Ltd
PMB Kia
ACCRA
Tel: +233-21-211876
Fax: +233-21-501196
Email: sharon.afrifah@gh.nestle.com

GREECE / GRÈCE / GRECIA

Mr Vasiliki GIANNOULI
Head of Food of Animal Origin Enterprises Control
Department
Hellenic Food Authority
Kifisias 124 & Iatridou 2 Avenue, Postal Number
11526
Athens, Greece
Tel: +30210 6971680
Fax: +302106971501
Email: vgiannouli@efet.gr

Mr Vasileios KONTOLAIMOS
Legal Advisor
Greek Ministry of Rural Development and Food
Acharnon 29
10439 Athens
GREECE
Tel: +302108250307
Fax: +302108254621
Email: cohalka@otenet.gr

GUATEMALA

Dr Guillermo BLANDING
Medico Veterinario
Comite Higiene de los Alimentos Codex
Coordinador Alimentarius
14 Ave 14-71 zona 10
Colonia Oakland
Guatemala CA
Tel: (502) 2368 1176
Fax: (502) 2333 46 17
Email: willie@intelnet.net.gt

HONDURAS

Dr Juan VELASQUEZ
Coordinador Divison Inocuidad de alimentos
SENASA-SAG
Apartado postal 309
Boulevard Miraflores
Tegucigalpa, Honduras
Tel: 00 504 232 6213
Fax: 00 504 231 0786
Email: Jvelasquez@senasa-sag.gob.hn

HUNGARY / HONGRIE / HUNGRÍA

Dr Maria Szeitzne SZABO
Director General
Hugarian Food Safety Office
Gyáli ut 2-6
H- 1097 Budapest
Hungary
Tel: +36 1 368 88 15
Fax: +36 1 387 94 00
Email: maria.szabo@mebih.gov.hu

INDIA / INDE

Mr R.K. CHAUDHRY
Director (Trade)
Department of Animal Husbandry, Fisheries and
Dairying
Ministry of Agriculture
Krishi Bhavan
New Delhi
Tel: 91 11 23 3 8 8534
Fax: 91 11 2 3388534
Email: diradmah@nic.in

Mr S. DAVE
Director
Agricultural and Processed
Food Products Exports, Development
Authority (APEDA)
NCUI Building
3 Siri Institutional Area
August Kranti Marg, Hauz Khas
New Delhi – 110016
Tel. +91 11 26516162
Fax. +91 11 26519259
Email: director@apeda.com

Dr D. CHATTOPADHYA
Assistant Director General (International Food)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhavan
New Delhi- 110011
India
Tel: 91 11 23061968
Fax: 91 11 23061083
Email: adg-mohfw@nic.in

Dr R. K. GUPTA
Assistant Commissioner (Trade),
Deptt. Of Animal Husbandry, Dairying and Fisheries,
Ministry of Agriculture,
Krishi Bhawan,
New Delhi
Tel: 91 11 23 3 8 8534
Fax: 91 11 2 3388534
Email: diradmah@nic.in

Mr Sunil BAKSHI
Senior Manager (International Projects),
National Dairy Development Board,
Anand 388001
Tel: 02690 226255
Fax: 02692-260157
Email: sbakshi@nddb.coop

Mr Aditya JAIN
Manager (International Projects),
National Dairy Development Board,
Anand 388001
Tel:02692 226256
Fax: 02692 260157
Email: aditya@nddb.coop

Dr S. C. KHURANA
Assistant Agriculture Marketing Advisor,
Directorate of Marketing Inspection,
Department of Agriculture & Cooperation
Ministry of Agriculture
C. G. O. Complex, NH 4,
Faridabad (Haryana) 121002
Tel: 91-0129-2415316
Email: khurana183@gmail.com

Ms Suneeti TOTEJA
Deputy Director,
Food and Agriculture Department,
Bureau of Indian Standards,
Bahadur Shah Zafar Marg,
New Delhi- 110002
Tel. 91 11 23231128
Fax. 91 11 23231128
Email: suneeti@bis.org.in

Mr Devendra PRASAD
Assistant General Manager
Agricultural and Processed
Food Products Exports, Development
Authority (APEDA)
NCUI Building
3 Siri Institutional Area
August Kranti Marg, Hauz Khas
New Delhi – 110016

Mr Sameer BARDE
Director,
FEDERATION OF INDIAN CHAMBER OF COMMERCE & INDUSTRY (FICCI)
Federation House, Tansen Marg,
New Delhi-110001
Tel: 011-23311920
Fax: 011-23320719
Email: sameer@ficci.com

Mr D. S. CHADHA
Senior Technical Advisor,
Confederation of Indian Industry,
The Mantosh Sondhi Center
Lodhi Road, 23, Institutional Area
New Delhi- 110003
Te: 011-24629994-7/011-24633461(D)
Fax: 011-24615693
Email: d.s.chadha@ciionline.org

Ms NEHA AGGARWAL
Executive (Food Regulatory Affairs)
Confederation Of Indian Industry (Cii),
The Mantosh Sondhi Center
23, Institutional Area, Lodhi Road,
New Delhi-110 003
Te: 91 11 24629994-7/24690715(D)
Fax: 91 11-24615693
Email: neha@ciionline.org

Ms Arti GUPTA
Research Associate
Confederation of Indian Food Trade and Industry (CIFTI),
Federation House,
Tansen Marg,
New Delhi-110001
Tel: 011-23736305
Fax: 011-23320714
Email: arti.cifti@ficci.com

IRAN (ISLAMIC REPUBLIC OF) / IRAN (RÉPUBLIQUE ISLAMIQUE D') / IRÁN (REPÚBLICA ISLÁMICA DEL)

Mr Seyed Abolghassem JAZAYERY
Professor of Nutrition
School of Public Health,
Tehran University of Medical Sciences
Ghods St., Enghelab Ave.,
P.O Box 14155-6446
Tehran, IRAN
Tel: +98 21-88 951404
Fax: +98 21-88 974462
Email: jazaiers@sina.tums.ac.ir

Mr Mohammadreza NOURBAKHSH
Regulatory Affairs Manager
Nestle Iran PJSCo
No 12, 21st Street, Khaled Eslamboli St
(Vozara) , Tehran, Iran
Tel: +98 21 88 729858
Fax: +98 21 88 550365
Email: mohammad.nourbakhsh@ir.nestle.com

IRELAND / IRLANDE / IRLANDA

Mr Kilian UNGER
Head of Delegation
Superintending Veterinary Inspector
Department of Agriculture Fisheries and Food
Agriculture House 6E
Kildare Street
Dublin 2
Phone: 353-1-6072844
Fax: 353-1-6072888
Email: Kilian.unger@agriculture.gov.ie

Mr Martin REA
Agriculture Inspector
Dept. of Agriculture & Fisheries and Food
3 C, Agriculture House
Kildare Street
Dublin 2
Tel: + 3531 607 2219
Fax: + 3531 607 2848
Email: martin.rea@agriculture.gov.ie

Dr Wayne ANDERSON
Chief Specialist of Food Science,
Food Safety Authority of Ireland, Block DEF,
Abbey Court,
Lower Abbey Street,
Dublin 1
Tel: 353 1 817300
Fax:353-1-817221
Email: wanderson@fsai.ie

ITALY / ITALIE / ITALIA

Ms Monica GIANFRANCESCHI
Instituto Superiore Sanita
National Center for Food Quality and risk Assessment
Tel: (39) 064990 2319
Fax: (39) 0649387101
Email: monica.gianfranceschi@iss.it

Ms Laura TOTI
Head of Unit
Instituto Superiore Sanita
National Center for Food Quality and risk Assessment
Tel: (39) 0649902779
Fax: (39) 064990 2045
Email: toti@iss.it

Ms Brunella LO TURCO
Codex Alimentarius Contact Point
Ministry of Agriculture
Via XX Settembre 20
00100 Rome
Tel: (39) 06446656042
Fax: (39) 064880273
Email: b.loturco@politicheagricole.it

IVORY COAST/COTE D IVOIRE

Dr Narcisse EHOUSSOU
Vice President
Chambre de Commerce et D'Industrie
President du Comite
National du Codex Alimentarius
De Cote D'Ivoire
20 BP 211 Abidjan 20
Rue Paul Langevin Prolongee
Zone 4 C, Marcory, Abidjan
Tel: (225)21 35 33 49/ (225) 01 01 55 96
Fax: (225) 21 35 33 50
Email: narcehoussou@yahoo.fr

Dr Souleymane BAKAYOKO
Conseiller technique
Ministere du Commerce
01 BP 490 Abidjan 01
Tel: (+225) 22 43 04.25//01 00 70 06
Fax: (+225) 20 21 91 72/20 21 75 47
E-mail: bsouley@hotmail.com

Mr Yapi Georges KOUASSI
Charge d Etudes
Ministere du Commerce
01 BP 938 Abidjan 01
Tel: (+225) 07 65 31 33
Fax: (+225) 20 21 91 72/20 21 75 47
Email: georgesyapi@yahoo.fr

JAMAICA / JAMAÏQUE

Dr Wintorph MARSDEN
Senior Veterinary Officer
Veterinary Services Division
Ministry of Agriculture and Lands
193 Old Hope Road
Kingston 6
Jamaica
Tel: 876-977-2492
Fax: 876-977-0885
Email: wfmarsden@moa.gov.jm

Dr Linnette PETERS
Policy & Programme Director,
Veterinary Public Health, Ministry of Health
2-4 King Street Kingston, Jamaica
Tel: 876-967-1100
Fax: 876-967-1280
Email: murray-petersl@motl.gov.jm

Mr Donald HINDS
Senior Food Storage Scientist
Microbiology
Ministry of Commerce, Science and Technology,
Food Storage and Prevention of Infestation
Division
15 Gorden Town Road, Kingston, 6
Jamaica
Tel: (876) 927-1929-30, 977-6816-20
Fax: (876) 977-7515
Email: microb@cwjamaica.com

JAPAN / JAPON / JAPÓN

Dr Chieko IKEDA
Director
Office of International Food Safety
Policy Planning and Communication Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki
Chiyoda-ku,Tokyo 100-8916
Japan
Tel: +81 3 3595 2326
Fax: +81 3 3503 7965
Email: codexj@mhlw.go.jp

Mr Yuka HAGINO
Technical Official
Food Safety Commission, Secretariat,
The Cabinet Office, Japan
6F Prudential Tower, 2-13-10,
Nagata, Chiyoda-ku
Tokyo
Tel: +81-3-5251-9218
Fax: +81-3-3591-2236

Dr Hajime TOYOFUKU
Senior Researcher
National Institute of Health Sciences
1-18-1 Kamiyouga, Setagaya-ku
Tokyo, 158-8501 Japan
Tel: +81-3-3700-1403
Fax: +81-3-3700-1483
Email: toyofuku@nihs.go.jp

Mr Yuichiro EJIMA
Assistant Director
Standards and Evaluation Division Dept. of Food
Safety
Ministry of Health, Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda,
Tokyo, 100-8916 Japan
Tel: +81-3-3595-2341
Fax: + 81-3-3501-4868
Email: codexj@mhlw.go.jp

Dr Mina KOJIMA
Section Chief
Inspection and Safety Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health Labour and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku,
Tokyo 100-8916, Japan
Tel: +81-3-3595-2337
Fax: +81-3-3503-7964
Email: codexj@mhlw.go.jp

Mr Akira HIRAO
Officer
Office of International Food Safety
Policy Planning and Communication Division
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health Labour and Welfare
1-2-2 Kasumigaseki Chiyoda-ku,
Tokyo 100-8916, Japan
Tel: +81-3-3595-2326
Fax: +81-3-3503-7965
Email: codexj@mhlw.go.jp

Dr Yayoi TSUJIYAMA
coordinator, Risk and Crisis Management
Food Safety and Consumer Policy Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture
Forestry and Fisheries
1-2-1 Kasumigaseki, Chiyoda-
Tokyo 100-8950, Japan
Tel: +81 3 3502 5722
Fax: +81 3 3597 0329
Email: yayoi_tsujiyama@nm.maff.go.jp

Dr Yoshimasa SASAKI
Microbiological Specialist
Food Safety and Consumer Policy Division
Food Safety and Consumer Affair Bureau,
Ministry of Agriculture, Forestry and Fisheries
1-2-1, Kasumigaseki,
Chiyoda-ku, Tokyo 100-8950
Japan
Tel: +81-3-3502-5722
Fax: +81-3-3597-0329
Email: yoshimasa_sasaki@nm.maff.go.jp

KENYA

Dr Moses GICHIA
Assistant Director of Veterinary Services
Department of Veterinary Services
Vet Research Laboratories
P.O. Box 00625 Kangemi Nairobi
Tel: 254202700575, 254724166421
Fax: 25420631273
Email: medwrin@yahoo.com

Ms Rosemary Njeri NGANGA
Chief Analytical Chemist
Kenya Plant Health Inspectorate Services
Box 49592- 00100 NAIROBI,
KENYA
254-020-3536171
Email: rnganga@kephis.org

Mr Charles NKONGE
Programme Officer
Kenya Agricultural Research Institute
PO Box 57811
Tel: 0722-327936
NAIROBI
Email: cnkonge@kari.org

Ms Victoria MUTUNGWA
Del Monte Kenya Ltd
Quality Control Manager
PO Box 147, Thika
Kenya
Tel: 2546724029
Email: vutungwa@delmonte.co.ke

Mr Peter MUTUA
Standards Officer
Kenya Bureau of Standard
PO Box 54974-00200
NAIROBI
Tel: 25420605455
Email: mutuap@kebs.org

KIRIBATI

Mr Tianuare TAEUEA
Chief Health Inspector
Ministry of Health
P.O. Box 268
Tarawa, Kiribati
Tel: 686 28100
Fax: 686 28152
Email: mhtp@tskl.net.ki

LAO PEOPLE'S DEMOCRATIC REPUBLIC / RÉPUBLIQUE DÉMOCRATIQUE POPULAIRE LAO / REPÚBLICA DEMOCRÁTICA POPULAR LAO

Ms Viengxay VANSILALOM
Deputy Head of Food Control Division
Ministry Of Health
Simuang Rd - Vientiane 01000
LAO PEOPLE'S DEM REP
Telephone No. : +8562121404304
Fax No. : +85621214015
Email : vsysanhouth@yahoo.com

MADAGASCAR

Mr Ratahinjanahary Nirina SITEFANA
Direction de la Qualite et de la Protection des Consommateurs
Ministre de L'Economie du Plan du Secteur Prive et du Commerce
Lot II J 145 Bis IVANDRY
Antananarivo (101)
Tel: 261 32 40 962 93
Email: rtahina2001@yahoo.fr

MALAYSIA / MALAISIE / MALASIA

Dr Azriman ROSMAN
Senior Principal Assistant Director
Food Safety and Quality Division
Ministry of Health,
Malaysia
Level 3 Block E7, Federal Administrative Building
Putrajaya 62590
Tel: 603-8883-3512
Fax: 603-8889-3815
Email: azriman@moh.gov.my

Prof Son RADU
Department of Food Science & Technology
University Putra Malaysia
43400 UPM Serdang
Selargor, Malaysia
Tel: 603 89468361
Fax: 603 89423552
Email: son@putra.upam.edu.my

MALI / MALÍ

Mr Mohamed Bakary DIARRA
Directeur Normes Alimentaire representation zone sahel/Nestle/Mali
Nestle/ membre du Comite National du Codex
BP E3414, Bamako, Niarela,
Derriere Etablissement Pere Michel
Tel: (00223) 221 01 53/920 46 06
Fax: (00223) 221 15 80
Email: Mohamed.Diarra@ml.nestle.com

MALAWI

Ms Elizabeth Chimwemwe THOMO
Standards Officer
Malawi Bureau of Standards,
PO Box 946
Blantyre, Malawi
Tel: +265 1 870 488, +265 8 893 318
Fax: +265 1 870 756
E-mail: mbs@mbsmw.org

MEXICO / MEXIQUE / MÉXICO

Mr José Noe Lizarraga-CAMACHO
Subdirector Ejecutivo de Dictamen Sanitario de Productos y Servicios,
Uso y Publicidad
Comisión Federal para la Protecciôn contra Riesgos, Sanitarios
Monterrey No. 33 Piso 3 Col. Roma
Delegación Cuauhtemoc C.P.. _ 06700
Tel: +52 55 50 80 5258
Fax: +52 55 50805200 Ext. 1150
Email: nlizarra@salud.gob.mx

Dr Juan Leos – RODRÍGUEZ
Profesor
Universidad Autónoma Chapingo
KM 38.5 Carretera México-Texcoco
Chapingo, México 56230
Tel: +595 95 216 68
Fax: +595 95 216 68
Email: jleos45@gmail.com

MOROCCO / MAROC / MARRUECOS

Mr Mohammed El HIMANI
Minister & Deputy Head of Mission
Embassy of the Kingdom of Morocco
GSM 981806888

NAMIBIA / NAMIBIE

Ms Mooy IITAMALO
Ministry Of Health, Food Quality Assurance Programe
Tel: 061-2032768
Fax : 061-234083

NEPAL

Mr Uttam Kumar BHATTARAI
Director General
Department of Food Technology and Quality Control
P.O Box 21265, Babarmahal
Kathamandu, Nepal
Tel: 00977 1 4262430
Fax: 00977 1 4262337
Email: dgdftqc@mail.com.np

NETHERLANDS / PAYS-BAS / PAÍSES BAJOS

Inge STOELHORST
Public Health Officer
Ministry of Health, Welfare and Sport
Parnassusplein 5
2500 EJ The Hague
Netherlands
Tel : +31 70 340 5658
Fax : +31 70 340 5554
Email : i.stoelhorst@minvws.nl

Enne De BOER
Senior Scientist
Food and Consumer Product Safety Authority
P.O. Box 202
7200 AE Zutphen
The Netherlands
Tel : 575 5 88100
Fax : 575 5 88200
Email : enne.de.boer@vwa.nl

NEW ZEALAND / NOUVELLE-ZÉLANDE / NUEVA ZELANDIA

Dr Steve HATHAWAY
Director (Science)
New Zealand Food Safety Authority
NZFSA, 86 Jervois Quay
Telecom House, South Tower
Post Code 6140
New Zealand
Tel : (64) 29 894 2519
Fax : (64) 6 868 5201
Email : steve.hathaway@nzfsa.govt.nz

Ms Judi LEE
Principal Advisor (Risk Management)
New Zealand Food Safety Authority
South Tower,
86 Jervois Quay
PO Box 2835
Wellington 6001
New Zealand
Tel : 64 4 894 2522
Fax : 64 4 894 2643
Email : judi.lee@nzfsa.govt.nz

Dr Scott CRERAR
Assistant Director (Technical Standards)and
New Zealand Standards
New Zealand Food Safety Authority
NZFSA, 86 Jervois Quay
Telecom House, South Tower
Post Code 6140
New Zealand
Tel : 64 4 894 2401
Fax :64 4 894 2643
Email : scott.crerar@nzfsa.govt.nz

NICARAGUA

Ms Clara Ivania SOTO ESPINOZA
Resp Vigilancia Sanitaria
Ministerio de Salud
Apto # 106, Contiguo a la colonia
Primero de Mayo
Tel: (505)2894717
Fax: (505)2894839
E-mail: eta@minsa.gob.ni

NIGERIA

Dr Yaya Adisa Olaitan OLANIRAN
Permanent Representation of the Federal Repubic
of Nigeria to Rome-Based UN Agencies
Embassy of Nigeria
Via Cassiodoro 21C
00193 Rome Italy
Tel: +39 06 6896093
Fax: +39 06 6877840
Email: nigeriapermrep@email.com

NORWAY / NORVÈGE / NORUEGA

Dr Bjorn GONDROSEN
Senior Adviser
Norwegian Food Safety Authority, Head Office
PO Box 383
N-2381 Brumundal
Norway
Tel : 47-23-21-67-85
Fax: 47-23-21-68-01
Email: bjorn.gondrosen@mattilsynet.no

PANAMA

Ms Aracelis DE VERGARA
Ingeniero Agronomo/Supervisora de Plantas
Ministerio de Salud
Departamento de Proteccion de Alimentos (DEPA)
Ministerio de Salud
Ministerio de Salud dificio 253 Ancon
P.O Box 813-0023 Panama
Tel: (507) 512-9180
Fax: (507)512-9114
Email: aracelisdv@hotmail.com

PERU / PÉROU / PERÚ

Ms Paola Aurora FANO CASTRO
Encargado del Area de Higiene de los Alimentos
Dirección General de Salud Ambiental – DIGESA
Calle Las Amapolas 350 Urb. San Eugenio Lince
Lima 14
Tel: (511)4428353 Ax 126
Fax: (511)4428353 Ax 204
Email: pfano@digesa.minsa.gob.pe

