

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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HEALTH  
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ALINORM 03/13

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
CODEX ALIMENTARIUS COMMISSION**  
*Twenty-fifth Session*  
*Rome, 30 June - 05 July 2003*

**REPORT OF THE THIRTY-FOURTH SESSION OF THE  
CODEX COMMITTEE ON FOOD HYGIENE**

*Bangkok, Thailand, 8 - 13 October 2001*

**NOTE:** *This report includes Codex Circular Letter CL 2001/32-FH*

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CX 4/20.2

CL 2001/32 - FH

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

**FROM:** Secretary, Codex Alimentarius Commission Joint FAO/WHO Food Standards Programme FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

**SUBJECT:** **Distribution of the Report of the Thirty-fourth Session of the Codex Committee on Food Hygiene (ALINORM 03/13)**

The report of the Thirty-fourth Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-fifth Session of the Codex Alimentarius Commission, Rome, 2003.

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

**Draft Code of Hygienic Practice for Fresh Fruits and Vegetables at Step 8. (ALINORM 03/13, Appendix II).** See also paras 19 through 65 of this report.

Governments wishing to propose amendments to or comment on the above matter should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts at Step 8 (*Procedural Manual of the Codex Alimentarius Commission*, Eleventh Edition, page 23). Comments or proposed amendments should be sent to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy preferably by e-mail: [codex@fao.org](mailto:codex@fao.org) or fax: +39 (06) 570.54593 before **1 February 2003**.

## **B. MATTERS FOR ADOPTION BY THE 50<sup>TH</sup> SESSION OF THE EXECUTIVE COMMITTEE:**

**Proposed Draft Revised Guidelines for the Application of HACCP System at Step 5. (ALINORM 03/13, Appendix III).** See also paras 137-151 of this report.

Governments and interested international organizations are invited to comment on the above cited Guidelines and should do so in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts at Step 5 (*Procedural Manual of the Codex Alimentarius Commission*, Eleventh Edition, page 22). Comments should be forwarded to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by fax: +39 (06) 570.54593 or e-mail: [codex@fao.org](mailto:codex@fao.org) before **1 March 2002**.

## **C. REQUEST FOR COMMENTS AND INFORMATION:**

**1. Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods.** See also paras 89 through 98 of this report.

Governments and interested international organizations are invited to provide their additional comments on the current document (see Appendix IV of this report). Comments should be forwarded to Dr Hans Dieter

Boehm, Head Division Food Hygiene and Food Trade, Federal Ministry of Health, Propsthof 78A, D-53121 Bonn, Germany, fax: (49) 228-941-4944, e-mail: [hans.boehm@bmvvg.bund.de](mailto:hans.boehm@bmvvg.bund.de) with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by Fax: +39 (06) 570.54593 or E-mail: [codex@fao.org](mailto:codex@fao.org) before **1 February 2002**.

**2. Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management** (document CX/FH 01/7). See also paras 99 through 128 of this report.

While considering the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management at Step 4, the Committee agreed to request comments on the document CX/FH 01/7, especially on Sections 6 - Guidelines for Implementation of Microbiological Risk Management Decisions and 7 – Monitoring and Review. Comments should be forwarded to Dr Claire Gaudot, Directrice de l'hygiène des aliments, Ministère de l'agriculture et de la pêche, 251, rue de Vaugirard, 75732 Paris Cedex 15, fax: 0149 55 56 80, e-mail: [claire.gaudot@agriculture.gouv.fr](mailto:claire.gaudot@agriculture.gouv.fr) with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by fax: +39 (06) 570.54593 or E-mail: [Codex@fao.org](mailto:Codex@fao.org) before **1 February 2002**.

**3. Obstacles to the Application of HACCP, particularly in Small and Less Developed Businesses and Approaches to Overcome Them** (Annex II of the document CX/FH 01/10). See also para. 151 of this report.

While advancing the Proposed Draft Revised Guidelines for the Application of the HACCP System to Step 5 for provisional adoption, the Committee agreed to request comments on Annex II of the above document - Obstacles to the Application of HACCP, particularly in Small and Less Developed Businesses (SLDBs) and Approaches to Overcome Them. Governments and interested international organizations are therefore invited to provide their comment on the above subject matter and should do so in writing to Dr Jaap Jansen, Ministry of Health, Welfare and Sports, P.O. Box 16108, 2500 BC Den Haag, The Netherlands, e-mail: [jaap.jansen@kvw.nl](mailto:jaap.jansen@kvw.nl), fax: (31) 70 340 5435, with a copy to Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (fax: +39 (06) 570.54593 or e-mail: [codex@fao.org](mailto:codex@fao.org)) before **1 February 2002**.

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## SUMMARY AND CONCLUSIONS

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

### **MATTERS FOR ADOPTION BY THE 25<sup>TH</sup> SESSION OF THE CODEX ALIMENTARIUS COMMISSION:**

- The Committee agreed to advance the Draft Code of Hygienic Practice for Fresh Fruits and Vegetables for adoption at Step 8, ALINORM 03/13, (paras 19-65 and Appendix II).