PHILIPPINES / FILIPINAS

Ms Almueda C. DAVID
Food-Drug Regulation Officer IV
Bureau of Food and Drugs
Civic Drive, Filinvest Corporate City,
Alabang, Muntinlupa City 1781
Philippines
Tel/Fax: +632-842 46 25
Email: acdavid24@yahoo.com

Ms Consuelo C. BALTAZAR
Head, Administrative Support and Product
Certification Unit
Bureau of Fisheries and Aquatic Resources
PCA Compound, Elliptical Road
Diliman, Quezon City
Philippines 1101
Tel: +63 2 929 3965
Fax: +63 2 929 3965
Email: cbaltazar2005@yahoo.com

Ms Fleda L. PAGUIRIGAN
Sr. Science Research Specialist
PQCRD, Philippine Coconut Authority
Diliman, Quezon City
Philippines 1101
Tel: +63-2-9284501/09
Fax: +63-2-9267631
Email: flpaguirigan008@yahoo.com.ph

PORTUGAL

Prof Fernando BERNARDO
Deputy CVO
Direcção Geral de Veterinária
Largo da Academia das Belas Artes,
21249 – 105 Lisboa
Portugal
Tel: 00351213239500
Fax: 00351213463518
Email: subdirgeral@dgv.min-agricultura.pt

Dr Miguel Oliveira CARDO
Head of Veterinary Public Hygiene Service
Direcção Geral de Veterinária
Largo da Academia das Belas Artes,
21249 – 105 Lisboa
Portugal
Tel: 00351213239500
Fax: 00351213463518
Email: miguelcardo@dgv.min-agricultura.pt

KOREA, REPUBLIC OF / CORÉE, REPUBLIQUE DE / COREA, REPÚBLICA DE

Mr In Gyun HWANG
Deputy Director
Korea Food & Drug Administration
194 Tongil-ro Eunpyung-gu
Seoul, 122-704, Korea
Tel: 82-2-380-1682
Fax: 82-2-355-6036
Email inghwang@kfda.go.kr

Ms Eun Jung KIM
Assistant Director
Korea Food & Drug Administration
194 Tongil-ro Eunpyung-gu
Seoul, 122-704, Korea
Tel: 82-2-380-1727
Fax: 82-2-388-6396
Email: atpoint@kfda.go.kr

Ms Mee Hyun CHO
Senior Researcher
Korea Food & Drug Administration
194 Tongil-ro Eunpyung-gu
Seoul, 122-704, Korea
Tel: 82-2-380-1635
Fax: 82-2-352-9444
Email: myunee81@kfda.go.kr

Mr Byoung Gon JEONG
Senior Veterinary Officer
National Veterinary Research & Quarantine Service
480 Anyang 6-dong, Manan-gu
Anyang city, Gyeonggi Province
Post code: 430-824
Tel: 82-31-467-1962
Fax: 82-31-467-1974
Email: jbgon@nvrqs.go.kr

Ms Young Jo KIM
Veterinary Officer
National Veterinary Research & Quarantine Service
480 Anyang 6-dong, Manan-gu
Anyang city, Gyeonggi Province
Post code: 430-824
Tel: 82-31-467-1993
Fax: 82-31-467-1989
Email: fmd2000@nvrqs.go.kr

ROMANIA / ROUMANIE / RUMANIA

Dr Csutak nagy LASZLO
vice president-state sub secretary
national sanitary veterinary and food safety authority
bucharest, 2 sector
1b negustori street
romania
Tel : (40) 213072399
Fax : (40) 213124967
Email : **csutak-saloj@ansv.ro**

SOLOMON ISLANDS

Ms Ethel MAPOLU
Health Inspector Food Safety
Environmental Health Division
Ministry of Health and Medical Services
P.O. Box 349
Honiara
Tel : +677 28166
Fax : +677 25513
Email: emapolu@moh.gov.sb

SPAIN / ESPAGNE / ESPAÑA

Ms Maria Luisa Aguilar ZAMBALAMBERRI
Jefe Servicio de Riesgos Biologicos
Agencia Espanola de la Seguridad Alimentaria y Nutricion
C/Alcala 56
28071 Madrid
Tel (+34)91 33 80 429
Fax: (+34) 91 33 80 169
Email: maguilar@msc.es

Mr Carmen Suarez GONZALO
Tecnico Superior
Agencia Espanola De Seguridad Alimentaria y Nutricion
C/ Alcala. 56
28071 Madrid
Espana
Tel. +34 91 338 07 38
Fax: +34 91 338 01 69
Email: csuarezg@msc.es

SRI LANKA

Mr Premasiri MADARASINGHE
Assistant Director
Food Control Administration Unit (FCAU)
Ministry of Health
Baddegama, Wimalwansahimi Mawatha
Colombo 10
Sri Lanka
Tel: 011-2672073
Fax: 011-2675526
E-mail: fdienfor@yahoo.com

SUDAN / SOUDAN / SUDÁN

Osama A.A. BARI
3 Shanti Path
Chanakyapuri
New Delhi

SWEDEN / SUÈDE / SUECIA

Ms Kerstin JANSSON
Deputy Director
Ministry of Agriculture,
SE-103 33 Stockholm
Sweden
Tel. 08-405 11 68
Fax: 08-2064 96
Email: kerstin.jansson@agriculture.ministry.se

Mr Lars PLYM-FORSHELL
Assistant Chief Veterinary Officer
National Food Administration
Box 622
SE-751 26 Uppsala
Sweden
Tel. +46 18 17 55 82
Fax: +46 18 10 58 48
Email: lapl@slv.se

SWITZERLAND / SUISSE / SUIZA

Ms Christina Gut SJOEBERG
Food Engineer ETH
Swiss Federal Office of Public Health
Consumer Protection Directorate ,
Food Safety Division
Schwarzenburgstrasse 165
BERN CH-3003
Tel : 41-31-322-68-89
Fax: 41-31-322-95-74
Email: christina.gut@bag.admin.ch

Mr Jean A. VIGNAL
Regulatory Affairs
NESTEC S.A
Avenue Henri Nestle, 55
Vevey CH-1800
Tel : 41-21-924-35-01
Fax: 41-21-924-45-47
Email: jean.vignal@nestle.com

SYRIA ARAB REPUBLIC/ REPUBLIQUE ARABE SYRIENNE/ REPUBLICA ARABE SIRIA

Mr Abdulrazzak AL HOMSI AJJOUR
Director of Alimentary Department at SASMO
SASMO Syrian Arab Organization for
Standardization and Metrology
Damascus, PO Box. 11836-Syria
Tel: +963 114529825-3
Fax: +963 114528214
E-mail: sasmo@net.sy

Mr Mounes Al SAWADI
Regulatory Affairs Officer
Chamber of Industry
Damascus P.O Box 9444
Sayria
Tel: +963 11 6831501
Fax: +963 11 6831505
Email: mounes7@gmail.com

TANZANIA

Mrs Theresia Hubert
Principal Standards Officer
Tanzania Bureau Of Standards
P.O Box 9524
Dar-Es-Salaam
Tanzania
Tel general: +255 22 2450206
+255 22 2450949
Fax: +255 22 2450959
Cell/Mobile: +255 71 3319981
Email: siargicha2001@yahoo.co.uk

THAILAND / THAÏLANDE / TAILANDIA

Mr Pisan PONGSAPITCH
Standards Officer
National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
Rajadamnern Nok Ave.
Bangkok, 10200 Thailand
Tel: 66 2- 2803887
Fax: 66-2-2803899
Email: pisanp@yahoo.com

Ms Suree WONGPIYACHON
Senior Public Health Technical Officer
Food and Water Sanitation Division
Department of Health
Ministry of Public Health
Tiwanon Rd., Nonthaburi 11000
Tel: 662 590 4184
Fax: 662 590 4186
Email: suree@anamai.moph.go.th

Dr Suwimon KEERATIPIBUL
Associate Professor
Food Industry Group, The Federation of Thai Industries
Department of Food Technology
Faculty of Science, Chulalongkorn University
Phyathai Road, Bangkok 10330
Thailand
Tel: 662-2185515
Fax: 662 2544314
Email: Suwimon.K@chula.ac.th

TUNISIA / TUNISIE / TUNEZ

MABROUK NEDHIF
Director of Hygiene and Environment Protection
Ministry of Public Health
Bab Saadoun Tunis
Tel: 0021671576115
Fax: 0021671576010
Email: mabrouk.nedhif@rns.tn

TURKEY / TURQUIE / TURQUÍA

Ms Pinar KALGAY
Veterinarian
Ministry of Agriculture and Rural Affairs
General Directorate of Protection and Control
Tarim ve Koyisleri Bakanligi
Koruma ve Kontrol Genel Mudurlugu
Akay Cad. No.3 Bakanliklar
Ankara/Turkey
Tel: +90-312-4174176 exp 6212
Fax: +903124254416
Email: pinark@kkgm.gov.tr

UGANDA / OUGANDA

Prof George William NASINYAMA
Deputy Director, Research
Makerere University
School of Graduate Studies, Rm 413, Makerere University, P.O. Box 7062, Kampala, Uganda
Tel: 256-41 530 983
Fax: 256-41 533 809
Email: nasinyama@vetmed.mak.ac.ug
gnasinyama@yahoo.com

UNITED KINGDOM / ROYAUME-UNI / REINO UNIDO

Mr Chris PRATT
Head of Delegation
Head of Hygiene Policy and Legislation Unit
Food Standards Agency
Aviation House
125 Kingsway
London WC2B 6NH
Tel : +44 (0)20 7276 8982
Fax: +44 (0) 20 7276 8910
Email: chris.pratt@foodstandards.gsi.gov.uk

Mr Kevin WOODFINE
Head of General Food Hygiene & Egg Products Branch
Food Standards Agency
Aviation House
125 Kingsway
London WC2B 6NH
Tel : +44 (0) 207 276 8964
Fax: +44 (0) 207 276 8908
Email: kevin.woodfine@foodstandards.gsi.gov.uk

Dr Paul COOK
Head of Foodborne Diseases Branch
Food Standards Agency
Aviation House
125 Kingsway
London WC2B 6NH
Tel : +44 (0) 207 276 8950
Fax: +44 (0) 207 276 8907
Email: paul.cook@foodstandards.gsi.gov.uk

UNITED REPUBLIC OF TANZANIA / RÉPUBLIQUE-UNIE DE TANZANIE/ REPÚBLICA UNIDA DE TANZANÍA

Ms Theresia HUBERT
Principal Standards Officer
Tanzania Bureau of Standards
POBox. 9524
Dar Es Salaam
TANZANIA
Tel: 255 22 2450206
Fax :255 22 245 0959
Email: siangicha2001@yahoo.co.uk

UNITED STATES OF AMERICA / ÉTATS-UNIS D'AMÉRIQUE / ESTADOS UNIDOS DE AMÉRICA

Dr Robert BUCHANAN
Senior Science Advisor
US Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
Tel : 301-436-2369
Fax : 301-436-2642
Email: Robert.Buchanan@fda.hhs.gov

Dr Rebecca BUCKNER
Science Policy Analyst
US Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
Tel : 301-436-1486
Fax : 301-436-2632
Email: Rebecca.Buckner@fda.hhs.gov

Dr Kerry DEARFIELD
Scientific Advisor for Risk Assessment
US Department of Agriculture
Food Safety and Inspection Service
1400 Independence Ave SW
380 Aerospace Building
Washington, DC 20250
Tel : 202-690-6451
Fax : 202-690-6337
Email: kerry.dearfield@fsis.usda.gov

Dr Catherine CHESNUTT
International Trade Specialist /AAAS Fellow
U.S. Department of agriculture
Foreign Agricultural Service,
Office Of Scientific And Technical Affairs
International Relations And Standards Division
1400 Independence Ave, SW Room . 5544
Washington, D.C. 20250-1027
Tel: 202-720-9444
Fax: 202-690-0677
Email: Catherine.Chesnutt@fas.usda.gov

Ms Barbara MCNIFF
Director, Codex Programs Staff
U.S. Department of Agriculture
Food Safety and Inspection Service
Office of International Affairs
1400 Independence Ave, SW
Washington, D.C. 20250
Tel: 202-690-4719
Email: Barbara.Mcniff@fsis.usda.gov

Mr Daniel A. MARCH
Director, Food Safety
Mead Johnson Nutritionals
2400 W. Lloyd Exp.
Evansville, IN 47721
Tel: 812-429-5402
Fax: 812-647-8770
Email: daniel.march@bms.com

Dr Brian Shawn EBLEN
Senior Scientist
Food and Chemicals Practice Exponent
4901 Telsa Drive, Suite L
Bowie, MD 20715
Tel : 301-464-4064
Fax: 301-464-4099
Email: beblen@exponent.com

Dr Karl E. OLSON
Manager, Microbiology and Sterilization Technology
Abbott Nutrition
3300 Stelzer Road
Columbus, OH 43219-3034
Tel : 614-624-7040
Fax : 614-727-7040
Email: karl.olson@abbott.com

Ms Jenny SCOTT
Vice President, Food Safety Programs
Grocery Manufacturers / Food Products Association
1350 I St. NW, Suite 300
Washington, DC 20005
Tel : 202-639-5985
Fax : 202-639-5991
Email: jscott@gmaonline.org

VIETNAM

Nguyen Duc HUNG
Vice Director
National Fisheries Quality Assurance & Veterinary Directorate Branche 4
30 Ham Nghi, District 1-Ho chi Minh City
Tel: 84 089 1426162
Fax: 84 088 2122613
Email: hungkinh@pmail.vnn.vn

Trannguyen Hoa WONG
Officer
Vietnam Food Administration –MOH
138[A] Giang Vo, Hanoi, Vietnam
Tel: 84-4-8464489
Fax: 84-4-8463739
Email: hoacuongtean@yahoo.com.vn

ZAMBIA / ZAMBIE

Ms Gladys Chirwa KABAGHE
Nutritionist food Quality
National Food and Nutrition Commission
P.O Box 32669
Lusaka, Zambia
Tel: 260 1 227803
Fax: 260 1 221426
Email: kabaghe@nfnc-gain.co.zm

Ms Magaret LWENJE LUNGU
Zambia Bureau Of Standards
P. O. Box 50259
Lechwe House Freedomway, Southend.
LUSAKA
ZAMBIA
Tel : +260 1 227075
Fax: 260 1 238483
Email : margiellungu@yahoo.com

ZIMBABWE

Mr Kudakwashe Sheperd NDORO
Commercial Farmers Union
PO Box WGT390
Westgate Harare
Zimbabwe
Tel: +263 4 309800, +263 91-2243706
Fax: +263 4 309849
Email: kudandoro@cfu.co.zw

Mr Chinyavanhu FREDY
Deputy Chief Gvt Analyst Food Control
Ministry of Health and Child Welfare
P.O. Box CY 231
Cause Way, Harare
Tel: 263-4792026/7
Email: fchinyavanhu@healthnet.org

UNITED NATIONS AND SPECIALIZED AGENCIES/ NATIONS UNIES ET INSTITUTIONS SPÉCIALISÉES / NACIONES UNIDAS Y ORGANISMOS ESPECIALIZADAS

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Dr Maria de Lourdes COSTARRICA
Senior Officer, Food Quality and Standards Service
Nutrition and Consumer Protection Division
Food and Agriculture Organization of the United Nations
V. le delle Terme di Caracalla
00153 Rome
Italy
Tel: +39 06 5705 6060
Fax: + 39 06 5705 4593
Email: lourdes.costarrica@fao.org

Dr Sarah CAHILL
Nutrition Officer (Food Microbiology)
Nutrition and Consumer Protection Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel : 39-06-5705-3614
Fax: 39-06-5705-4593
Email: sarah.cahill@fao.org

WORLD HEALTH ORGANIZATION (WHO)

Dr Peter Karim BEN EMBAREK
Scientist, food microbiology
Department of Food Safety, Zoonoses and Foodborne diseases
Environment And Healthy Security
Tel: +41227914204
Operator: + 41227912111
Fax: +41227914807
Mobile: +41794673538
Email: benembarekp@who.int

Ms Jenny BISHOP
Scientist,
Department of Food Safety,
Zoonoses and Foodborne diseases
20, Avenue Appia, 1211 Geneva 27
Switzerland
Tel: +41 22 791 14 34
Mobile: +41 79 832 38 35
Fax: +41 22 791 48 07
Email: bishopj@who.int

INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS / ORGANISATIONS NONGOUVERNEMENTALES INTERNATIONALES / ORGANIZACIONES INTERNACIONALES NO GUBERNMENTALES

ASOCIACIÓN LATINO AMERICANA DE AVICULTURA (ALA)

Mr J. Isidro MOLFESE
ALA Codex Observer
ALA – Asociación Latinoamericana de Avicultura
Arce 441-3F
C1426BSE Buenos Aires
Republica Argentina
Tel: 54 11 4774-4770
Cell: 54 9 11 4539 2595
Email: avicolatina@ciudad.com.ar

INTERNATIONAL ASSOCIATION OF CONSUMER FOOD ORGANIZATIONS (IACFO)

Ms Caroline Smith DEWAAL
Director, Food Safety
Center for Science in the Public Interest (CSPI)
1875 Connecticut Ave., NW
Suite 300
Washington, D.C. 20009
Tel : 202 777-8366
Fax : 202 265-4954
Email cdewaal@cspinet.org

INTERNATIONAL BABY FOOD ACTION NETWORK (IBFAN)

Ms Elisabeth STERKEN
Executive Director
Infact Canada
6 Trinity Square
Toronto ON M5G 1B1
Tel: 416-595-9819
Email: esterken@infactcanada.ca

INTERNATIONAL FEDERATION OF AGRICULTURAL PRODUCERS (IFAP)

Ms Fhumulani MASHAU
International Federation of Agricultural Producers
60 rue St Lazare, 75009 Paris, France
Tel : +33.1.45.26.05.53
Fax : +33.1.48.74.72.12
Email : fmashau@sacau.org

INTERNATIONAL DAIRY FEDERATION/ FÉDÉRATION INTERNATIONALE DE LAITERIEFEDERATIÓN INTERNACIONAL DE LECHERÍA (FIL/IDF)

Mr Claus HEGGUM
Chief Consultant
Danish Dairy Board
Frederiks Allé 22, 8000 Aarhus C
Denmark
Tel.: +45 87 31 21 98
Fax: +45 87 31 20 01
Email: ch@mejeri.dk

Mr Jöerg SEIFERD
Technical Director
International Dairy Federation
Diamant Building
Boulevard Auguste Reyers, 80
1030 Brussels
Belgium
Tel : +32 2 733 98 88
Fax : +32 2 733 04 13
Email : jseifert@fil-idf.org

Dr Robin CONDRON
Manager Research & Development - Consumer and Market Assurance Division
Dairy Australia
Locked Bag 104 Flinders Lane
Victoria 8009
Australia
Tel.: +61 3 9694 3831
Fax: +61 3 9694 3833
Email: RCondron@dairyaustralia.com.au

INTERNATIONAL FEDERATION OF ENVIRONMENTAL HEALTH (IFEH)

Ms Jenny MORRIS
Chartered Environmental Health practitioner
Policy Officer
Chadwick Court
15 Hatfields, London , SE1 8DJ
Tel: 44(0)20 7827 5835
Fax: 44(0)20 7827 6322
Email: j.morris@cieh.org

Prof Eunice TAYLOR
Centre Director
International Centre for HACCP Innovation
Salford Business School
Room No. 635, Maxwell Building
University of Salford
Salford, Greater Manchester
England M5 4WT
Tel: 0161 295 5107
Fax: 07979 700756
Email: e.taylor@salford.ac.uk

INTERNATIONAL COUNCIL OF BEVERAGES ASSOCIATIONS (ICBA)

Mr Adsule SUNIL
Enkay Towers
Udyog Vihar Phase V
Gurgaon, Haryana 122106
India
Tel: 91-124-234-8660
Email: sadsule@apac.ko.com

INTERNATIONAL SPECIAL DIETARY FOODS INDUSTRIES (ISDI)
FÉDÉRATION INTERNATIONALE DES INDUSTRIES DES ALIMENTS DIÉTÉTIQUES

Ms Amandine DEVERGIES
194 rue de Rivoli
75001 Paris
Email: andree.bronner@isdifederation.org

INTERNATIONAL COMMISSION ON MICROBIOLOGICAL SPECIFICATIONS FOR FOODS (ICMSF)

Dr Leon GORRIS
Prof., Head of the Delegation
Senior Scientist
Unilever
Address: Colworth Science Park, Sharnbrook, K44 1LQ, United Kingdom
Tel : +44 1234 264798
Fax : +44 1234 264929
Email : Address: Leon.Gorris@Unilever.com

INTERNATIONAL LACTATION CONSULTANT ASSOCIATION (ILCA)
ASSOCIATION INTERNATIONALE DES CONSULTANT(E)S EN LACTATION

Ms Maryse ARENDT
Initiativ Liewensufank
20 rue de Contern
L 5955 Itzig
Luxemburg –Europe
Tel: +352 360597
Fax: +352 366134
Email: info@liewensufank.lu

INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)

Mr D.H. Pai PANANDIKER
Chairman, ILSI India
First Floor, Y 40 B, Hauz Khas
New Delhi, 110016 India
Fax: 91-11-2696-8752/91-11-26523477/
91-11-26853056
Email: ilsiindia@nda.vsnl.net.in;

Mr Rekha SINHA
Executive Director, ILSI India
First Floor, Y 40 B, Hauz Khas
New Delhi, 110016 India
Fax: 91-11-2696-8752/91-11-26523477/
91-11-26853056
Email: ilsiindia@mda.vsnl.net.in

Ms Shilpa AGRAWAL
Associate Manager – Scientific Regulatory Affairs
Coca-Cola India
Enkay Towers, Vijaya Nikunj
Udyog Vihar, Phase-5
Gurgaon-122106
Haryana, India
Tel : 91-0124-2348041, Ext.: 1531
Email: shagrawal@apac.ko.com

Dr Bizhan POURKOMAILIAN
Senior Food Safety Manager
McDonald's Europe
Quality Assurance Europe
11-59 High Road, East Finchley
London N2 8AW
United Kingdom
Tel: 44-20-8272-5198
Fax: 44-20-8700-7069
Email: Bizhan.Pourkomailian@uk.med.com

INDIAN SECRETARIAT

Dr D. CHATTOPADHYA
Assistant Director General (International Food) and Nodal Officer National Codex Contact Point and SPS Enquiry Point
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Tel: +91-11-23061968
Fax: +91-11-23061083
Email: adgif-mohfw@nic.in

Mr Paramjeet S. CHOPRA
Assistant Director General (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Tel: +91-11-23062290
Fax: +91-11-23061083
Email: adgpfa@nic.in

Mr Arun K. SRIVASTAV
Deputy Assistant Director General (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Telfax: +91-11-23063030
Email: dadgaks@nic.in

Mr Jaipal SINGH
Technical Officer (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Telfax: +91-11-23063030
Email: to1pfa-dghs@nic.in

Mr Subhash C. KATHURIA
Technical Officer (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Telfax: +91-11-23063030
Email: to2pfa-dghs@nic.in

Mr Prakash CHANDRA
Technical Officer (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Telfax: +91-11-23063030
Email: to3pfa-dghs@nic.in

Mr Sunita GEHANI
Technical Officer (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Telfax: +91-11-23063030

Mr Arun KUMAR
Research Assistant (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108

Mr Deepak KUKREJA
Private Secretary to Joint Secretary
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi—110108
Telfax: +91-11-23061447

Mr Udaynatha KHATUA
Research Assistant (IF)
Ministry of Health and Family Welfare
Nirman Bhavan
New Delhi-110011
Tel: +91-11-23061968
Email: uday.un@gmail.com

Mr Satish KUMAR
Research Assistant (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110108
Email: kumarsatish70@hotmail.com

Mr Veenu SANGWAN
Research Assistant (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110011

Mr Pushpender KAUR
Technical Assistant (PFA)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110011

Mr Ashok K. DAS
DEO (IF)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan,
New Delhi-110011
Tel: +91-11-23061968
Email: ashokkdas53@gmail.com

Mr Ajai K YADAV
DEO (IF)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan, New Delhi-110011,
Tel: +91-11-23061968
Email: ak_yadav77@yahoo.co.in

Ms Malu BHATIA
DEO (IF)
(International Food)
Directorate General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi-110011
Tel: +91-11-23061968
Email: malubhatia@yahoo.co.in

US SECRETARIAT

Mr Syed Amjad ALI
International Policy Issue Analysts
US Codex Office
US Department of Agriculture Food Safety and Inspection Service
1400 Independence Ave, SW
South Building, Room 4861 Washington,
DC 20250
Tel : 202-205-7760
Fax: 202-720-3157
Email: syed.ali@usda.gov

Ms Samantha BAILEY
Food Safety Program Specialist
USDA
Room 3832 South Bldg.
1400 Independence Ave., SW
Washington DC 20250-1085
Tel: 202-720-3372
Fax: 202-690-3982
Email :Samantha.Bailey@fas.usda.gov

Ms Jasmine MATTHEWS
US Codex Office
Program Analyst
Codex Office US Department of Agriculture
Food Safety Inspection Service 1400
Independence Avenue,
SW South Building, Room 4861 Washington,
DC 20250
Tel : 202-690-1124
Fax: 202-720-3157
Email: jasmine.matthews@fsis.usda.gov

Ms Obi NDUBUISI
Program Assistant
USDA/FAS/OCBD/TSCBD/ Regulatory &
Capacity building branch
1400 Independence Avenue, SW
Room 3840 South Building
Washington DC 20250-1093
Tel: 202-720-2802
Fax: 202-690-3982
Email: Obi.Ndubuisi@fas.usda.gov

Dr Matthew B. WEST
AAAS Science and Technology Policy Fellow
USDA, Trade and Scientific Capacity Building ,
Office of Capacity Building and Development
1400 Independence Ave. , S.W
Rome 3834S
Washington , DC 20250 – 1085
Tel: 202 690 2744
Fax: 202 690 3982
Email: Matthew.west@fas.usda.gov

CODEX SECRETARIAT /
CODEX SECRÉTARIAT /
CODEX SECRETARÍA

Dr Jeronimas MASKELIUNAS
Food Standards Officer
Secretariat of the Codex Alimentarius Commission,
Vialle delle terme di Caracalla
00153, Rome
Italy
Tel : +39 06 570 53967
Fax : +39 06 570 54593
Email : Jeronimas.Maskeliunas@fao.org

Ms Verna Carolissen- MACKAY
Food Standards Officer
Secretariat of the Codex Alimentarius Commission,
Vialle delle terme di Caracalla
00153, Rome
Italy
Tel : +39 06 570 53967
Fax : +39 06 570 54593
Email: verna.carolisen@fao.org

Ms Noriko ISEKI
Senior Food Standards Officer
Secretariat of the Codex Alimentarius Commission,
Room C-284
Viale, delle Terme di Caracallla
00153 Rome,
Italy
Tel : (39) 06 57053195
Fax : (39) 06 57054593
Email : noriko.iseki@fao.org

Appendix II

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN

(N10-2004)

(At Step 5/8 of the Procedure)

(Intended to replace the Recommended International Code of Hygienic Practice for Foods for Infants and Children – CAC/RCP 21-1979)

INTRODUCTION

It is recognized internationally that breast milk is the best source of nutrition for infants. However, there are instances where it may be insufficient or not available and thus, may need to be supplemented or replaced. In those instances, one of the dietary options is the use of powdered formulae (PF).

For the purposes of this document, "powdered formulae" include the following:

- Infant formulae and formulae for special medical purposes intended for infants, which serve as the sole source of nutrition[1];
- Follow-up formulae which are used in combination with other foods as part of the weaning diet of older infants and young children[2];
- Powdered formulae for special medical purposes for infants and young children, intended to partially replace or supplement breast milk, infant formulae or follow-up formulae[3];
- Human milk fortifiers used to supplement breast milk.

These products are to be distinguished from ready-to-feed liquid formulae that have been commercially sterilized.

As dehydrated products, it is not possible using current technology to produce powdered formulae that are devoid of low levels of microorganisms, i.e., the products cannot be sterilized. Thus, their microbiological safety requires strict adherence to good hygienic practices during both manufacture and use.

Two FAO/WHO "meetings of experts" on the microbiological safety of powdered infant formula[4,5] considered cases of illnesses in infants associated with PF consumption either epidemiologically or microbiologically. They identified three categories of microorganisms based on the strength of evidence of a causal association between their presence in PF and illness in infants: A) microorganisms with a clear evidence of causality, namely, *Salmonella enterica*[6] and *Enterobacter sakazakii*[7]; B) microorganisms for

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[1] Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-108).
[2] Standard for Follow-up Formula (CODEX STAN 156-1987).
[3] Covered in the scope of the Standard for Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991).
[4] FAO/WHO. 2004. *Enterobacter sakazakii* and other microorganisms in powdered infant formula: meeting report, Microbiological Risk Assessment Series 6.
[5] FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: meeting report, Microbiological Risk Assessment Series 10.
[6] *Salmonella enterica* subsp. *enterica* includes the various *Salmonella* serotypes associated with foodborne illness such as *S. enterica* subsp. *enterica* serotype Typhimurium, which is commonly referred to as *Salmonella* Typhimurium. The genus name *Salmonella* will be used in the text to refer to the pathogenic serotypes of *S. enterica* subspecies *enterica*.
[7] The reclassification of *Enterobacter sakazakii* into a new genus, *Cronobacter* has been proposed based on a manuscript by Iversen *et al.*, BMC Evolutionary Biology, 2007, 7:64.

which the causality is plausible but not yet demonstrated, i.e., they are well-established causes of illness in infants and have been found in PF, but contaminated formula has not been convincingly shown, either epidemiologically or microbiologically, to be the vehicle and source of infection, e.g., other Enterobacteriaceae; and C) microorganisms for which causality is less plausible or not yet demonstrated, including microorganisms, which despite causing illness in infants, have not been identified in PF, or microorganisms which have been identified in PF but have not been implicated as causing such illness in infants, including *Bacillus cereus, Clostridium botulinum, C. difficile, C. perfringens, Listeria monocytogenes* and *Staphylococcus aureus.*

Salmonella is a well-known long-standing foodborne human pathogen. The incidence of salmonellosis among infants, originating from various sources, was reported to be more than eight times greater than the incidence across all ages in the United States of America (CDC, 2004). Infants are also more likely to experience severe illness or death from salmonellosis, and infants with immunocompromising conditions are particularly vulnerable. It is unclear whether the increased incidence of salmonellosis among infants results from greater susceptibility, or whether infants are more likely than persons in other age groups to seek medical care or have stool cultures performed for symptoms of salmonellosis.

At least 6 reported outbreaks of salmonellosis involving approximately 287 infants have been associated with PF between 1985 and 2005. Most of these outbreaks involved unusual *Salmonella* serotypes, which likely aided in recognition of those outbreaks. It is recognized that outbreaks and sporadic cases of salmonellosis due to powdered infant formula are likely to be under-reported[5].

Enterobacter sakazakii has recently emerged as a pathogen of infants. The FAO/WHO expert meetings have identified all infants (<12 months of age) as the population at particular risk for *E. sakazakii* infections. Among this group, those at greatest risk are neonates (<28 days), particularly pre-term, low-birthweight (<2500 g), and immunocompromised infants, and those less than 2 months of age[4,5]. Infants of HIV-positive mothers are also at risk, because they may specifically require infant formula and may be more susceptible to infection[5, 8].

Infections from *E. sakazakii* have been documented as both sporadic cases and outbreaks. While the incidence of these *E. sakazakii* infections in infants appears to be low, the consequences can be severe. The primary manifestations of *E. sakazakii* infection in infants, i.e., meningitis and bacteraemia, tend to vary with age. *E. sakazakii* meningitis tends to develop in infants during the neonatal period, while *E. sakazakii* bacteraemia tends to develop in premature infants outside of the neonatal period with most cases occurring in infants less than 2 months of age. However, infants with immunocompromising conditions have developed bacteraemia as late as 10 months of age and previously healthy infants have also developed invasive disease outside the neonatal period. Infections have occurred in both hospital and outpatient settings. It was noted that as older infants generally live at home in the community, infections in such infants may be more likely to be under-reported.

Reported fatality rates of *E. sakazakii* infections in infants vary considerably with rates as high as 50 percent reported in at least one outbreak. In addition, a portion of surviving infants has permanent disabilities such as retardation and other neurological conditions.Although all known outbreaks have involved infants, sporadic cases have been reported in children and adults, however these have not been linked to PF.[4]

While PF was established as the source of *E. sakazakii* in some of the cases, in many others it was neither epidemiologically nor microbiologically implicated as the source of infection. However, in such cases, no other source of infection has been epidemiologically or microbiologically implicated. *E. sakazakii* is widely found in the environment, so infants, children and adults may be exposed to this organism from a range of sources.

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[8] WHO, HIV and infant feeding: framework for priority action. Geneva: World Health Organization, 2003. HIV and Infant Feeding: New Evidence and Programmatic Experience (Report of the Technical Consultation, Geneva, Switzerland, 25-27 October 2006, held on behalf of the interagency task team (IATT) on preventing HIV infection in pregnant women, mothers and their infants (2007).

Outbreaks of *E. sakazakii* infections have led to the link with PF, especially in the context of neonatal intensive care setting. *E. sakazakii* is known to be present at low concentration in a proportion of PF. While the microorganism has been detected in other types of food and environmental settings, only PF has been linked to outbreaks of disease.

For infants at greatest risk, e.g. neonatal intensive care settings, commercially sterile liquid infant formula should be used if available unless the attending physician recommends otherwise. If a non-commercially sterile feeding option is chosen, an effective point-of-use decontamination procedure should be used.

There are four routes by which *E. sakazakii* and *Salmonella* can enter PF: 1) through the ingredients added in dry mixing operations during the manufacturing of PF, 2) through contamination of the formula from the processing environment in the steps during or following the drying, 3) through contamination of the PF after the package is opened, and 4) through contamination during or after reconstitution by the caregiver prior to feeding. *E. sakazakii* may be found in many environments such as food factories, hospitals, institutions, day-care facilities and homes. In manufacturing, the organism may gain access to the processing line and product, since current technology cannot completely eliminate this organism from the manufacturing environment.

Prevention efforts must be multi-faceted, directed at manufacturers, health-care providers, day care centres as well as infant caregivers in home settings, and take into consideration the risk to infants both within and beyond the neonatal period.

Product labelling, consumer education programs and staff training at hospitals should be updated as appropriate to provide adequate information to caregivers on the safe use of the product and to provide caution regarding the health hazards of inappropriate preparation and handling of PF.

SECTION I. – OBJECTIVES

The objective of this Code is to provide practical guidance and recommendations to governments, industry, health care professionals/caregivers of infants and young children, as appropriate, on the hygienic manufacture of PF and on the subsequent hygienic preparation, handling and use of reconstituted formulae. The Code supplements the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004), with an emphasis on the control of microbiological hazards, in particular *Salmonella* and *E. sakazakii*. The Code identifies relevant control measures at the various steps in the food chain that can be employed to reduce the risks for infants and young children that are associated with the consumption of PF.

SECTION II. – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

This Code covers the production, preparation and use of products available in powdered form, referred to as Powdered Formulae (PF) for the purpose of this document, and specifically manufactured to be used for infants and young children either as a breast milk substitute, to supplement infant formula or fortify human milk or in combination with other foods as part of the weaning diet for older infants and young children. Products included are infant formulae, follow-up formulae, formulae for special medical purposes intended for infants and which serve as the sole source of nutrition, human milk fortifiers and powdered formulae for special medical purposes for infants and young children intended to partially replace or supplement breast milk, infant formulae or follow-up formulae.

The nutritional specifications of these products are beyond the scope of this document. Products should meet the nutritional specifications of the applicable Codex standards[1,2].

2.1.2 ROLES OF GOVERNMENTS, INDUSTRY, AND CONSUMERS[9]

[9] In this context, the term “consumers” also includes caregivers of infants and children.

Intended users of the document include national governments, manufacturers, health care professionals and professional caregivers to infants and young children.

Although the primary responsibility lies with the manufacturer for ensuring that PF manufactured are safe and suitable for their intended use, there is a continuum of effective control measures that need to be performed by other parties, including manufacturers of ingredients and packaging materials and caregivers of infants and young children, to minimize the risk and to assure the suitability of PF.

The interrelationship and impact of one segment of the food chain on another segment is important to ensure that potential gaps in the food chain are addressed through communication and interaction between the suppliers of ingredients, the manufacturer, the distributor and the caregivers. It is principally the responsibility of the manufacturer to conduct the hazard analysis within the context of developing a control system based on HACCP or other equivalent systems and thus to identify and control hazards associated with the incoming ingredients; however, the caregivers should also have an understanding of the hazards associated with PF, so as to assist in minimizing risks associated with the hazards involved.

To achieve an effective continuum for the purpose of reducing risk, the various parties should pay particular attention to the following responsibilities:

- Producers and manufacturers of raw materials should ensure that good agricultural, hygienic and animal husbandry practices are employed at the farm level. These practices should be adapted, as appropriate, to any specific safety-related needs specified and communicated by the manufacturer.

- Manufacturers of ingredients and packaging materials should utilize good manufacturing and good hygienic practices and have HACCP systems implemented. Any needs for additional measures communicated by the PF manufacturer, and that are needed to control hazards in PF should be implemented.

- Manufacturers of PF should utilize good manufacturing and good hygienic practices, especially those presented in this Code. Any needs for additional measures with regard to controlling hazards earlier in the food chain should be effectively communicated to suppliers to enable them to adapt their operations to meet these measures. Likewise, the manufacturer may have to implement controls or adapt their manufacturing processes based on the ability of the ingredients supplier to minimize or prevent hazards associated with the ingredients. Such additional needs should be supported by an adequate hazard analysis and should, where appropriate, take into consideration technological limitations during processing.

- Manufacturers should provide accurate and understandable information to enable the subsequent person(s) in the food chain, including the final user/caregiver, to use the product appropriately. This includes the additional measures to control hazards in the formulae during and after reconstitution.

- Distributors, transporters and retailers should assure that PF under their control are handled and stored properly and according to the manufacturers' instructions.

- Hospitals and institutions should establish hygienically designed rooms designated for preparation of formulae and good hygienic practices (e.g. HACCP, labelling of prepared food, hygiene and cleaning instructions, temperature control, first in first out, etc.), and should provide effective training to their caregivers of infants.

- Health care professionals and professional caregivers should provide effective hygienic training to consumers (parents and other caregivers) to ensure that PF are prepared, handled and stored properly[10] and according to the manufacturers' instructions.

- Caregivers of infants should ensure that PF are prepared handled and stored properly[10] and according to the manufacturer's instructions.

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

- To ensure effective implementation of this Code, competent authorities should have in place legislative framework (e.g. acts, regulations, guidelines and requirements), an adequate infrastructure and properly trained inspectors and personnel. For food import and export control systems, reference should be made to the *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997) and related Codex texts. Control programs should focus on auditing relevant documentation that shows that each participant along the chain has met their individual responsibilities to ensure that the end products meet established food safety objectives and/or related objectives and criteria. Furthermore, adequate consumer guidance and consumer education programs should be provided.

It is important that clear communications and interactions exist between all parties to help assure that best practices are employed, that problems are identified and resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.

2.2 USE

This document follows the format of the Codex *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969). The provisions in this document are supplemental to and should be used in conjunction with the *General Principles of Food Hygiene* (CAC/RCP 1-1969), including its Annex on *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application*, and the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).

Where applicable, this document should be used in combination with the International Code of Marketing of Breast Milk Substitutes, relevant WHA resolutions and the WHO Global Strategy for Infant and Young Child Feeding.

2.3 DEFINITIONS

Infant – a person not more than 12 months of age[1].

Young Children – persons from the age of more than 12 months up to the age of three years (36 months)[2].

Human milk fortifier – (also referred to as *Human milk complement* or *breast milk fortifier* in some countries) product that may be added to human milk to provide additional nutrients for feeding low-birth weight and premature infants.

Powdered formulae – for the purpose of this Code of Practice includes all types of powdered formulae for infants and young children, including: powdered infant formulae, follow-up formulae, formulae for special medical purposes intended for infants as sole source of nutrition, human milk fortifiers, and formulae for special medical purposes for infants and young children, intended to partially replace or supplement breast milk, infant formulae or follow-up formulae.

Infant formula - means a breast milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding[1].

Follow-up formula – means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children[2].

Formula for special medical purposes intended for infants (sole source of nutrition) - means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding[1].

Formula for special medical purposes for infants and young children (not sole source of nutrition) - means a formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, in combination with breast milk or infant formula or follow-up formula, the special nutritional requirements of infants and young children with specific disorders, diseases or medical conditions.

Wet-mix process – manufacturing process by which all constituents of the infant formulae are handled in a liquid phase, and may involve homogenization, heat-treatment, concentration by evaporation, and then dried.

Dry-mix process – manufacturing process by which all constituents of the infant formulae are processed dry and blended to obtain the desired final formula.

Combined process – manufacturing process by which some of the constituents of the infant formulae are wet processed and dried and other ingredients are added in a dry form after the heat treatment.