### **MATTERS FOR CONSIDERATION BY THE 50<sup>TH</sup> SESSION OF THE EXECUTIVE COMMITTEE:**

#### **1. Adoption of texts at Step 5**

- Proposed Draft Revised Guidelines for the Application of HACCP System at Step 5, ALINORM 03/13, Appendix III (paras 137-151).

#### **2. The following new work is proposed on:**

- Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures (paras 167).

#### **3. Antimicrobial resistance**

The Committee generally supported the conclusions of the Executive Committee, especially as related to convening a multidisciplinary expert consultation to address antimicrobial resistance. It noted that regardless of whether or not an *Ad Hoc* Task Force was established, a comprehensive and multidisciplinary approach to these risk assessments would be required. The Committee agreed that the emergence of pathogen-specific antimicrobial resistance such as fluoroquinolone-resistant *Campylobacter* in poultry be examined as data are available for future risk assessments (paras 159 - 162).

### **OTHER MATTERS :**

The Committee:

- Requested FAO and WHO to convene an expert consultation to assist the Committee to integrate risk assessment results in the development of standards and related texts (para. 83);
- Suggested that the Joint FAO/WHO Expert Consultations on Microbiological Risk Assessment be given permanent status in order to further enhance the risk assessment work of FAO and WHO and to support the risk management work of this Committee (para. 87);
- Stressed the need for FAO and WHO to provide assistance to developing countries to strengthen their technical capabilities for the application of risk assessment and address the need for risk assessors (para. 88);
- Recommended that the results of the *ad hoc* Expert Consultations on risk assessment of *Listeria monocytogenes* in ready to eat foods and *Salmonella enteritidis* in eggs be used in developing/revising the relevant Codex documents and suggested that the report of the Expert Consultation on *Salmonella* spp. in poultry be considered by the Committee on Meat and Poultry Hygiene in the context of their work related to the elaboration of codes of hygienic practice (paras 72-74);
- Agreed to prepare discussion papers in order to develop risk management strategies for *Campylobacter* spp. in poultry and *Vibrio* spp. in fish and shellfish with a view towards defining specific questions to be addressed in risk assessments, and to prepare a risk profile for enterohemorrhagic *Escherichia coli* in commodities of concern (paras 76-79);
- Decided to discontinue for the time being the consideration of the Proposed Draft Guidelines for the Hygienic Reuse of Processing Water in Food Plants and of the Discussion paper on the Proposed Draft Guidelines for Evaluating Objectionable Matter in Food, in view of its heavy

workload, with the understanding that this decision would be reviewed at its 36<sup>th</sup> Session (paras 135-136 and 168-169);

## **MATTERS OF INTEREST TO OTHER COMMITTEES:**

### **CODEX COMMITTEE ON GENERAL PRINCIPLES (CCGP)**

#### **Risk Analysis and Hazard Analysis**

The Committee clarified the differences between “Risk Analysis” and “Hazard Analysis”, and attached the document to the report as Appendix V, with the understanding that it be forwarded to the Committee on General Principles as requested by the Executive Committee<sup>1</sup> (para. 8).

### **CODEX COMMITTEE FOR FISH AND FISHERY PRODUCTS (CCFFP)**

#### **Hygiene Provisions of the Codex Code of Practice for Fish and Fishery Product**

The Committee generally endorsed the food hygiene provisions of the Code of Practice for Fish and Fishery Products, however since some parts of the above Code were at different stages of development, requested the Committee on Fish and Fishery to forward such provisions to the Committee of Food Hygiene once the above Code had been adopted in its entirety at Step 5 (paras 14-18).

### **FAO/WHO REGIONAL COORDINATING COMMITTEE FOR LATIN AMERICA AND THE CARIBBEAN (CCLAC)**

#### **Guidelines for the Obtaining Data of Interest for Microbiological Risk Assessment (ALINORM 01/36, paras 33-37)**

The Committee suggested that this paper be forwarded to FAO and WHO for their consideration. The Representative from FAO informed the Committee that an expert consultation would be convened in November to address the issue of surveillance data and its use in risk assessment (para 85).

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<sup>1</sup> CX/EXEC 00/47/7.

**LIST OF ABBREVIATIONS USED IN THIS REPORT**

ALA	Asociación Latinoamericana de Avicultura
CAC	Codex Alimentarius Commission
CCGP	Codex Committee on General Principles
CCFH	Codex Committee on Food Hygiene
CCMPH	Codex Committee on Meat and Poultry Hygiene
CRD	Conference Room Document
CEC	Commission of the European Community
EC	European Community
FAO	Food and Agriculture Organization of the United Nations
HACCP	Hazard Analysis and Critical Control Point System
ICMSF	International Commission for Microbiological Specifications for Foods
IDF	International Dairy Federation
OIE	Office international des épizooties
PAHO	Pan American Health Organization
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization

## **REPORT OF THE THIRTY-FOURTH SESSION OF THE COMMITTEE ON FOOD HYGIENE**

### **INTRODUCTION**

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-fourth Session in Bangkok, Thailand from 8 to 13 October 2001, at the kind invitation of the Government of the United States of America in cooperation with the Government of the Kingdom of Thailand. Dr Kaye Wachsmuth, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture, chaired the meeting. The Session was attended by 191- participants from forty four Member countries, one Observer country and ten- international governmental and non-governmental organizations including UN agencies. A complete list of participants is given in Appendix I to this report.