SECTION III – PRIMARY PRODUCTION

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

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES

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

Facilities and equipment should be designed, constructed and laid out to prevent entry of *Salmonella* and *E. sakazakii* into high hygiene areas and to minimize their establishment or growth in harbourage sites. It is well known that:

- The entry of *Salmonella* and *E. sakazakii* in high hygiene areas of establishments manufacturing PF is favoured by an inadequate separation of wet and dry areas and/or by poor control over the movement of employees, equipment and goods.

- The establishment of *Salmonella* and *E. sakazakii* in harbourage sites is favoured by conditions such as the presence of water and the occurrence of sites or structures which allow collection of process material and prevent the rapid elimination of the organisms through appropriate cleaning procedures.

- The increase of *E. sakazakii*, usually already part of the normal microbial flora of such high hygiene areas, is favoured by the presence of water, even in minute quantities as can be found, for example, in condensation spots.

- The application of wet cleaning procedures has been linked to the occurrence and spread of *Salmonella* and particularly *E. sakazakii*.

4.1 LOCATION

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

4.1.1 Establishments

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

4.1.2 Equipment

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

Equipment should be designed, placed, installed and maintained in a manner that facilitates effective cleaning and disinfection, thus avoiding the occurrence of sites where accumulation of residues can take place. If water is available, such residues may lead to microbial growth, thus increasing the risk of contamination.

4.2 PREMISES AND ROOMS

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

4.2.1 Design and layout

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

Dry processing areas where operations from the drying step up to the filling and hermetic closure of containers are performed, should be maintained as high hygiene areas. The internal design and layout of establishments manufacturing PF need to be such so as to ensure the strict physical separation of wet processing areas from the dry processing areas where post-process contamination from the environment could occur.

To be effective, the physical separation, known as zoning, needs to be complemented by appropriate measures such as maintaining a positive air pressure to prevent the entry of unfiltered air into high hygiene areas.

The access to high hygiene areas needs to be restricted and controlled through measures designed to avoid or minimize the entry of pathogens. This is generally achieved through appropriately designed interfaces such as locks for the personnel (e.g., to allow for putting on protective outer clothing and footwear covers), for incoming materials (e.g., ingredients used in dry-mixing operations or packaging material), for equipment requiring transportation out of the high hygiene areas and back in again (e.g. for maintenance and/or wet cleaning). Filtration systems for the air used in the building or for the transport of ingredients or product are also part of this zoning principle and need to be designed and installed accordingly.

Condensation should be prevented in high hygiene areas.

4.2.2 Internal structures and fittings

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

Structures within establishments manufacturing PF should be soundly built of durable materials and easy to maintain, clean and, where appropriate, easy to disinfect. The requirements need to be adapted to the conditions encountered in the different areas (wet and dry) of the establishment as outlined in Section 4.2.1. Particular attention is required in the dry high hygiene areas to avoid the creation of inaccessible hollow sites favouring the accumulation of dust and product residues which may, in the presence of water, lead to the formation of a harbourage site.

Due to the ability of *Salmonella* and *E. sakazakii* to survive in dry environments for prolonged periods of time, care should be taken when construction activities are planned, e.g. modifications of layout requiring displacing pieces of equipment. Such activities may dislodge *Salmonella* or *E. sakazakii* from harbourage sites that were previously hidden, and contribute to the spread of the organisms throughout the plant. It is therefore important to isolate these construction areas and to reinforce cleaning procedures as well as environmental monitoring as described in Annex III.

4.2.3 Temporary/mobile premises and vending machines

Not applicable for the products considered in this Code.

4.3 EQUIPMENT

4.3.1 General

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

Due to the ability of *Salmonella* and *E. sakazakii* to persist in harbourage sites for prolonged periods of time, processing equipment should be designed, constructed and maintained to avoid, for example, cracks, crevices, rough welds, hollow tubes and structures, close fittings, metal-to-metal or metal-to-plastic surfaces, interfaces between floors and equipment, inadequately installed and maintained insulations, worn seals or other sites that cannot be reached during cleaning.

While these elements need to be addressed correctly in the whole establishment, particular attention is required in high hygiene areas where contamination should be prevented.

In the case of equipment located in the high hygiene area, particular attention is required to ensure that equipment can be cleaned using dry-cleaning techniques. It is also important to avoid any conditions which may lead to the occurrence of condensation, including on the internal surfaces of equipment.

4.3.2 Food control and monitoring equipment

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

4.3.3 Containers for waste and inedible substances

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

4.4 FACILITIES

4.4.1 Water supply

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

In order to maintain high-hygiene areas as dry as possible, the availability and presence of water and corresponding distribution systems should be limited to the extent possible in these areas.

4.4.2 Drainage and waste disposal

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

In order to maintain high hygiene areas as dry as possible, the use of dry drains is recommended as it would prevent the presence of water residues which could lead to growth and spread of microorganisms including relevant pathogens and process hygiene indicators.

In wet areas, the use of appropriately designed hygienic drains is recommended.

4.4.3 Cleaning

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

In order to maintain high hygiene areas completely dry or as dry as possible, the application of appropriate dry-cleaning procedures is recommended. Such cleaning techniques are applicable to premises as well as to equipment.

If not feasible, controlled wet cleaning may be used as long as prompt and thorough drying of the equipment and environment is ensured.

Where wet cleaning procedures are applied, appropriate management options should be implemented such as operating procedures that would ensure a well-controlled cleaning and the rapid elimination of any water residues immediately thereafter.

4.4.4 Personnel hygiene facilities and toilets

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

4.4.5 Temperature control

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

4.4.6 Air quality and ventilation

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

It is important to install air handling and ventilation units in such a way as to ensure the integrity of the zoning principles. It is important to install and maintain air handling units so that they do not become a source of contamination. For example, appropriate design and installation of the filters should avoid any bypass of unfiltered air, and accumulation of condensates should be avoided through an appropriate design of the drainage.

Air filters should be tightly fitted and properly sealed with gaskets to prevent the entrance of unfiltered air. Outside air intakes should be located away from the exhausts of the drier, boiler and other environmental contaminants. Filters should be replaced or cleaned and disinfected regularly in a manner that does not contaminate the processing environment.

4.4.7 Lighting

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

4.4.8 Storage

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

SECTION V – CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

Refer to the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969). In addition, the procedure described in Section 5.1 of the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) also applies to PF.

Although chemical, microbiological and physical hazards may be associated with PF, this Code of Practice focuses on the microbiological hazards, and specifically on *Salmonella* and *E. sakazakii*. A combination of control measures should effectively control the identified microbial hazards in PF.

When milk and milk products are used in the manufacturing process, these should meet the requirements of the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

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

Time/temperature recording devices for any time/temperature control point (heating or chilling) should be checked at regular intervals and tested for accuracy against a calibrated probe. In manufacturing operations where heat treatments are critical control points (CCPs) for the reduction or elimination of a pathogen, appropriate records of the processing time and temperature should be maintained.

5.2.2 Specific process steps

PF is generally manufactured using a wet-mix, dry-mix or combined process.

For all types of processes used, steps should be taken to avoid contamination of the product during dry product handling, following the thermal processing steps that would ensure elimination of *Salmonella* and *E. sakazakii*.

Steps that contribute to good manufacturing practices include:

5.2.2.1 Thermal processing

For wet-mix process:

The heat treatment is a key step in ensuring the safety of PF and is therefore considered a CCP.

Heat treatments intended as microbiocidal processes[11] should, at a minimum, be sufficient to achieve pasteurization, which is based on the reduction of vegetative pathogens to a level where they do not constitute a significant hazard to health. The time/temperature combinations used to achieve pasteurization should take into consideration the properties of the product, e.g., fat content, dry matter, total solids, etc., which may have an impact on the heat resistance of the target organisms. These heat-treatments are considered as CCPs and therefore procedures must be in place to detect deviations, such as temperature drops and insufficient treatment times, and to take appropriate corrective measures such as the redirection of the product to waste or reprocessing[12].

5.2.2.2 Intermediate storage

For wet-mix process:

Raw materials as well as intermediate products can support microbial growth and have therefore to be maintained at temperatures that would prevent such growth from occurring, taking as well the storage time into consideration. While storage under refrigeration is usually applied, storage at high temperatures that do not allow growth may be a suitable alternative.

Intermediate storage of liquids may occur at different steps of the process:

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[11] Pasteurization and other heat treatments of milk that have at least an equivalent efficiency are applied at such intensities (sufficient time/temperature combinations) that they practically eliminate specific pathogens. They have therefore been traditionally used as key microbiocidal control measures in the manufacture of milk products (Annex II, *Code of Hygienic Practice for Milk and Milk Products*, CAC/RCP 57-2004).

[12] Section 4.1.1. FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula; Meeting Report. Microbiological Risk Assessment Series 10.

(i) Liquid raw materials such as raw milk;

(ii) Intermediate products before the heat processing step;

Uncontrolled microbial growth at these steps may impact the effectiveness of the heat processing. In case of point (i) above, refer to the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).

(iii) Intermediate products after the heat processing step and before the drying step.

Microbial growth at this step may lead to non-compliant products as the drying is not considered a controlled killing step.

5.2.2.3 Steps from the Heat Process to the Drying

Control of the contamination of the heat-processed intermediate products is based on the application of high hygiene concepts to all elements of the processing line up to the spray nozzle, i.e., enclosed systems. Such elements may range from simple pipes to more complex combinations of pipes with other pieces of equipment (e.g., storage tanks).

For wet-mix process:

A drying process is used to convert the liquid mixture into a dry powder. For example, a spray dryer could be used, in which the liquid is heated and pumped under high pressure to spray nozzles or an atomizer mounted in a large drying chamber. This is usually not considered as a microbiocidal step. The drying step needs to be done under strict hygienic conditions to avoid microbial contamination of the final product.

5.2.2.4 Cooling

For wet-mix process:

During the drying process, the powder is cooled after the drying chamber. For example, it could pass from the drying chamber to a fluidized cooling bed. The air in contact with the product should be appropriately filtered to prevent microbial contamination of the powder.

5.2.2.5 Blending

For dry-mix and combined processes:

Blending should be done under strict hygienic conditions to avoid contamination of the final product. Refer to Section 5.3 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Incoming Material Requirements.

5.2.2.6 Storage

Finished products should be stored under strict hygienic conditions to avoid contamination of the product. Refer to Section 4.4.8 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Storage.

5.2.2.7 Filling and Primary Packaging[13]

Refer to Section 5.4 of the *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), Packaging. In addition, the following principles should be applied to the manufacture of PF:

- Access to the packaging room should be limited to essential personnel only (*Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), section

[13] Primary packaging is packaging that comes in direct contact with the product.

5.2.4). Access to the packaging area should be through ante rooms where personnel can wash their hands and change their outer garments, hair covering and footwear or footwear covers.

- The packaging area should be supplied with suitably filtered air to prevent airborne contamination of product or packaging. Ideally, the packaging area should be maintained under positive air pressure to prevent the infiltration of contaminated air from the outside or surrounding areas of the manufacturing facility (*Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969), section 4.4.6).

- Packaging materials (including cans and flexible packaging) should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged. Container cleanliness can be ensured by processes such as the use of can inverters, air jets and anti-static electricity devices.

5.2.3 Microbiological and other specifications

Refer to the *Principles for the Establishment and Applications of Microbiological Criteria* (CAC/GL 21-1997) and to Annexes I & II**.** In addition:

Manufacturers are responsible for ensuring the compliance of finished products. In view of the limitations of end-product testing, compliance should be ensured through the design of an appropriate food safety control system and verification of the effectiveness of control measures through appropriate auditing methods, including review of monitoring records and of deviations and confirmation that CCPs are kept under control and GHPs are adhered to.

These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, production line, ingredients and finished products. Verification and monitoring procedures using environmental testing for PF are described in Annex III. Environmental samples should be taken from those areas most likely to lead to contamination of the product.

When monitoring of control measures and surveillance or verification results demonstrates deviations, appropriate corrective action should be taken and the finished product should not be released until adequate investigation has shown that it complies with appropriate specifications.

5.2.4 Microbiological cross-contamination

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

Contamination of the product with *Salmonella* and/or *E. sakazakii* may occur after drying and during the subsequent processing steps such as conveying, tipping, mixing, and blending with additional ingredients, up to the point of filling/packaging. Contamination is usually related to the following three factors, the first two of which are linked:

(1) the presence of these microorganisms in the processing environment, i.e., external parts of equipment and surroundings of the processing lines, presenting the possibility that they may get into the processing lines;

(2) the presence of these microorganisms, originating from the processing environment (item 1 above), on internal surfaces of equipment that is in direct contact with the product; and,

(3) the presence of these microorganisms in ingredients added and mixed into the dry base powder after the heat-processing step[12].

Raw or unprocessed foods should be physically separated from processed/ready-to-use foods. Where possible, packaged dry-mix ingredients should be packaged with strippable bags (bags from which the outer

layer can be stripped) to prevent contamination at ingredient dumping stations. Packaging material entering restricted area should be clean.

Pathogens such as *Salmonella* and *E. sakazakii* can, to varying degrees, contaminate and become established in PF manufacturing plants. Harbourage sites can serve as a source of product contamination unless these areas are identified, cleaned and disinfected to eliminate pathogens. Manufacturers should implement an ongoing microbiological monitoring program for the drying, blending and packaging areas of the plant and for food contact surfaces/equipment (Annex III). When pathogens or indicator microorganisms are detected in the plant environment, appropriate measures should be taken to investigate the source of contamination and to eliminate or control the microorganism(s) in the environment.

Increases in the levels or frequency of detection of *E. sakazakii* or more generally levels of Enterobacteriaceae in processing environments can be either due to a massive and sudden entry of microorganisms due to poorly planned construction or maintenance activities, or more commonly due to conditions which allow the proliferation of the low number of microorganisms already present in the environment[14].

Growth is only possible in the presence of water, therefore the environment has to be kept as dry as possible. Dry conditions should be maintained in the processing environment, including drying, blending and packaging areas. The presence of water in the processing environment can be as a result of wet cleaning of environments or equipment without appropriate immediate drying, the formation of condensation spots, leaking water valves, backed up floor drains, etc., or occasionally as a result of water infiltration following heavy rains or the use of water showers in the case of fire emergencies.

5.2.5 Physical and chemical contamination

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

5.3 INCOMING MATERIAL REQUIREMENTS

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

For dry-mix and combined processes:

Since a dry-mix process and combined processes incorporate ingredients that may not include a microbiocidal heat treatment by the formulae manufacturer, the microbiological safety of these ingredients is dependent on the treatments performed by the ingredient manufacturers and the assurance that the integrity of the packaging has been maintained during shipment and storage.

Manufacturers should take steps to ensure that the microbiological quality of the dry-mix ingredients meets the requirements for the finished products. They should take into consideration the procedures and safeguards employed by their ingredient suppliers and should have in place a verification procedure that can verify their suppliers' performance. This can be achieved through such measures as carefully selecting suppliers, performing audits to assess the suppliers' processes, controlling and monitoring procedures, and periodic evaluations of incoming ingredients.

5.4 PACKAGING

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

[14] Section 4.1.2. FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula; Meeting Report. Microbiological Risk Assessment Series 10.

5.5 WATER

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

5.6 MANAGEMENT AND SUPERVISION

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

5.7 DOCUMENTATION AND RECORDS

Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

Manufacturers should establish documentation and records concerning all procedures and applications related to the HACCP plan or other food safety control systems in addition to documentation and records pertaining to good hygienic practices. In particular, the manufacturer should keep records detailing all incoming material (e.g., dry ingredients, liquid milk); the monitoring of CCPs (e.g., records outlining effective thermal processing with actual processing temperatures); the verification of the HACCP plan; the cleaning practices and sanitation processes; and the application of procedures to verify that microbiological specifications for finished products and environmental sampling and testing are met. Documentation should be sufficient to facilitate product traceability in the event that a recall may prove necessary.

5.8 RECALL PROCEDURES

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

As PF is regularly traded internationally, the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations *(CAC/GL 19-1995),* the Principles and Guidelines for the Exchange of Information between Countries on Rejection of Imported Food *(CAC/GL 25-1997),* Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System (CAC/GL 60-2006) *and* International Health Regulation (WHA, 2005) *should be used in the event of a product recall.*

SECTION VI. – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

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

6.1.2 CLEANING PROCEDURES AND METHODS

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

Wet cleaning should be minimized and limited to parts of equipment that can be taken out to a dedicated room or where adequate drying parameters can be applied immediately after wet cleaning. Implementation of dry cleaning procedures for the processing lines, equipment and the processing environment is considered to be the most effective method of avoiding multiplication of microorganisms[15].

[15] Recommendations. FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula; Meeting Report. Microbiological Risk Assessment Series 10.

6.2 CLEANING PROGRAMMES

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

6.3 PEST CONTROL SYSTEMS

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

6.4 WASTE MANAGEMENT

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

6.5 MONITORING EFFECTIVENESS

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

Manufacturers of PF should establish effective supervisory procedures to ensure that critical procedures such as manual cleaning, cleaning-in-place (CIP) systems operation, and equipment maintenance are conducted according to established protocols and standards. In particular, it is important to ensure that cleaning and disinfection solutions are appropriate for their intended use and are of the proper concentration, that temperature and flow rate requirements are met for CIP systems and that equipment is properly rinsed when required.

A critical activity to minimize the risk associated with PF is the implementation of environmental management programs (environmental samples, product contact surfaces, finished products) based on Enterobacteriaceae as indicators for process hygiene, and *Salmonella* and *E. sakazakii* in relevant samples to demonstrate control or to detect deviations and assess the effect of corrective actions[16]. Guidance on the establishment of an environmental monitoring program for *Salmonella*, *E. sakazakii* and other Enterobacteriaceae is given in Annex III.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

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

SECTION VIII – TRANSPORTATION

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

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

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

Microbiological hazards are controlled through the appropriate selection and combination of control measures applied during the manufacture of PF in combination with control measures applied during and after reconstitution.

[16] Section 4.1.4. FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in Powdered Infant Formula; Meeting Report. Microbiological Risk Assessment Series 10.

Even when products have been manufactured according to this Code, a certain number of servings may contain pathogenic microorganisms (see Annexes I and II[17]). Additional risk may be associated with any contamination of the formula during its preparation, handling and use. Therefore, control measures during reconstitution, handling and feeding of reconstituted formula are necessary.

All health care professionals and caregivers should be informed that, because powdered formulae are not sterile, the use of Good Hygienic Practices during reconstitution, handling, and feeding, including appropriate storage is essential to minimize the risk of foodborne illness.

Clear instructions for the appropriate preparation, handling and use of PF should be communicated to caregivers and health care professionals. Various combination of hygienic measures can achieve significant risk reduction and are addressed in the report of the 2006 FAO/WHO expert meeting on *E. sakazakii* and *Salmonella* in powdered infant formula[5] and can be used according to the risk reduction strategy chosen. For example, one risk reduction strategy includes feeding the formula immediately after reconstitution and rapid cooling to the appropriate feeding temperature. To this effect, (i) the feeding period[18] should be minimized and should not exceed two hours, (ii) leftover formula should be discarded, and (iii) any formula prepared for later use should be refrigerated immediately following reconstitution and used within 24 hours. Various other risk reduction strategies for the preparation, storage and handling are provided in the guidelines of the FAO/WHO on the safe preparation, storage and handling of powdered infant formula (2007)[10] .

In certain situations, e.g., where there is a high confidence in the microbiological quality of the product and adherence with good hygienic practices in the preparation, handling and use of the formula, or when there are heat-labile components in the formula, alternative risk management strategies are available to the reconstitution temperature of 70°C recommended in the FAO/WHO guidelines. The 2006 report of the FAO/WHO expert meeting[5] and the associated web-based tool provide a means to consider different risk management options which may be appropriate in certain situations as described above.

Control measures should be communicated to different stakeholders such as parents, caregivers and healthcare professionals through appropriate product labelling (which may include separate written information), written procedures (e.g., in professional institutions) and/or through oral instructions and/or training. These instructions, if adhered to, would help manage the risk associated with the product.

In hospitals and other health care delivery institutions, milk/formula preparation units require special precautions in the preparation, storage, and handling of PF, and guidance can be found in the FAO/WHO guidelines[10].

Recommendations regarding the type of formula to be used, e.g., commercially sterile liquid formula, PF, etc., should be made by health care professionals, as needed.

For infants at greatest risk, when feasible, commercially available sterilized liquid products or other equivalent infant feeding options which have undergone an effective point of use decontamination procedure should be used instead of PF.

9.1 LOT IDENTIFICATION

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

9.2 PRODUCT INFORMATION

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

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[17] Annex II is under elaboration.

[18] Feeding period is defined here as the time after re-warming (or after storage, if no re-warming) until all of the prepared formula has been consumed[21].

9.3 LABELLING

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

The label should communicate the control measures that the caregiver should follow for the safe preparation, handling and use of PF.

The label should carry clear graphic instructions illustrating the method of preparation.

Guidance should be provided on: i) the use of hygienic practices, e.g., clean hands, preparation surfaces, and clean utensils (nipples, caps, utensils, including sterilization, as necessary); ii) the need to boil water and sterilise utensils, as necessary; iii) the need to cool the formula before feeding if using hot water for reconstitution; and iv) the need to refrigerate product, if formula is not used immediately. The importance of discarding leftovers should be emphasized.

The label should include information to make clear the potential risks of inappropriate preparation, handling and use because powdered formula is not sterile and because failure to follow manufacturers' instructions may cause serious illness. Industry and national governments should be encouraged to cooperate in order to ensure that the intended messages are understood by all potential users. When considering the wording of such information, consideration should also be given to any potential risk of caregivers being inadvertently encouraged to use inappropriate alternatives to powdered infant formulae (e.g., milk powder). The label should also include information that can enable consumers to easily identify products in the event of a recall.

9.4 EDUCATION

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

The development and distribution of educational documents related to the preparation, handling and use of PF to all caregivers should be encouraged. These programs should enable one to i) understand the importance of product information, ii) follow instructions accompanying products, and iii) make informed choices after discussing with professional caregivers, as needed.

Infants and young children who are not breastfed require a suitable breast milk substitute. When PF is used, national governments are encouraged to provide all caregivers with appropriate educational material. The guidelines for the safe preparation, storage and handling of powdered infant formula developed by the FAO/WHO[10] may be used.

All caregivers should be informed of the potential risks associated with the inappropriate preparation, handling and use of PF which may result in serious illness. It should also be noted that other ingredients which are added to formula during/after reconstitution may not be sterile and thus, may also present a potential for contamination.

Stringent hygienic preparation and storage conditions should be emphasized due to the potential for contamination of the product from various sources, e.g., equipment, utensils, the preparation environment, other ingredients/foods. Likewise, the water used to rehydrate PF will greatly impact the safety of the product. Appropriate preparation and handling, according to manufacturer's instructions reduces the risk of illness and, when appropriate, these should be emphasized by national governments. Additionally, experience has indicated that all caregivers need to be periodically reminded that bottled water is not a sterile product unless specifically indicated as such on the product. Information/education about the need to follow good hygiene practices during preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized. It is important to stress the fact that reconstituted formula may allow the growth of microorganisms, and temperature abuse may lead to foodborne illness. Reconstituted powdered formula should be fed immediately when possible or kept refrigerated for no more than 24 hours. Reconstituted PF should be refrigerated promptly in containers and volumes that allow the reconstituted PF to cool rapidly. Thus, it should be kept refrigerated if not used immediately following preparation.

Refrigerated storage should not exceed 24 hours following reconstitution. Temperature abuse may lead to foodborne illness. Improper handling and storage of reconstituted PF can promote the growth of pathogens (e.g., *Salmonella*, *E. sakazakii*, and other microorganisms such as sporeformers) which may be present initially at low levels, or which may have contaminated the product during handling and preparation.

Guidance on microbiological monitoring in powdered formula preparation units in health care settings is provided in Annex III and should be followed as appropriate.

SECTION X – TRAINING

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

The FAO/WHO Guidelines for the Safe Preparation, Storage and Handling of Powdered Infant Formula (2007)[10] should be used as a reference for training.

ANNEX I

MICROBIOLOGICAL CRITERIA FOR POWDERED INFANT FORMULA, FORMULA FOR SPECIAL MEDICAL PURPOSES[19] AND HUMAN MILK FORTIFIERS

Microbiological criteria should be established in the context of 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 pathogens and a second for process hygiene indicators.

Criteria for pathogenic microorganisms

These are 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.

Microorganisms	**n**	**c**	**m**	**Class Plan**
*Enterobacter sakazakii**	30	0	0/10 g	2
*Salmonella***	60	0	0/25 g	2

Where n = number of samples that must conform to the criteria: 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 good quality from defective quality.

*The mean concentration detected is 1 cfu in 340g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 100g (if the assumed standard deviation is 0.5 and probability of detection is 99%)

**The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%)[20].

The methods to be employed for *E. sakazakii* and *Salmonella* should be the most recent editions of ISO/TS 22964:2006 and ISO 6579, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

The criteria above are applied with the underlying assumption that the history of the lot is unknown, and the criteria are 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[21]. The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected lot from being released for human consumption and (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 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.

[19] This category includes formula for special medical purposes intended for infants as the sole source of nutrition and formula for special medical purposes for infants, intended to partially replace or supplement breast-milk or infant formula.

[20] International Commission on Microbiological Specifications for Foods, 2002, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, Kluwer Academic/Plenum Publishers.

[21] Section 4.3, FAO/WHO. 2006. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: meeting report, Microbiological Risk Assessment Series 10.

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[22]	0/10 g	Not applicable	2

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

* 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 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 should be the most recent editions of ISO 4833:2003 and ISO 21528-1/21528-2, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc. The criteria above are intended to be used as a means of achieving ongoing verification of a facility's microbiological hygiene programs. Such indicators

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[22] This 2 class plan is proposed because a 3 class plan with equivalent performance would not be practical analytically, given the low levels of 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 MCs for *Salmonella* and *E. sakazakii*) 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 MCs for *Salmonella* and *E. sakazakii* 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 ICMSF, 2002. Microorganisms in Foods. Book 7. Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum, NY. ISBN 0-306-47262-7.

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, environmental surveillance (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 aerobes). Continued failures should be accompanied by increased sampling of the product for *E. sakazakii* and *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.

ANNEX III

GUIDANCE FOR THE ESTABLISHMENT OF MONITORING PROGRAMS FOR *SALMONELLA*, *ENTEROBACTER SAKAZAKII* AND OTHER ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS AND IN POWDERED FORMULA PREPARATION UNITS

1. GUIDANCE FOR THE ESTABLISHMENT OF AN ENVIRONMENTAL MONITORING AND PROCESS CONTROL PROGRAM IN HIGH HYGIENE PROCESSING AREAS

Even under adequate hygienic conditions, low levels of Enterobacteriaceae (EB), including *E. sakazakii*, may be present in the processing plant environment. This could lead to the sporadic presence of low levels of EB in the finished product due to post-pasteurization contamination from the environment. Tracking the level of EB in the processing plant environment is a useful means of verifying effectiveness of the hygienic procedures applied and also allows undertaking corrective actions in a timely manner. Environmental monitoring of EB provides baseline levels and therefore allows the tracking of changes over time. Although it is recognized that there is no universally demonstrated correlation to date between counts of EB and *E. sakazakii*/*Salmonella*, it has been demonstrated at the individual processing plant level that a reduction in the levels of the EB in the environment leading to lower levels of EB (including *E. sakazakii* and *Salmonella*) in the finished product.

In view of the limitations of end product testing alone, it is important to have an environmental monitoring program for these products, particularly since contamination has led to several recognized outbreaks.

Such a monitoring program could be used to assess control of the processing plant environment in the high hygiene areas (dry areas) where contamination might take place, and, thus, would be an essential food safety management tool.

The monitoring program should be part of a food safety control system incorporating prerequisite programs such as good hygienic practices and a HACCP program.

In order to design an appropriate monitoring program, it is important to understand the ecology of *Salmonella* and *E. sakazakii* as well as the ecology of EB (used as indicators of process hygiene).

- *Salmonella* is rarely found in dry processing areas and monitoring should be designed to assess whether the control measures to prevent entry have been effective. It should also allow one to assess whether, in case of entry, establishment in harbourage sites and spread throughout the area could be prevented or has taken place.

- *E. sakazakii* is more frequently found than *Salmonella* in dry processing areas and is found regularly when using appropriate sampling and testing methods. The monitoring program shouldbe designed to assess whether *E. sakazakii* is increasing and whether the control measures are effective to prevent the growth of the organism.

- Enterobacteriaceae are widespread and therefore part of the normal flora in dry processing areas. They are found regularly when using appropriate sampling and testing (quantitative) methods. EB have been used for decades as indicators of process hygiene to detect deviations in good hygienic practices.

A number of factors (a – i) should be considered when developing the sampling program to ensure its effectiveness:

(a) Type of product and process/operation

The need for and extent of the sampling program should be defined according to the characteristics of the products and in particular the age and health status of the consumer. While *Salmonella* is considered a pathogen for all categories of products included in this Code, *E. sakazakii* may only be relevant for specific products.

Monitoring activities should be focused in areas where contamination is likely to occur, i.e., in the dry processing areas located in the high hygiene zones. Particular attention should be given to interfaces between these areas and external areas of a lower hygiene level as well as areas close to processing line and to equipment where contamination is more likely to occur, e.g., due to the design of equipment, presence of openings such as hatches which may be opened occasionally for inspections. Known or likely harbourage sites should be given priority for monitoring.

Sampling of areas far from the processing line or even external areas is of limited use.

(b) Types of samples

Two types of samples should be included in monitoring programs:

(1) Environmental samples collected from non food contact surface areas such as external parts of equipment, floors surrounding the line, pipeline and platforms. In this case, the risk of contamination will depend on the location and design of the processing line and equipment as well as on the levels determined.

(2) Samples (line samples) collected from food contact surfaces inside the equipment located after the dryer and prior to packaging and which present a higher risk of directly contaminating the product. Examples of such areas are sifter tailings where product lumps will accumulate and which may be indicative of moisture uptake. The presence of indicator microorganisms, *E. sakazakii* or *Salmonella* on food contact surfaces represents a very high risk of directly contaminating the product.

(c) Target organisms

While *Salmonella* and *E. sakazakii* are the main target organisms, industry has found it advantageous to include EB as indicators of process hygiene. Their levels are good indicators of conditions supporting the potential presence of *Salmonella* and the potential for growth of *Salmonella* and *E. sakazakii*.

(d) Sampling locations and number of samples

The number of samples will vary with the complexity of the process and processing lines.

Preferential locations for sampling should focus on areas where harbourage or entry leading to contamination is likely to occur. Information on appropriate locations can be found in the published literature and can be based on process experience and expertise, or on historical data gathered through plant surveys. Sampling locations should be reviewed on a regular basis and additional ones may need to be included in the program, depending on special situations such as major maintenance or construction activities or where there is any observed indication of poor hygiene.

Care should be taken not to introduce a bias in the time samples are taken. This includes ensuring that there is adequate sampling of all manufacturing shifts and production periods within these shifts. Additional samples just prior to start-up are good indices of the effectiveness of cleaning operations.

(e) Frequency of sampling

The frequency of environmental sampling for the different parameters should be based primarily on factors outlined under (a). It should be defined based on existing data on the presence of relevant microorganisms in the areas submitted to such a monitoring program. In the absence of such information, sufficient suitable data should be generated to correctly define the appropriate frequency. Such data should be collected over sufficiently long periods of time so as to provide representative and reliable information on the prevalence and occurrence of *Salmonella* over time, and/or *E. sakazakii*, where appropriate.

The frequency of the environmental monitoring program needs to be adjusted according to the findings and their significance in terms of risk of contamination. In particular, the detection of pathogens and/or

increased levels of indicator organisms in the finished product should lead to increased environmental and investigational sampling to identify the contamination sources. The frequency also needs to be increased in situations where an increased risk of contamination can be expected, e.g., in case of maintenance or construction activities or following wet cleaning activities.

(f) Sampling tools and techniques

It is important to choose and adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example, scrapings of residues or residues from vacuum cleaners provide useful samples, and humidified sponges (or dry swabs) may be more appropriate for larger surfaces.

(g) Analytical methods

The analytical methods used to analyse environmental samples should be suitable for the detection of the target organisms. Considering the characteristics of environmental samples it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Under certain circumstances, it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample. Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed-field gel electrophoresis) can potentially provide very useful information about the source(s) of *E. sakazakii* and pathway(s) that lead to contamination of PF.

(h) Data management

The monitoring program should include a system to record the data and their evaluation, e.g. performing trend analyses. A continual review of the data is important to revise and adjust monitoring programs. For EB and *E. sakazakii*, it can also reveal low level, intermittent contamination that may otherwise go unnoticed.

(i) Actions in case of positive results

The purpose of the monitoring program is to find target organisms if present in the environment. Decision criteria and responses based on these monitoring programs should be articulated prior to the establishment of the program. The plan should define the specific action to be taken and the rationale. This could range from no action (no risk of contamination), to intensified cleaning, to source tracing (increased environmental testing), to review of hygienic practices up to holding and testing of product.

Generally manufacturers should expect to find EB and *E. sakazakii* in the processing environment. Therefore an appropriate action plan should be designed and established to adequately respond where decision criteria are exceeded. A review of hygiene procedures and controls should be considered. The manufacturer should address each positive result of *Salmonella* and evaluate changes in the trends of *E. sakazakii* and EB counts; the type of action will depend upon the likelihood of contaminating the product with *Salmonella* and *E. sakazakii*.

2. MICROBIOLOGICAL MONITORING IN POWDERED FORMULA PREPARATION UNITS

The extrinsic microbiological contamination of powdered formulae during preparation is a factor which needs to be taken into consideration in the design of preventive measures in health care and child care facilities. Such measures are based, as in the case of the manufacture of the powdered formulae, on the application of Good Hygienic Practices as relevant for any establishment handling foods (*Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969*) and on the application of HACCP or similar systems to address specific hazards.

Such extrinsic microbiological contamination can occur either from the preparation environment, from preparation surfaces, and/or from utensils used during preparation. It is therefore important to assess and verify that the implemented measures are effective.

Microbiological monitoring of powdered formula storage areas, preparation areas, and surfaces in direct contact with the product (e.g., utensils) represents an essential element of the quality assurance program.

Results from a properly designed monitoring program will assist in identifying potential sources of contamination and in demonstrating the efficacy of cleaning and disinfections procedures.

As for section 1 of this annex, a number of factors should be considered when developing the sampling program to ensure its effectiveness, including the target organisms, types of samples, sampling locations, number of samples, frequency of sampling and tools and techniques, analytical methods, data management and actions to take in case of positive results.

A monitoring program of PF preparation units is best achieved through sampling and testing of environmental samples for relevant microorganisms such as *Salmonella* and *E. sakazakii* or hygiene indicators such as EB. It should include swabs from surfaces of preparation areas, sinks, equipment and utensils used as well as residues, for example from vacuum cleaners, collected in the area.

It is important that the sampling be done using appropriate sampling tools and techniques, adapted to the type of surfaces and location, and from relevant sites which may, if contaminated, lead to (extrinsic) contamination of PF.

The analytical methods used should be suitable for the detection of the target organisms. Considering the characteristics of samples, it is important to demonstrate that the methods are able to detect, with acceptable sensitivity, the target organisms. This should be documented appropriately. Under certain circumstances, it may be possible to composite (pool) certain samples without losing the required sensitivity. However, in the case of positive findings additional testing will be necessary to determine the location of the positive sample. Fingerprinting isolates by one or more of the available genetic techniques (e.g., pulsed-field gel electrophoresis) can potentially provide very useful information about the source(s) of *E. sakazakii* and pathway(s) that lead to contamination of PF.

It is important as well to document sampling activities and to include a system to record the data and their evaluation, e.g., performing trend analyses, and to use the data to initiate corrective actions where necessary. For this purpose, it is important to define targets to be achieved, e.g., in terms of acceptable levels of hygiene indicators or absence of pathogens. Such targets should be based on historical data or, if not available, on an initial survey that would permit one to define the normal microbiological status of the different sampling points. For EB and *E. sakazakii*, it can also reveal low level, intermittent contamination that may otherwise go unnoticed.

The purpose of the monitoring program is to find target organisms, if they are present. Generally, it is expected that EB and *E. sakazakii* would be present in the preparation room environment. Decision criteria and responses based on the monitoring program should be articulated prior to the establishment of the program. The plan should define the specific action to be taken where decision criteria are exceeded and the rationale for such action. Each positive result for *Salmonella* and *E. sakazakii* should be addressed and changes in the trends of EB counts should be evaluated. The type of action will depend upon the likelihood of contaminating the formulae with *Salmonella* and *E. sakazakii*. This could range from no action (no risk of contamination), to intensified cleaning, to source tracing, to the review of hygienic practices.

It is also important to review the monitoring program on a regular basis to take into account changes in the set-up, trends, etc.

Appendix III

PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD SAFETY CONTROL MEASURES

(At Step 5/8 of the Procedure)

I. INTRODUCTION

The control of hazards potentially associated with foods typically involves the application of control measures in the food chain, from primary production, through processing, to consumption. In the current environment of systems-based food safety controls that provide flexibility with the selection of control measures, validation of these control measures acquires increased importance. It is through the validation process that one demonstrates that the selected control measures are actually capable, on a consistent basis, of achieving the intended level of hazard control.

It is important to make a clear distinction between the role of industry[1] and the role of the competent authority in validating control measures. Industry is responsible for validation of control measures, while the competent authority ensures that industry has effective systems for validation and that control measures are appropriately validated. Governments may provide guidance to industry on how to conduct validation studies and how validated control measures may be implemented. Governments or international organizations may also conduct validation studies in support of risk management decisions or provide information on control measures considered to be validated, especially where the resources are not available to conduct such studies (e.g. small and less-developed businesses).

These guidelines present information on the concept and nature of validation, tasks prior to validation, the validation process, and the need for re-validation. These guidelines also address the difference between validation, monitoring and verification. Annex I provides examples of validation scenarios which are for purpose of illustration only and which do not represent actual validation of control measures and which do not have global application.

II. SCOPE

These guidelines apply to validation of control measures at any stage of the food chain[2]. These guidelines are intended as guidance to industry and governments on the validation of individual control measures, a limited combination of control measures, or sets of control measure combinations forming a food safety control system (e.g. HACCP, GHP).

The tools, techniques, and statistical principles that would be used to validate specific food safety control measures are beyond the scope of the current document. Advice on specific applications should be acquired from scientific organizations, competent authorities, process control experts or related sources of scientific expertise that can provide the specific principles and best practices upon which the validation of a specific control measure should be based.

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[1] For the purposes of this document, it is understood that industry includes all relevant sectors associated with the production, storage and handling of food, from primary production through retail and food service level (adapted from *Working Principles for Risk Analysis for Application in the Framework of Codex Alimentarius* and taken from *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

[2] The focus of this document is the validation of elements of a food safety control system; however, the recommendations in this document also may be applied in the validation of other food hygiene measures.

III. DEFINITIONS[3]

Control Measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[4]

Food Safety Control System: The combination of control measures that, when taken as whole, ensures that food is safe for its intended use.

Monitoring: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.[5]

Validation: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.[6]

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.[7]

IV. CONCEPT AND NATURE OF VALIDATION

Validation focuses on the collection and evaluation of scientific, technical and observational information to determine whether control measures are capable of achieving their specified purpose in terms of hazard control. Validation involves measuring performance against a desired food safety outcome or target, in respect of a required level of hazard control.[8]

Validation is performed at the time a control measure or a food safety control system is designed, or when changes indicate the need for re-validation (see section VII). Validation of control measures is, whenever possible, performed before their full implementation.

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[3] In many cases, existing definitions such as those contained in the SPS Agreement, the General Principles of Food Hygiene, HACCP Annex and the CCFH Risk Management document, were suitable for use in this document. In other cases, where a definition was too limiting outside of its original context (e.g. some HACCP Annex definitions), another definition was developed that was more suitable for use within the context of these guidelines.

[4] *International Recommended Code of Practice: General Principles of Food Hygiene,* (CAC/RCP 1-1969), HACCP Annex.

[5] Derived from *Recommended International Code of Practice - General Principles of Food Hygiene (*CAC/RCP 1-1969), HACCP Annex, but was modified to apply to all control measures, whether or not a HACCP system is employed.

[6] Ibid.

[7] Ibid.

[8] See *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007) and *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

Interrelationships among Validation, Monitoring and Verification

There is often confusion among the concepts of validation, monitoring and verification. Validation of control measures as described in this document is different from monitoring and verification, which both take place after the validated control measures have been implemented. Monitoring and verification are the tools used to check whether the control measures are being adhered to and to demonstrate that they are operating as intended.

- Monitoring of control measures is the on-going collection of information at the step the control measure is applied. The information establishes that the measure is functioning as intended, i.e., within established limits. Monitoring activities are typically focused on "real-time" measurements and on the performance of a specific control measure.

- Verification is an ongoing activity used to determine that the control measures have been implemented as intended. Verification occurs during or after operation of a control measure through a variety of activities, including observation of monitoring activities and review of records to confirm that implementation of control measures is according to design.

The following example for uncooked fermented sausages illustrates the interrelationship of validation, verification and monitoring:

- Validation: The competent authority established the need for control measure(s) that achieve a specified log reduction in pathogenic *Escherichia coli.* The validation process indicated that industry could consistently achieve a specified log reduction through ensuring a specific decrease in pH during fermentation and a specific decrease in water activity during maturation, coupled with ensuring that the raw materials have less than a specified level of pathogenic *E. coli* based on statistically-based microbiological testing.

- Monitoring: Measuring pH drop during fermentation and weight loss (or water activity) during maturation.

- Verification: Periodic process control testing for pathogenic *E. coli* to verify that incoming levels in the raw materials are within specification and that fermentation and maturation achieve the intended outcome in the semi-finished or finished product. Examination of monitoring records to check for continuous control over time.

V. TASKS PRIOR TO VALIDATION OF CONTROL MEASURES

Prior to the validation of control measures by the food establishment, it is important to complete certain tasks so that validation can be accomplished effectively and efficiently. The following tasks could be carried out either independently or in conjunction with the establishment of GHPs, HACCP, etc.

Tasks prior to validation include:

a) Identify the hazards that are intended to be controlled in the commodity and/or environment concerned, taking into account all relevant information, including information from a risk assessment if available.

b) Identify the food safety outcome required.

The food safety outcome can be determined in a number of ways. Industry should determine if there are existing food safety outcomes or targets, established by the competent authority, relevant to the intended use of the food. In the absence of food safety outcomes or targets established by the competent authority, targets should be identified by industry, as appropriate. Industry may also set stricter targets than those set by the competent authority.

c) Identify the measures that are to be validated, taking into account:

- The importance of the control measure in achieving control of the hazard to a specified outcome. Examples might include:
  - Heat treatment step in a canning process
  - Cooling to a specified temperature within a specific timeframe
- Whether the control measure has already been validated

Identify whether the control measure has previously been validated in a way that is applicable and appropriate to the food business (e.g. a control measure required by a competent authority or validated by a competent authority or other national or international organization) or whether its performance is so well established for the application under consideration that further validation is not necessary. In either case, a food business operator must ensure that the conditions (e.g. raw materials, relevant hazards, combinations of control measures, intended use, and distribution and consumption patterns) in their particular operation do not differ from the conditions under which the control measure was previously validated.

- Priority of validation

Considering that food safety outcomes are often dependent on multiple control measures, prioritization of validation activities may be necessary and may take into account:

- Adverse health effect: The higher the potential for an adverse health effect from a hazard, the more attention should be paid to assuring that the set of control measures selected is effective. Consideration should be given to the size of the population and the age/sex of groups most at risk.
- Historical experience: For many food production and processing scenarios, there is extensive history that specific measures used to control food borne hazards are effective. If little or no experience exists with respect to the performance of a control measure in controlling a particular hazard within a specified context, it becomes more important that validation be undertaken.

  In certain instances, these historical data may obviate the need to conduct validations. However, it is important to avoid assuming that a food production or processing system is safe based solely on historical experience. All relevant current information should be considered when evaluating the adequacy of historical information, as it may be outdated. For example, sampling and testing procedures used to obtain the original data may be insufficient in the context of current operating procedures. New strains of microbial pathogens may now exist that do not behave in the same manner as the strains of pathogens or surrogate microorganisms used for determining early food control processes. New epidemiological and/or clinical information may indicate that the control measures used in the past were less effective than previously thought.
- Other factors/constraints
  - Ability to monitor and verify the control measure
    - In prioritizing control measures for validation, consideration should be given to the amenability of the control measure to monitoring and/or verification after implementation.
    - Control measures that are of such a nature that it is not feasible to determine their quantitative effect on specific hazards may not always be considered

priority for validation. Examples of such control measures include air locks to minimize cross contamination, hand washing procedures, and several other basic hygiene practices described in the International Recommended Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969).

- Scientific and technical feasibility

  - In prioritizing control measures for validation, consideration should be given to any scientific and/or technical challenges to validating the measure. This would include consideration of the variability associated with the control measure being validated, the food being considered, and the hazards being controlled.

- Resources

  - Validation activities may be resource intensive. Particular validation activities, such as experimental trials, process capability studies, surveys, mathematical modelling, product or environmental sampling and analytical testing, particularly when applied in an appropriate statistical fashion, require significant resources. The extent to which sufficient resources are available and such activities can be undertaken will place limits on the ability to develop and validate food safety control measures. Necessary assistance (e.g. development of guidelines for industry, training and technical assistance), particularly to small and less-developed businesses, provided by national and international organizations could help to perform validation of food safety control measures.

VI. THE VALIDATION PROCESS

A range of approaches to validation are available. The precise approach will depend, among other things, on the nature of the hazard, the nature of the raw ingredients and product, the type of control measures or food safety control system selected to control the hazard, and the intended stringency of control of the hazard.

Approaches for validating control measures

The following approaches to validation may be used individually or in combination, as appropriate. These are presented in no particular order.

- **Reference to scientific or technical literature, previous validation studies or historical knowledge of the performance of the control measure.** Scientific or technical information needed to validate control measures may, in many instances, be available from many sources. These include scientific literature, government guidance, guidelines on GHP and HACCP control measures with a known history of good performance validated by competent authorities or independent scientific authorities, international standards or guidelines (e.g. Codex Alimentarius), and validation studies from industry and/or equipment manufacturers. However, if relying on such knowledge, care should be taken to ensure that the conditions of application in a food safety control system are consistent with those identified in the scientific information examined. For certain well-established processes (e.g. time and temperature combinations for milk pasteurization), it may be sufficient to acquire only the data on the conditions or attributes specific for the operation in question.

- **Scientifically valid experimental data that demonstrate the adequacy of the control measure.** Laboratory challenge testing designed to mimic process conditions and industrial or pilot plant trials of particular aspects of a food processing system are validation techniques that are used commonly, particularly in food processing unit operations. Quantitative demonstration and documentation of appropriate log reduction of a specified pathogen by a specific microbiocidal process is an example of validation of a control measure by experimental trials. If the risk from a hazard is associated with growth of the pathogen to unacceptable numbers, then the conditions (e.g. product formulation,

processing parameters, packaging or conditions of storage and distribution) that prevent the growth of the pathogen may need to be validated and documented using appropriately designed experimental trials. For example, if water activity must be controlled in a product to prevent growth of *Staphylococcus aureus*, then validation can be achieved by demonstrating that the water activity of the product under expected conditions of storage and distribution will be equal to or less than the specified water activity.

Scale up of laboratory-based experimental trials in a pilot plant is helpful in ensuring that the trials properly reflect actual processing parameters and conditions. However, this almost always requires the availability of appropriate non-pathogenic surrogate microorganisms, as viable pathogenic microorganisms should not be purposefully introduced into a food production facility. When surrogate microorganisms are used, validation should cover the appropriateness of the surrogates. Validation may have to be limited to a laboratory/pilot plant if there are no appropriate surrogate microorganisms available that can be used to acquire data under actual production conditions.

Additional safety margins may be required to account for the uncertainty or variability of the control measure or combination of control measures in achieving the desired level of control when implemented in a full scale operation.

- **Collection of data during operating conditions in the whole food operation.** When this approach is used, biological, chemical or physical data relating to the hazards of concern are collected for a specified period (e.g. 3-6 weeks of full scale production) during operating conditions representative of the whole food operation, including periods where production is increased, e.g. holiday rush. For example, when the food safety control system is contingent upon the use of good veterinary or agricultural practices in the field or good hygienic practices in the processing establishment, it may be necessary to validate these measures through the use of intermediate/finished product and/or environmental sampling and testing. Sampling should be based on the use of appropriate sampling techniques, sampling plans and testing methodology. Data collected should be sufficient for the statistical analyses required.

- **Mathematical modelling.** Mathematical modelling is a means of mathematically integrating scientific data on how factors affecting the performance of a control measure or combination of control measures affect their ability to achieve the intended food safety outcome. Mathematical models, such as pathogen growth models to assess the impact of changes in pH and water activity on the control of pathogen growth or the use of z-value models to determine alternative thermal processing conditions, are used extensively by industry. This can also include the use of risk-based models that examine the impact of a control measure or combination of control measures further along the food chain. Effective use of mathematical modelling typically requires that a model be appropriately validated for a specific food application. This may require additional testing. Validation based on the use of mathematical modelling should take into consideration the uncertainty/variability limits associated with the models' predictions.

- **Surveys.** Surveys can be used to validate control measures, as appropriate, in conjunction with other approaches to demonstrate the expected level of control of hazards can be achieved. For example, an evaluation of consumers' understanding of information on the label prior to or during the design of a label can be considered a validation approach for labelling as a control measure.[9] Care should be taken to ensure that statistically valid surveys or other activity provide data that are accurate and appropriate for use by an individual food business operator or competent authority.

Steps Involved in the Validation Process

After completing the tasks needed prior to validation, the process of validating control measures includes the following steps:

[9] Note that surveys carried out after the product is in the market place to assess whether consumers are following the instructions is a verification activity.

- Decide on the approach or combination of approaches.
- Define the parameters and decision criteria[10] that will demonstrate that a control measure or combination of control measures, if properly implemented, is capable of consistently controlling the hazard to the specified outcome.
- Assemble relevant validation information and conduct the studies where needed.
- Analyze the results.
- Document and review the validation.

Results of a validation will either demonstrate that a control measure or combination of control measures,

- is capable of controlling the hazard to the specified outcome if properly implemented, and thus, could be implemented, or
- is not capable of controlling the hazard to the specified outcome and should not be implemented.

The latter may lead to re-evaluation of product formulation, process parameters, or other appropriate decisions/actions.

Information gained in the validation process may be useful in designing verification and monitoring procedures. For example, if a control measure or combination of control measures produces a reduction of a pathogen well in excess of the reduction needed for hazard control, it may be possible to decrease the frequency of verification e.g. frequency of microbiological testing of end product.

VII. NEED FOR RE-VALIDATION

There are many changes that could lead to a need to re-validate a control measure or combination of control measures. Examples include:

- System failure: If monitoring or verification identifies failures for which a process deviation cause cannot be identified, re-validation may be needed. Non-compliance with monitoring or verification criteria may indicate a need for a change in the parameters (i.e., the selection and specification of the control measures) on which the design of the food safety control system is based. A system failure may also result from an inadequate hazard analysis and may require re-validation.
- Process changes: The introduction in the food safety control system of a new control measure, technology or a piece of equipment that is likely to have a decisive impact on the control of the hazard may necessitate that the system or parts of it be re-validated. Similarly, changes made in product formulation or the application of current control measures (e.g. time/temperature changes) may result in the need for re-validation of control measures.
- New scientific or regulatory information: Re-validation may be needed if the hazard associated with a food or ingredient changes as a result of (i) higher concentrations of hazards than originally encountered and accounted for in the design, (ii) a change in response of a hazard to control (e.g. adaptation), (iii) emergence of a previously unidentified hazard, (iv) new information indicating that the hazard is not being controlled to the level specified (e.g. new epidemiological findings or new validated and internationally accepted analytical technologies) or (v) a new food safety outcome.

[10] Decision criteria should take into account the uncertainty and variability associated with the validation methodology and the performance of the control measure or combination of control measures.

ANNEX I

EXAMPLES OF VALIDATION OF FOOD SAFETY CONTROL MEASURES

This Annex contains examples of several approaches to validating control measures or combinations of control measures. All of the examples described below are for purposes of illustration only, do not represent actual validation scenarios in a global sense and should not be replicated as presented. . Also, the examples below are presented in a specific format only for consistency and this format is not intended to be a general model for validation.

In the examples below, it is assumed that the control measures have not been previously validated, that they have a decisive impact on the control of the specific hazard, and that they have been prioritized for validation.

EXAMPLE ONE: VALIDATION OF POST-HARVEST DEHYDRATION TO PREVENT AFLATOXIN CONTAMINATION OF TREE NUTS[11]

1. Pre-validation Tasks.

    a. Hazard: Aflatoxin contamination has been identified as a hazard that is reasonably likely to occur in tree nuts. Its control requires applications of measures both pre-harvest and post-harvest. Post-harvest measures are focused on rendering the tree nuts incapable of supporting continued aflatoxin production by *Aspergillus* spp.

    b. Food safety outcome required: The recognized international standard for aflatoxin B_1 is 20 µg/kg. However, to take into account process and analytical uncertainties, the food safety outcome is set at 10 µg/kg

    c. Control measure to be validated: Post-harvest dehydration of tree nuts

2. Approach: There are sufficient scientific data in the literature to allow the control measure to be validated without the need for additional studies.

3. Parameters and Decision Criteria:

    a. Parameters:

        i. Aflatoxin-producing *Aspergillus* spp. cannot grow and synthesize the toxins when the water activity of the product falls below 0.70.[12]

        ii. The amount of aflatoxin that is produced post-harvest is dependent on the speed that tree nuts can be dehydrated and the rate at which the mold can grow. The scientific literature suggests that germination of the spores and initiation of toxin synthesis can occur with 24 to 48 hours of exposure of post-harvest tree nuts to a moist environment.

        iii. The level of aflatoxin B_1 present in post-harvest tree nuts will also be dependent on the levels present prior to the initiation of dehydration.

    b. Decision Criteria:

        i. A post-harvest dehydration control measure will be validated if

[11] Ongoing discussion is taking place in the Codex Committee on Contaminants in Foods regarding maximum levels for aflatoxin in tree nuts. The values used in the example are for illustration purposes only and shall not be considered as guidance in any way.

[12] *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts* (CAC/RCP 59-2005).

1. The water activity in lots of tree nuts being treated can be consistently reduced to <0.70 within 24 hours,

2. After dehydration there is an absence of "wet spots" that have a water activity ≥ 0.70 in the lot.

3. The level of aflatoxin B_1 in the tree nuts after a water activity <0.70 has been attained does not exceed 10 µg/kg.

4. The treatment includes appropriate packaging/storage of the dried tree nuts

4. Assemble relevant validation information and conduct the studies where needed.

   a. Confirm incoming level of aflatoxin under a variety of harvest conditions

   b. Obtain scientific references documenting that aflatoxin-producing *Aspergillus* spp. cannot synthesize the toxins when the water activity of the product falls below 0. 70.

   c. Obtain information to support that toxin production is not likely to occur if tree nuts are dried to this water activity in 24 to 48 hours; this may include use of mathematical models for the rate of growth and toxin production by *Aspergillus* species.

   d. Determine that the technology to be used will consistently produce tree nuts that have water activity levels < 0.70 within 24 h.

   The available scientific literature and related scientific data relating water activity levels to aflatoxin production in tree nuts should be reviewed to determine their pertinence to the specific procedures being employed by the business operator. If there is uncertainty about the applicability of the scientific literature, acquisition of additional analytical data may be required. At a minimum, data on the water activity of tree nuts after 24 hours drying should be obtained.

5. Analyze the results.

   a. Data acquired by the business operator on the ability of the dehydration technology employed by the operator to consistently achieve the dehydration outcomes should be analyzed to ensure key operating parameters of the equipment are being followed and are achieving the expected water activity within the expected timeframe in this specific operation.

   b. As appropriate, statistical analyses should be performed to assess the variability in the processes.

6. Document and review the validation.

   All analyses, data, and decisions should be documented.

7. Conclusion

   a. Data indicate that if the incoming level of aflatoxin B_1 in the untreated tree nuts is < 1 µg/kg, then the levels after dehydration can be appropriately controlled and thus the control measure can be implemented.

   b. Storage/packaging conditions must be adequate to maintain the desired water activity of the dried tree nuts.

   c. These data can be used to establish a program of monitoring for water activity levels, and periodic analysis of the dehydrated tree nuts for aflatoxin B_1.

EXAMPLE TWO: MEETING A PERFORMANCE OBJECTIVE FOR VERO-TOXIN PRODUCING *ESCHERICHIA COLI* IN A HARD RAW MILK CHEESE

1. Pre-validation Tasks:

a. Hazard: Vero-toxin producing *Escherichia coli* (VTEC) in hard raw milk cheese.

b. Food Safety Outcome: A performance objective (PO) of <0.001 cfu VTEC/g at the end of production.

c. Control Measure: A combination of control measures (level of the pathogen in the raw milk, time/temperature during processing, pH, water activity) contribute to the level of VTEC at the end of production, which includes a defined ripening period under specified conditions.

2. Approach: Use of scientifically valid experimental data to demonstrate the adequacy of the control measures

3. Parameters and Decision Criteria: The combination of control measures will be considered validated as achieving the PO[13] if the calculated geometric mean (x) + 3 standard deviations (σ) level of VTEC at the end of production (ripening) is < 0.001 cfu/g (-3 $\log_{10}$(cfu/g))

4. Assemble relevant validation information:

a. the level (e.g. geometric mean (x) + 3σ) of the pathogen in the raw milk is estimated, using microbiological testing of the milk

b. a model of the manufacturing process (time, temperature, pH, water activity) based on data collected from production (e.g. experimental production), including the possible variation in the process

c. growth/reduction rates during the manufacturing process are identified from literature, other sources, or from experimental trials if necessary

d. the changes in hazard levels that are reasonably likely to occur during processing steps (i.e. those steps that are technologically needed to manufacture the product)

e. Initial selection of the manufacturing process that is likely to simultaneously yield the desired level of VTEC control and the desired product quality—this will identify the control measures required (time, temperature, pH, water activity).

5. Design an experimental study that mimics the selected process:

a. Raw milk of the same status as intended for production is spiked with levels of VTEC (mixture of relevant strains, isolated from milk) that can be measured throughout the process

b. The cheese is manufactured (pilot scale) and samples are taken for analysis at relevant points needed to validate the initial model.

c. All parameters specifying the process are monitored during the trial to ensure comparability with full scale production

6. Analyze the results

a. Data on the end product

b. Data relating to the model and the process used

[13] Ibid

7. Document and review the validation

Documentation should include:

a. result of literature research

b. results of the experimental study

c. statistical analysis of raw data and analytical results

d. description of the various models

e. rationale for selecting the scenario for experimental trial (control measures and processing steps)

f. data on VTEC strains used for spiking

g. documentation of the variability in process

8. Conclusion

The PO can be met under the following conditions:

a. That the process parameters (time, temperature and pH profiles during cheese making) are within tolerance under monitoring and are not changed

b. That the raw milk does not exceed xx cfu/g

c. That the cheese is ripened for a minimum of yy days prior to release.

EXAMPLE THREE: VALIDATION OF CLEANING AND DISINFECTING PROTOCOLS (Sanitation Standard Operating Procedures, SSOPs)

1. Pre-validation Tasks

a. Hazard(s): Generic microbial contaminants

b. Food Safety Outcome: Effective sanitation of food-contact surfaces as demonstrated by compliance with microbiological criteria.

c. Control Measure(s): Cleaning and disinfection protocols (SSOPs) within a facility

2. Approach: Collection of scientific data.

3. Parameters and Decision Criteria: SSOPs will be considered to be validated if, after implementation of cleaning and disinfection protocols, food contact surfaces meet microbiological criteria established for aerobic plate counts or other indicator microorganisms as appropriate.

4. Assemble the relevant validation information

a. SSOPs will be implemented as intended for 3-4 weeks of operation.

b. Microbiological testing of food contact surfaces will be conducted after cleaning and disinfection protocols have been used at the end of each day's production.

5. Analyze the results

a. Compare results obtained at the end of each day's production to the established microbiological criteria.

b. Conduct appropriate statistical analyses to determine the variability in efficacy of the cleaning and disinfection procedures.

6. Document and review the validation

a. Data from implementation of SSOPs should be documented.

b. All data from food contact surface testing should be documented.

7. Conclusion

If review and analysis of the validation results indicate that the SSOPs are capable of consistently delivering results that comply with the established microbiological criteria during 3-4 weeks of the validation period, then the cleaning and disinfection protocols can be considered validated.

This same protocol with a reduced rate of testing can be used as an ongoing verification activity that the SSOPs are being implemented properly.

EXAMPLE FOUR: CONTROL OF METAL FRAGMENTS

1. Pre-validation Tasks:

a. Hazard: Metal fragments

b. Food Safety Outcome: Less than 1 metal fragment over 2 mm in 100,000 kg of product.

c. Control Measure: Introduction of a sieve into a production line

2. Approach: Collection of data during normal operation.

3. Parameters and Decision Criteria:

Control measure will be considered validated if a metal detector indicates that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product. Operational data will be collected for one month and reviewed to determine the size of any metal pieces in products rejected by the metal detector.

4. Assemble relevant validation information.

a. Determine the size of metal fragments in products rejected by the metal detector.

b. Ensure that the metal detector is sensitive enough and calibrated to detect metal pieces of 2 mm or more in the specific product.

c. Ensure that the sieve remains intact during normal operations.

5. Analyze the results

Determine the rate at which the sieve allowed fragments of 2 mm or more in the final product.

6. Document and review the validation

a. Document all findings from the metal detector.

b. Document the integrity of the sieve and the sensitivity and calibration of the metal detector.

7. Conclusion

a. Control measure can be implemented if data indicate that production with the sieve will allow < 1 metal fragment ≥ 2 mm in 100,000 kg of final product.

b. Validation will likely provide information on monitoring needed to ensure that sieve remains intact.

c. The metal detector can be used after the validation as an ongoing verification activity to ensure that the sieve is controlling the hazard as intended.

EXAMPLE FIVE: VALIDATION BY A COMPETENT AUTHORITY (NEW ZEALAND) OF MEAT INSPECTION PROCEDURES FOR *TAENIA SAGINATA*[14]

1. Pre-validation Tasks:

a. Hazard: Cysts of *Taenia saginata* in slaughtered cattle.

b. Food safety outcome: No increase in risks to consumers

c. Control Measure: A new post-mortem inspection procedure for the identification and removal of cysts. Post mortem inspection is the only available control measure. Traditional inspection involves slicing of a large number of tissues (and also results in a high degree of microbiological cross-contamination). The new inspection package would limit slicing to a minimum.

2. Approach: Experimental trial and mathematical modelling

3. Parameters and Decision Criteria

a. The food safety outcome is no decrease in the current level of consumer protection, i.e. mean rate of 1.1 cases of infection per year in the total population per year.

b. The decision criterion for validation is that any difference in non-detection rate at post mortem inspection does not result in a decrease in the current level of consumer protection.

c. The decision criteria included consideration of probability distributions generated by the model.

4. Assemble information and conduct studies

Detailed experimental trials to determine non-detection rates for the traditional and the alternative inspection measures, and mathematical modelling to determine impact on the chosen food safety outcome

5. Analyze the results

The food safety outcome of the new control measure was presented as a frequency distribution and a mean value was chosen for purposes of comparison. The level of consumer protection was estimated to be a mean rate of 1.3 cases of infection in the total New Zealand population per year. Given the uncertainty in the biological system, primarily related to the very low sensitivity of any type of post mortem inspection (less than 25%) and the extremely low prevalence of *Taenia saginata* in New Zealand, this result met the decision criteria for validation.

Note: This validation process would likely not give the same result in a country with a moderate to high level of infection in the slaughter population.

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[14] This example is documented in Van der Logt, P., Hathaway, S. C. and Vose, D. (1997): Risk assessment model for human infection with the cestode *Taenia saginata*. Journal of Food Protection 60:1110-1119.

6. Document and review

a. Document the methodology for the experimental trials and the results

b. Document the development of the mathematical model and its validation.

c. Document the results of the modelling.

7. Conclusion: The new inspection package results in the same level of consumer protection as the old inspection package that involved considerably more slicing.

EXAMPLE SIX: VALIDATION OF A SAFE-HANDLING LABEL FOR TABLE EGGS

1. Pre-validation Tasks:

a. Hazard: *Salmonella* Enteritidis (SE) in table eggs (shell eggs).

b. Food Safety Outcome: Reduced frequency of consumption of eggs contaminated with SE.

c. Control Measure: Labelling (one control measure among several beginning at primary production (on-farm practices) through consumer use (cooking, storage temperatures)). The label will state: "To avoid illness, refrigerate eggs at 5ºC (41ºF) and cook eggs until the yolk is firm."

2. Approach: A representative survey of consumers

3. Parameters and Decision Criteria:

a. A risk assessment has shown that, in concert with control measures elsewhere in the food chain, the number of servings of eggs contaminated with SE will be significantly reduced if there is a 25% increase in the number of consumers that store table eggs at 5ºC (41ºF) and cook eggs until the yolks are firm.

b. The control measure (label) will be considered validated if a specified percentage of the population understands the label (i.e., having read it, they can state what they would do if following the label instructions) and indicates that they plan to follow the instructions.

4. Assemble relevant validation information:

a. Identify target demographic for survey

b. Design a statistically-valid survey to determine

- Current consumer practices
- Whether the label is understandable
- Whether consumers plan to change their current practices, if necessary, based on the label instructions.

5. Analyze the results:

a. Determine the percentage of the population that is not currently following the practices described on the label.

b. Determine the percentage of the population that understands the label instructions.

c. Determine the percentage of the population that indicates that they plan to change their current practice and follow the label instructions.

6. Document and review the validation:

a. Document the development of the survey

b. Document the identification of the target demographics for the survey

c. Document the survey results

7. Conclusion

The control measure can be implemented because data indicated that because of the label instructions more than 25% of the population plan to change their current practice and begin refrigerating eggs at 5ºC (41ºF) and, when appropriate, cooking eggs until the yolk is firm.

Appendix IV

PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT

PROPOSED DRAFT ANNEX II: GUIDANCE ON MICROBIOLOGICAL RISK MANAGEMENT METRICS

(At Step 5/8 of the Procedure)

Introduction

Three general principles are articulated in the "Recommended International Code of Practice General Principles of Food Hygiene," its annex "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application," and the recently adopted "Principles and Guidelines for the Conduct of Microbiological Risk Management:" (i) the stringency of food safety systems should be appropriate for the dual goals of managing risks to public health and ensuring fair practices in the food trade; (ii) the level of control required of a food safety control system should be based on risk and determined using a scientific and transparent approach; and (iii) the performance of a food safety control system should be verifiable. These goals have traditionally been achieved, in part, through the establishment of microbiological criteria (MC), process criteria (PcC), and/or product criteria (PdC). These metrics have provided both a means of articulating the level of stringency expected of a food safety control system and verifying that this level of control is being achieved. However, these traditional risk management tools have generally not been linked directly to a specific level of public health protection. Instead, these metrics have been based on qualitative consideration of the levels of hazards that are "as low as reasonably achievable," a hazard-based approach that does not directly consider the level of control needed to manage a risk to public health. The recent adoption of the "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" and the "Working Principles for Risk Analysis for Food Safety for Application by Governments" has emphasized the goal of Codex Alimentarius to develop risk-based approaches that can more directly and transparently relate the stringency of control measures to achievement of a specified level of public health protection.

A risk management approach based on risk is an important step in improving a food safety system based on science by linking food safety requirements and criteria to the public health problems they are designed to address. Recent advances in microbiological risk assessment (MRA) techniques, such as quantitative microbiological risk assessments (QMRA), qualitative risk assessments, and formalized expert elicitations, are increasingly making it possible to more systematically relate the performance of a control measure, a series of control measures or even an entire food safety control system to the level of control needed to manage a food safety risk. This has been particularly true with QMRA techniques which allow the impact of different degrees of stringency to be considered quantitatively in relation to predicted public health outcomes. This increased analytical capability has led to a series of new food safety risk management metrics, such as the Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC), which are intended to provide a bridge between traditional food safety metrics (i.e. MC, PcC, PdC) and the expected level of public health protection. Such metrics provide a potential means of articulating the level of stringency required of a food safety system at different points in the farm-to-table continuum, thereby providing a means for "operationalizing" the Appropriate Level of Protection (ALOP) concepts envisioned in the WTO SPS Agreement.

As outlined in the main body of this document, the ability to articulate the expected performance of control measures and food safety control systems in terms of the necessary management of public health risks is a critical component of the evolving Codex Alimentarius risk analysis paradigm. While MRA is increasingly used to evaluate the ability of control measures and food safety control systems to achieve a desired degree of public health protection, its application to the development of metrics that can be used to communicate this stringency within an international or national food safety risk management framework is still in its infancy. In particular,

the risk assessment tools for linking the establishment of traditional metrics and other guidance for the hygienic manufacture, distribution, and consumption of foods to their anticipated public health impact can be complex and not always intuitive. Furthermore, effective risk assessments generally have to consider the variability and uncertainty associated with risk factors, whereas most risk management decisions which are consistent with the legal frameworks underpinning the authority of most competent authorities must ultimately be simplified to a binary criterion (e.g. "acceptable or not acceptable", "safe or unsafe").

Scope

The purpose of this annex is to provide guidance to Codex and national governments on the concepts and principles for the development and implementation of microbiological risk management metrics, including how risk managers and risk assessors may interact during this process.

The guidance provided by the annex should also prove useful to the food industry and other stakeholders who have the responsibility of devising, validating, and implementing control measures that will ensure that, once established, a microbiological risk management metric will be achieved on a consistent basis.

It is beyond the scope of this document to consider in detail the risk assessment tools, techniques, and mathematical/statistical principles that may be pertinent to the development and implementation of specific metrics for a specific food/hazard.

Use of the Document

This annex provides general guidance on approaches to the establishment of microbiological risk management metrics to more objectively and transparently relate the level of stringency of control measures or entire food safety control systems to the required level of public health protection. The annex also addresses the use of these metrics as a means of communicating and verifying risk management decisions. Recourse to microbiological risk management metrics is not always the most appropriate approach to address all food safety management questions. In some cases where a full risk assessment is not available, sound scientific information may be entirely valid and sufficient to inform risk managers, who may decide to implement control measures without directly linking their impact to the public health outcomes. The level of application by competent authorities may vary, taking into account knowledge and availability of scientific information. It is up to competent authorities to prioritize foods relevant to the countries for considering the application of MRM metrics.

This annex should be used in conjunction with the Codex "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[1]," "Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)," "Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL 63-2007)", "Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007)," "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application" (Annex to CAC/RCP 1-1969), "Principles for the Establishment and Application of Microbiological Criteria for Food (CAC/GL 21-1997)" and "Guidelines for the Validation of Food Safety Control Measures".

Its application is also dependent on having risk assessment and risk management teams that are familiar with the concepts, tools and limitations of both risk management and risk assessment. Accordingly, it is recommended that the members of such teams use this annex in conjunction with standard references such as the technical information developed by FAO/WHO and Codex Alimentarius. It is recognized that given the recent elaboration of the MRM metrics concept, there is a need for development of a practical manual to facilitate implementation by countries which have no experience in implementation of these metrics.

Principles for the establishment and implementation of microbiological risk management metrics

These principles are in addition to those identified in the "Principles and Guidelines for the Conduct of Microbiological Risk Management."

[1] Codex Alimentarius Commission, *Procedural Manual.*

1. The establishment and implementation of microbiological risk management metrics should follow a structured approach, with both the risk assessment phase and the subsequent risk management decisions being fully transparent and documented.
2. Microbiological risk management metrics should be applied only to the extent necessary to protect human life or health and set at a level that is not more trade restrictive than required to achieve an importing member's ALOP.
3. Microbiological risk management metrics should be feasible, appropriate for the intended purpose, and applied within a specific food chain context at the appropriate step in that food chain.
4. Microbiological risk management metrics should be developed and appropriately implemented so they are consistent with the requirements of the regulatory/legal system in which they will be used.

Relationship between Various Risk Management Metrics

A key food safety responsibility of competent authorities is to articulate the level of control that it expects industry to achieve. One tool commonly used by competent authorities has been the development and use of food safety metrics. The metrics employed by competent authorities have been evolving over time as management of food safety issues has moved from a hazard-based approach to a risk-based approach.

Traditional Metrics

Traditional metrics for establishing the stringency of one or more steps in a food safety control system include PdC, PcC, and MC.

Product Criterion. A PdC specifies a chemical or physical characteristic of a food (e.g. pH, water activity) that, if met, contributes to food safety. Product criteria are used to articulate conditions that will limit growth of a pathogen of concern or will contribute to inactivation, thereby decreasing the potential for risk to increase during subsequent distribution, marketing and preparation. Underlying a PdC is information related to the frequency and level of the contamination in the food and/or raw ingredients that is likely to occur, the effectiveness of the control measure, the sensitivity of the pathogen to the control measure, the conditions of product use, and related parameters that ensure that a product will not have the pathogen at an unacceptable level when the product is consumed. Ideally, each of these factors that determine the effectiveness of a PdC would be transparently considered when the criterion was being established.

Process Criterion. A PcC specifies the conditions of treatment that a food must undergo at a specific step in its manufacture to achieve a desired level of control of a microbiological hazard. For example, a milk pasteurization requirement of a heat treatment of 72°C for 15 seconds specifies the specific time and temperature needed to reduce the levels of *Coxiella burnetii* in milk by 5 logs. Another example would be specifying the times and temperatures for refrigerated storage which are based on preventing the growth of mesophilic pathogenic bacteria such as *Salmonella enterica* in raw meat. Underlying a PcC should be a transparent articulation of the factors that influence the effectiveness of the treatment. For the milk pasteurization example, this would include factors such as the level of the pathogens of concern in raw milk, the thermal resistance among different strains of the microorganisms, the variation in the ability of the process to deliver the desired heat treatment, and degree of hazard reduction required.

Microbiological Criterion. An MC is based on the examination of foods at a specific point in the food chain to determine if the frequency and/or level of a pathogen in a food exceed a pre-established limit (e.g., the microbiological limit associated with a 2-class sampling plan). Such microbiological testing can either be employed as a direct control measure (i.e., each lot of food is tested and unsatisfactory lots removed) or, in conjunction with a HACCP plan or other food safety control system, as a periodic means of verifying that a food safety control system is functioning as intended. As a technological and statistically-based tool, an MC requires articulation of the number of samples to be examined, the size of those samples, the method of analysis and its sensitivity, the number of "positives" and/or number of microorganisms that will result in the lot of food being considered unacceptable or defective (i.e., has a concentration or percentage of contaminated units exceeding the pre-determined limit), and the probability that the pre-determined limit has not been exceeded. An MC also requires articulation of the actions that are to be taken if the MC is exceeded. The effective use of an MC is

dependent on a selection of a sampling plan based on the above parameters to establish the appropriate level of stringency. Since the levels of a pathogen in many foods can change over the course of their manufacture, distribution, marketing and preparation, an MC is generally established at a specific point in the food chain and that MC may not be pertinent at other points. Underlying an MC should be a transparent articulation of the pre-determined limit and the rationale for the sampling plan chosen.

Emerging ~~Risk Management~~ Metrics

The increased emphasis on risk analysis as a means for managing food safety concerns has led to increased interest in the development of risk-based metrics that can be more directly related to public health outcomes through a risk assessment process. Three such risk-based metrics that have been defined by the CAC are the FSO, PO, and PC. The quantitative aspects of these metrics have been specifically defined by the CAC,[2] but application of metrics that have variations in their quantitative expression may still satisfy the goals and principles presented in this Annex.

Food Safety Objective. The FSO is a metric articulating the maximum frequency and/or concentration of a pathogen in a food at the time of consumption that provides or contributes to the ALOP. An FSO can be an important component of a risk-based system of food safety. By setting an FSO, competent authorities articulate a risk-based limit that should be achieved operationally within the food chain, while providing flexibility for different production, manufacturing, distribution, marketing, and preparation approaches.

Because of the link between FSO and ALOP, FSOs are established only by national competent authorities. Codex can help in establishing FSOs, for instance, through recommendations based on national or international microbiological risk assessments. Food safety objectives should be given effect by actions at earlier stages in the food chain by the competent authority and/or the individual food business operator (e.g. food manufacturer) setting POs, PCs or MCs, as appropriate.

There are two approaches to establishing an FSO. One is based on an analysis of the public health data and epidemiological surveys. The other is based on analysis of data on the level and/or frequency of a hazard in a food to develop a risk characterisation curve linking hazard levels to disease incidence. If such a curve is available for a given hazard, it can be a helpful basis to relate the FSO to the ALOP.

In countries, FSOs can be used:

- to express the ALOP (whether explicit or implicit) as a more useful parameter for the industry and other interested parties;
- to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance food safety;
- for communication to parties involved in food trade;
- as a performance target for entire food chains to enable industry to design its operational food safety control system (through establishing appropriate POs, PCs and other control measures and interaction between the participants of the food chain in question).

Since the FSO relates to the time of consumption, it is unlikely that a competent authority would set an FSO as a regulatory metric due to the unverifiable nature of this point in the food chain.

FSOs may not be universal among all countries and may need to take into account regional differences.

Performance Objective. The articulation of a PO by a risk manager provides an operational (see below) risk-based limit in a food at a specific point in the food chain, i.e. the maximum frequency and/or concentration of a microbiological hazard in a food at that point in the food chain which should not be exceeded if one is to have confidence that the FSO or ALOP will be maintained. Since a PO is conceptually linked to the FSO and ALOP, the impact of the steps in the food chain both before and subsequent to the PO should be considered in setting its value. For example, consider a PO for bottled water that specifies that the level of salmonellae after a microbiocidal treatment must be less than -2.0 $\log_{10}$cfu/ml. This would require consideration of the level of

[2] Codex Alimentarius Commission, *Procedural Manual*.

salmonellae in the incoming untreated water over a period of time, as well as the effectiveness of the microbiocidal treatment to reduce that level of contamination. The establishment of the PO in relation to controlling the overall risk would also have to consider any post-treatment increases in the level of surviving salmonellae or recontamination of the product prior to consumption.

The frequency and/or concentration of a hazard at individual steps throughout the food chain can differ substantially from the FSO. Therefore, the following generic guidelines should apply:

- If the food is likely to support the growth of a microbial hazard between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO. The difference in stringency will depend on the magnitude of the increase in levels expected;
- If it can be demonstrated and validated that the level of the hazard will decrease after the point of the PO (e.g. cooking by the final consumer), the PO may be less stringent than the FSO. By basing a PO on the FSO, the frequency of cross-contamination could also be factored into the control strategy. For example, establishing a PO for frequency of salmonellae contamination of raw poultry earlier in the food chain would contribute to a reduction of illness associated with poultry mediated cross-contamination in the steps to follow;
- If the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO would be the same.

A MRA can assist in determining the relationship between a PO and an FSO. A MRA can also provide the risk manager with knowledge of hazard levels possibly occurring at specific steps in the chain and of issues regarding the feasibility in practice to comply with a proposed PO/FSO. In designing its food safety control system such that the PO (set by a competent authority or the individual food business) and the FSO (set by a competent authority) are met, the individual food business will have to make provisions reflecting its ability to consistently meet these standards in operational practice, including consideration of a margin of safety.

The individual food business may find it beneficial to establish its own POs. These POs should normally not be universally common and should take into account the position of the business within the food chain, the various conditions at the subsequent steps in the food chain (probability and extent of pathogen growth under specified storage and transport conditions, shelf-life, etc.) and the intended use of the end_products (domestic consumer handling, etc.). Although compliance with POs is not always verified by analytical means, verifying that a PO is being consistently met can be achieved by measures such as:

- monitoring and recording of pertinent validated control measures, including establishment of a statistically-based, validated MC for end products;
- monitoring programs on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).

Performance Criterion. A PC articulates an outcome that should be achieved by a control measure or a series or a combination of control measures. Generally, a PC is used in conjunction with a microbiocidal (e.g., thermal treatment, antimicrobial rinse) or microbiostatic (e.g., refrigeration, water activity reduction) control measure. A PC for a microbiocidal control measure expresses the desired reduction of the microbial population that occurs during the application of the control measure (e.g., 5-log reduction in the levels of *L. monocytogenes*). A PC for a microbiostatic control measure expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied (e.g., less than a 1-log increase in *L. monocytogenes* during refrigerated distribution of a ready-to-eat food). In many instances, the PC describes the outcome that is needed in order to achieve a PO at a specified point in the food chain. There are a number of factors that would have to be considered in reaching a decision on the value of a PC, such as the variability of pathogen levels in raw ingredients or the variability associated with a processing technology.

PCs are generally set by individual food businesses. A PC may be set by national governments for a specific control measure, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.

Such PCs are often translated by industry or sometimes by competent authorities into a PcC or a PdC. For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criteria would stipulate the specific time and temperature combination(s) that would be needed to achieve the PC. Similarly, if a PC required that an acidification treatment of a food reduce the rate of growth of a hazard to less than 1-log in two weeks, then the product criterion would be the specific acid concentration and pH that would be needed to achieve the PC. The concepts of process criteria and product criteria have been long recognised and used by industry and competent authorities.

Integration of Microbiological Risk Management Metrics Within a Food Safety Control System

A key concept underlying the "Recommended International Code of Practice General Principles of Food Hygiene" (CAC/RCP 1-1969) is that key control measures must be integrated into a "farm-to-table" food safety control system in order to consistently produce a food product that achieves the desired level of public health protection (i.e., the ALOP). Since the purpose of establishing and implementing microbiological risk management metrics is to articulate and verify, in an objective and transparent manner as far as possible, the stringency of control measures needed to achieve a specific level of public health protection, it is likely that metrics may be implemented at multiple points along the food chain. A key to understanding the development of such metrics is an appreciation that the metrics implemented along a food chain should be interconnected. There are two types of interconnections. The first is the relationship among different types of microbiological risk management metrics at a specific step in the food chain. The second is that ideally metrics implemented along the food chain would be integrated such that the establishment of a metric at one point in the food chain can be related to the outcome at another and ultimately to the desired public health outcome.

The PO is likely to be the primary risk-based metric used by competent authorities to articulate the level of control (i.e., frequency and/or concentration) of a hazard at a specified point in the food chain. Once articulated, the PO in conjunction with additional information can be used to derive other microbiological risk management metrics. As a simplified example, consider a PO after a heat treatment of a food is a *Salmonella* concentration of $\leq$ -4.0 $\log_{10}$(cfu/g). If the maximum level of *Salmonella* likely to occur in the food prior to heating is +1.0 $\log_{10}$(cfu/g), then the PC for this step would be a 5-log reduction. The PC value in conjunction with information on the thermal resistance of *Salmonella* could be used to articulate specific time/temperature combinations (i.e., PcC values) that would achieve the 5-log reduction. The same concept underpins the relationship between a PO and an MC. In this instance, the MC is used to verify that a PO is not being exceeded. The PO value in conjunction with information on the likely variance of the pathogen's presence and the level of confidence required by the risk managers is used to develop a sampling plan and decision criteria associated with an MC. In general, the microbiological limit associated with an MC will have to be more stringent than its corresponding PO to take into account the degree of confidence required that the food does not exceed a PO. It is also important for risk managers to appreciate that, in the absence of an explicit PO, the establishment of microbiological risk management metrics such as a PC, PcC, PdC, or MC, in combination with the additional information described above, will allow the PO for a control measure to be inferred.

As indicated earlier, the establishment of microbiological risk management metrics at different points along the food chain should take into account the changes in the frequency and/or concentration of a hazard that occur during a specific segment of the food safety control system if the desired level of overall control is to be achieved. Recent advances in MRA are increasingly allowing microbiological risk management metrics at different points to be related to each other and to the overall level of protection achieved by the food safety control system. The ability to relate PO and other metrics implemented at intermediate steps in the food chain to a PO or FSO established by a competent authority would be a useful tool for industry to design and verify that their control measures are achieving the desired level of control.

The integration of microbiological risk management metrics both at a specific point in the food chain and between points in the food chain will require the availability of subject matter experts and appropriate models and data pertinent to the food product and the processes and ingredients used in its manufacture, distribution, and marketing.

Key Risk Assessment Concepts Related to the Development and Use of Microbiological Risk Management Metrics

An integral part of the development of food safety metrics is a consideration of the variability inherent in the food ingredients, the control measures, and ultimately the food that determine the range of results that can be expected when a food safety control system is functioning as intended. Likewise, any uncertainties associated with the parameters affecting the food safety control system should be considered when establishing an integrated set of food safety risk management metrics. Both variability and uncertainty can be evaluated using QMRA techniques in conjunction with an appropriately designed risk assessment, providing a tool for formally evaluating and documenting how these important attributes were considered in the decision-making process.

One of the challenges in establishing and integrating the risk management metrics described above is translating the results of a risk assessment into a set of simple limits that can be communicated and implemented. This reflects the fact that QMRAs are often based on probabilistic models that typically employ unbounded distributions (e.g., log-normal distributions for microbial populations) that have no maximum value. Thus, there is calculable probability that a metric could be exceeded when the control measure or food safety control system is functioning as intended. For example, if a control measure was designed to ensure that the level of bacteria at an intermediate processing step had a geometric mean of $\log_{10}$(cfu/g) = 3.0 and a standard deviation of 0.3 and was operating as intended, it would be expected that approximately one serving in 200 would have $\log_{10}$(cfu/g) = 4.0 and approximately one serving in 1,000,000 would have $\log_{10}$(cfu/g) = 4.7.

The implication of this concept is a characteristic inherent to the use of microbiological risk management metrics. Using the example above, if it is assumed that an MC was set by the risk manager to have a degree of confidence that a lot having servings that exceeded $\log_{10}$(cfu/g) = 4.5 would be detected and rejected, any occasion when the MC is exceeded will be considered a loss of control, even though there is a small possibility that the system may be working as intended. Microbiological risk management metrics will have to be made "operational" by deciding what portion of a potentially open-ended distribution for an "under control" control measure will be considered as exceeding the limit and the degree of confidence, such that any serving of food exceeding that value is rejected (e.g., 95% confidence that 99% of servings of a ready-to-eat food have less than 1 *Salmonella* per 100 g). While there are techniques that can be used to include some consideration of distributions within risk management decisions and verification criteria (e.g., 3-class attribute sampling plans), a series of operational assumptions will be required for any microbiological risk management metric. A critical component of establishing such a metric is ensuring that the underlying assumptions are understood by the risk managers and interested parties.

An Example of a Process for Establishing and Implementing Microbiological Risk Management Metrics

While the development of microbiological risk management metrics should follow a structured approach, the processes and procedures put into place by competent authorities for the establishment of integrated microbiological risk management metrics should be highly flexible in relation to what metric is initially used to begin relating the performance of the food safety control system to its public health outcomes. The process can begin with an articulation of a level of disease control that must be achieved (i.e., ALOP), the exposure level that should not be exceeded at consumption (i.e., FSO), a level of control of a hazard that must be achieved at a specific point in the food chain (i.e., PO), a required processing outcome at a specific step (PC), an MC, etc.

When development of a microbiological risk management metric is being considered, there will likely be a need for close communication and mutual understanding between risk assessors and risk managers. The development of specific microbiological risk management metrics will likely require the formation of appropriate risk analysis teams consisting of appropriate subject matter experts. Scientific advice and data for specific hazard/food applications should be acquired from appropriate scientific organizations, competent authorities, process control experts or related sources of scientific expertise.

Where appropriate, risk assessors and risk managers may wish to consider the following protocol, or some variation thereof, as a means of ensuring the principles for microbiological risk management lead to transparent, informed decisions.

a. The risk managers commission the risk assessors to develop a risk assessment or other suitable scientific analysis that can inform the possible development of microbiological risk management metrics.

b. The risk managers, after consultation with the risk assessors, select one or more sites along the food chain for the product where a risk management metric may be pertinent, useful, and practical.

c. The risk assessors use the risk assessment to evaluate how different values for the microbiological risk management metric being considered are related to the consumers' exposure and the subsequent public health outcomes. Whenever feasible, the risk assessors should provide the risk managers with an array of values for potential microbiological risk management metrics, information on uncertainty that may indicate a need for margins of safety and the corresponding level of protection expected if implemented.

d. The risk assessors use the risk assessment and related tools to ensure that the microbiological risk management metrics being considered by the risk manager are consistent with each other, appropriately taking into account the increases and decreases in hazard levels that may occur during that portion of the food chain.

e. The risk managers evaluate the practical feasibility of achieving the specific level of stringency through implementation of the metric being considered, including consideration of how to verify that the microbiological risk management metric is effectively met.

f. Risk assessors provide advice on the public health implications of non-compliance with a metric being considered.

g. The risk manager selects the microbiological risk management metrics to be implemented, their level of stringency, and the strategy for their implementation.

h. At the request of the risk managers, the risk assessors calculate additional microbiological risk management metrics that may be derived or inferred from the decision in step g.

i. Risk managers implement, in conjunction with industry, the risk management metrics.

j. Risk managers review implemented microbiological risk management metrics for the degree of implementation, efficacy, and ongoing relevance. The criteria for review should be decided when the microbiological risk management metrics are initially implemented. For instance, review can be periodic and/or may also be triggered by other factors such as new scientific insights, changes in public health policy, or changes in the food chain context in which the metrics are applied.

Appendix V

PROJECT DOCUMENT

ELABORATION OF A COMMODITY-SPECIFIC ANNEX TO THE *CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES*

1. Purpose and Scope of the New Work

The purpose of the proposed new work is to provide to member countries and industry, within the framework of annexes to the Code of Hygienic Practice for Fresh Fruits and Vegetables (the Code), guidance on control of microbial hazards associated with specific fresh fruits and vegetables. The scope of the new work encompasses several annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern, which would likely include leafy green vegetables, tomatoes, melons, green onions, sprouted seeds, herbs, berries, and root vegetables. The Committee is proposing to begin the process by developing a commodity-specific annex for leafy green vegetables.

2. Relevance and Timeliness

Outbreaks of foodborne illness due to contamination of fresh fruits and vegetables have been reported world-wide with increasing regularity. The global nature of produce production, processing, and marketing requires an international perspective in addressing this problem.

Over the past decade in the United States, there have been at least two dozen outbreaks associated with fresh leafy green vegetables, especially lettuce and spinach. In several instances where a source was identified, the outbreak was the result of sources from outside of the U.S. The international public health literature has documented outbreaks linked leafy green vegetables in several other countries.

The US CDC recently reported that 40% of foodborne outbreaks associated with produce from 1998-2004 implicated leafy greens as the source. In addition, the severity of illness from infection by the typical pathogen observed in leafy green vegetables during an outbreak, *E. coli* O157:H7, frequently includes the life-threatening development of hemolytic uremic syndrome (HUS), characterized by renal failure and hemolytic anemia.

3. Main Aspects to Be Covered

- Review the advice from expert consultations conducted by FAO/WHO regarding the safety of agricultural and manufacturing practices for fresh produce.
- Develop a draft annex to the current *Code of Hygienic Practice for Fresh Fruits and Vegetables* for leafy green vegetables.
- Consider the development of additional annexes for other vegetables and fruits.

4. 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 practice in food trade, and taking into account the identified needs of developing countries: This new work will enhance consumer protection by reducing microbial hazards associated with fresh produce, in particular leafy green vegetables.

Criteria Applicable to General Subjects

(a) *Diversification of national legislations and apparent resultant or potential impediments to international trade:* This new work will provide scientific guidance, in the form of annexes to the Code, which countries will be able to use to develop their own risk management strategies for the control of microbial hazards in leafy green vegetables. This may assist in providing a harmonized approach for these products internationally.

(b) *Scope of work and establishment of priorities between the various sections of the work:* The scope of the new work is envisioned to encompass several annexes to the Code for commodities that epidemiological evidence suggests are of primary public health concern. The Committee is proposing to begin the process

by developing a commodity-specific annex for leafy green vegetables.

(c) *Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):* The new work does not duplicate work undertaken by other international organizations and it builds on work undertaken previously by CCFH in elaborating the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. It is also timely for CCFH to focus on this issue because FAO/WHO will have completed an expert consultation on microbial hazards in fresh fruits and vegetables by March 2008.

5. Relevance to the Codex Strategic Objectives

The work proposed falls under all six Codex strategic objectives:

Objective 1: Promoting Sound Regulatory Framework

The results of this work will assist in promoting sound national food control infrastructure and promote the safety of foods entering domestic and international trade by expanding Good Agricultural Practices and Good Manufacturing Practices to help control microbial hazards associated with various produce commodities.

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

This work will establish sound working principles for the analysis and identification of microbial hazards associated with various agricultural and manufacturing practices in the production of fresh produce. By understanding the relative risk of various practices, the most effective mitigation strategies can be implemented to ensure the greatest public health benefit.

Objective 3: Promoting Linkages between Codex and other Multilateral Regulatory Instruments and Conventions

FAO and WHO will provide expert consultations for the development of the commodity-specific annexes. The involvement of FAO and WHO in CODEX activities has already formed a close link and their involvement in this effort will continue to support this linkage.

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

By taking on this work and expanding its expertise with specific commodities, Codex will enhance its capacity and will be able to respond more quickly and effectively to commodity-specific safety issues.

Objective 5: Promoting Maximum Membership and Participation

By developing commodity-specific annexes to the Code, there is an opportunity for the CAC to reach out to member countries that may have an interest in a particular commodity for participation where they might not typically be involved.

Objective 6: Promoting Maximum Application of Codex Standards

Developing annexes to the Code which incorporate commodity-specific recommendations and the most up-to-date science currently available will make the document more relevant to potential users, thus expanding the application of these Codex standards.

6. Information on the Relation Between Proposal and Other Existing Codex Documents

The proposed work would directly modify the *Code of Hygienic Practice for Fresh Fruits and Vegetables* through the addition of commodity-specific annexes.

7. Identification of Any Requirement For and Availability of Expert Scientific Advice

FAO/WHO is convening expert consultations on international produce safety for CCFH. The scope of these consultations includes evaluation of pathogen-specific hazards associated with produce and the role of various agricultural and manufacturing practices in enhancing or mitigating these hazards for consumers. FAO/WHO is empanelling appropriate experts worldwide to focus on the identification, impact, and practical application of GAPs and GMPs on the safety of produce. The consultation will consider the entire farm-to-table continuum including processing and marketing. The consultation will also focus on the factors at primary production that contribute to the risk of foodborne disease, especially environmental hygiene, water for primary production and packing, and personnel health, personnel hygiene and sanitary facilities.

While the greatest information needs are associated with primary production, the expert consultation will also consider packing establishments, field packing operations, and other post-harvest handling facilities, particularly key aspects of hygiene control systems such as post-harvest water use, worker health and hygiene, cleaning/sanitizing of equipment and facilities, and the maintenance of the cold chain.

8. Identification of Any Need for Technical Input to the Standard from External Bodies That Can Be Planned For

None identified.

9. Proposed Timeline for Completion of the New Work, Including Start Date, the Proposed Date for Adoption at Step 5, and the Proposed Date for Adoption by the Commission; the Timeframe for Developing a Standard Should Not Normally Exceed 5 Years

A five-year timeline is proposed for the completion of the leafy green annex. The expert consultation on produce is scheduled to be completed by March 2008, with a report available soon after. A draft template for the leafy green vegetable annex would be ready for initial discussion by CCFH in 2008, with a proposed date for adoption at Step 5 in 2010 and adoption by the CAC in 2012.

Appendix VI

PROJECT DOCUMENT

ELABORATION OF A CODE OF HYGIENIC PRACTICE FOR *VIBRIO* SPECIES IN SEAFOOD

1. Purpose and Scope of the New Work

The purpose of the proposed new work is to provide to member countries and industry, within the framework of a code of hygienic practice, guidance on control of pathogenic *Vibrio* species in seafood. The scope of the new work is envisioned to encompass a base document for the control of all pathogenic *Vibrio* species, with annexes developed for individual *Vibrio* species or seafood products if CCFH finds that they are necessary to provide more specific guidance. It is anticipated that this new work would be undertaken in close collaboration with Codex Committee for Fish and Fishery Products (CCFFP).

2. Relevance and Timeliness

During the past several years there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. The incidence of *Vibrio parahaemolyticus* gastroenteritis has been increasing worldwide, causing both sporadic cases and large national and pandemic outbreaks. There have been several instances in the last few years where concerns about the presence of pathogenic *Vibrio* species in seafood have led to a disruption in international trade, impacting in particular developing countries. The food safety concerns associated with these microorganisms and the concomitant need to provide scientifically sound risk management guidance warrants the attention of the Committee.

This increased concern has been particularly evident with *V. parahaemolyticus* where there has been a series of pandemic outbreaks due to consumption of raw seafood, its emergence in regions of the world previously thought to be unaffected by this pathogen, and the emergence of strains with increased pathogenicity (i.e., serotype O3K6). The number of *Vibrio* species recognized as being potential human pathogens continues to increase.

3. Main Aspects to be covered

The proposed new work will focus on the development of risk management guidance for the control of pathogenic *Vibrio* species using the framework of code of hygienic practice. This focus on a core risk management document will include all general components of food safety systems that would be needed to control these pathogens in finfish, crustaceans, and bivalve shellfish. The general format outlined in the Codex Alimentarius General Requirements (Food Hygiene) will be followed, with a focus on identifying those components that are unique to this group of product/pathogen pairs that will require guidance in greater detail than outlined in the general text. The document will address each of the ten sections within the general international code of practice for food hygiene, spanning the continuum from primary production through consumer use.

It is anticipated that one or more annexes may need to be developed to cover in more detail specific guidance needed to adequately manage the food safety risk associated with specific *Vibrio* species/product combinations. An additional annex may be needed to provide the scientific rationale and details for any microbiological criteria or other risk management metrics recommended for development after consultation with CCFFP. The identification of how to assess and validate the effectiveness of food safety systems will be particular important with these classes of product where guidance must be flexible due to the anticipated development of new control measures and risk management strategies.

4. Assessment against the Criteria for the Establishment of Work Priorities

General Criterion

Consumer protection from they point of view of health, food safety, ensuring fair practice in food trade and taking into account the identified needs of developing countries: this new work will contribute to enhance of

consumer protection by providing guidance as to how to manage risk associated with pathogenic *Vibrio* species in seafood.

Criteria applicable to general subjects

(a) Diversification of national legislations and apparent resultant or potential impediments to international trade:
This new work will provide scientific guidance which countries will be able to use to develop risk management guidance for the control of pathogenic *Vibrio* species using the framework of code of practice.

(b) Scope of work and establishment of priorities between the various sections of the work:
See Section 1. Target hazards including pathogenic *V.pagahemolyticus, V.vulnificus* and Choleragenic *Vibrio cholerae* in seafood, including finfish, crustaceans, and bivalve molluscan shellfish that are marketed in an uncooked state, and cooked state.
In addition, the new work focuses on the identification of risk-based control measures at different steps along with the entire food chain.
The body document of the Code of hygienic practice is the first priority, followed by annexes for individual *Vibrio* species or seafood products if CCFH finds that they are necessary.

(c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):
The new work does not duplicate work undertaken by other international organizations and builds on work undertaken by the joint FAO/WHO Expert Consultations on Microbiological hazards in Food. It is also timely for CCFH to focus on this issue because FAO/WHO has conducted and, by fall of 2007, will have completed five risk assessments on various pathogenic *Vibrio*/product combinations.

5. Relevance to the Codex strategic objectives

The work proposed fall under all six Codex strategic objectives:

Objective 1. Promotion of Sound National Food Control and Regulatory Systems from Farm to Table.

The results of this work will assist in promoting sound national food control infrastructure and promote safety of seafoods entering domestic and international trade by using scientific knowledge and risk assessments to develop risk-based guidance that provides foci and options for prevention and mitigation strategies to control pathogenic *Vibrio* species in seafood.

Objective 2. Promotion of the Widest Application of Risk Analysis.

This work will establish risk management options and strategies for the control of pathogenic *Vibrio* species based on risk assessment and supporting scientific analyses. It will serve as a positive example of how risk analysis can be effectively used within a code of hygienic practice framework, including providing flexibility in achieving public health goals.

Objective 3. Promotion of Seamless Linkages between Codex and Other Multilateral Bodies.

This work is based on a close coordination between FAO, WHO, and CODEX and will additionally rely of ongoing close collaboration with CCFFP.

Objective 4. Increased Efficiency and Stronger Management Oversight of Codex Work.

By establishing a general framework for the management of food safety risks associated with seafood, CCFH will provide a general document that can be referenced by CCFFP and thereby eliminating the need for that committee to develop a detailed series of hygienic codes as they develop standards for fish and fish products.

Objective 5. Full Participation by Codex Members and Interested Parties.

Due to the international nature of this problem, this work will support and embrace all aspects of this objective by requiring participation of both developed and developing countries to conduct the work.

Objective 6: Promoting Maximum Application of Codex Standards.

By articulating the risk management options that are effective for controlling pathogenic *Vibrio* spp. in seafoods, the hygienic guidance provided will enhance the application of the standards developed by the CCFFP. In

addition developing Code of Hygienic Practice which incorporate the most up to date science currently available will make the document more relevant to potential users thus expanding the application of Codex standards.

6. Information on the relation Between Proposal and Other Existing Codex documents

The proposed new work may require review and possible modification of several existing Codex documents from different Codex committees, particularly documents from the Codex Committee for Fish and Fishery Products.

7. Identification of any requirement for and Availability of Expert Scientific Advice

Substantial scientific advice has already been obtained or is pending, and additional scientific advice is not likely to be necessary for completion of the proposed new work. The FAO/WHO conducted five risk assessments on *Vibrio* species. in seafood to address the following pathogen/commodity combinations (see ALINORM 05/28/18, para 20 and 21):

• *Vibrio vulnificus* in oysters;
• Choleragenic *Vibrio cholerae* in warm waters shrimp in international trade;
• *Vibrio parahaemolyticus* in bloody clams;
• *Vibrio parahaemolyticus* in finfish; and
• *Vibrio parahaemolyticus* in oysters.

Of these five risk assessment, FAO/WHO has completed the risk assessments on *V. vulnificus* in oysters and choleragenic *Vibrio cholerae* in warm waters shrimp in international trade have been completed, and the other risk assessments related to *Vibrio parahemolyticus* in finfish and shellfish are being combined into a single report which is expected to be published during the fall of 2007.

In addition, the United States delegation led a CCFH working group that developed a risk profile in 2002 for CCFH that reviewed existing Codex guidance on codes of hygiene for the control of *Vibrio* in fish and shellfish. Additional risk assessments and risk profiles developed by individual member nations are also available.

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

None identified.

9. Proposed Timeline for Completion of the New Work, including start date, the proposed date for adoption at Step5 and the proposed date for adoption by the Commission ; the timeframe for developing a standard should not normally exceeding 5 years

It should be feasible to produce the core code of hygienic practice within four years. Additional product or *Vibrio* species annexes should be feasible within the same time frame unless identified late in the process of developing the core document.