### **OPENING OF THE SESSION**

2. Dr Kaye Wachsmuth thanked the Government of Kingdom of Thailand for its efforts in hosting the meeting, and invited the following persons to provide welcoming remarks :

- Mr Cherdpong Siriwit, Secretary-General, TISI
- Dr Edward Scarbrough, U.S. Manager for Codex
- Dr R.B.Singh, Representative of FAO
- Dr Jorgen Schlundt, Representative of WHO
- Dr Jeronimas Maskeliunas, Codex Secretariat
- H.E. Richard E. Hechlinger, U.S. Ambassador to the Kingdom of Thailand

3. These officials noted that this was the first time the Codex Committee on Food Hygiene was held in the Region of Asia. The Committee noted that this decision was taken in part as a result of the Commissions' efforts to promote the maximum participation of all Codex Member governments in its activities by holding Codex sessions in various countries and regions of the world.

4. The Session was officially opened by Mr Manu Leopaiprote, Permanent Secretary of the Thai Ministry of Industry, who welcomed all the participants to the meeting. Mr Leopaiprote stressed the importance of Codex work to ensure consumers' health and the facilitation of international trade in foods and in this regard, noted the Committees efforts in developing guidelines and recommendations for the management of microbiological risks. He also pointed out that Codex texts were the main reference points related to food safety under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures. He wished all participants the utmost success in their deliberations as well as an enjoyable and pleasant stay in Bangkok.

### **ADOPTION OF THE AGENDA (AGENDA ITEM 1)<sup>2</sup>**

5. The Committee adopted the Provisional Agenda as the Agenda for the Session. The Committee agreed to consider the Brazilian document concerning obtaining data from developing countries under Agenda Item 5.

### **MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES (AGENDA ITEM 2)<sup>3</sup>**

6. The Committee noted matters arising from the 24<sup>th</sup> Session of the Codex Alimentarius Commission and the 48<sup>th</sup> and 49<sup>th</sup> sessions of the Executive Committee, as follows:

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<sup>2</sup> CX/FH 01/1, CX/FH 01/1-ADD 1.

<sup>3</sup> CX/FH 01/2; CX/FH 01/2-Add.1; CRD 10 (Extract from the 49<sup>th</sup> Session of the CCEXEC). This and other CRDs are available at the request from the Codex Secretariat.



**Antimicrobial resistant bacteria in food**

7. Due to the relevance of the subject matter to its work, the Committee decided to consider it under Agenda Item 12 (Antimicrobial Resistant Bacteria in Food).

**Risk Analysis – Hazard Analysis**

8. Following the request of the 47<sup>th</sup> Session of the Executive Committee<sup>4</sup> to clarify the differences between Risk Analysis and Hazard Analysis, the Committee amended the second paragraph of the subsection on Hazard Analysis in document CX/FH 01/2-Add.1 and agreed to attach the document to the report as Appendix V, with the understanding that it be forwarded to the Committee on General Principles, as requested by the Executive Committee.

**Draft Medium-Term Plan (MTP) 2003-2007 and the Chairperson's Action Plan**

9. The Committee noted that objectives of the MTP contained in CL 2001/26-EXEC sufficiently covered working areas and activities for the CCFH and encouraged member governments and interested international organizations to provide their individual comments to the MTP by 30 November 2001 as directed in the above Circular Letter.

**Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Foods**

10. In response to the request of the 24<sup>th</sup> Session of the CAC that the Committee evaluate the deletion of the provision regarding food transported directly from the field to the market in Section 2.1 of the above code, the Committee accepted the clarification provided by the Delegation of the Netherlands that deletion of the above provision would not have implications since it was only one of examples in relation to foods moving into international trade and therefore no further action in this regard was necessary.

**Review of the Codex Alimentarius Work Programme**

11. The Representative of WHO informed the Committee that in order to meet growing demands of the Member countries and due to the increased workload, the matter had been considered at the last Executive Committee meeting and that FAO and WHO had agreed to the need for a comprehensive review of the Codex programme, including the scope of Codex activities.

**Traceability**

12. In addressing traceability, the 49<sup>th</sup> Session of the Executive Committee agreed that the subject would be considered by relevant Codex Committees, including the CCFH, as they deemed appropriate within their terms of reference. The Delegation of Canada noted that traceability would have implications to the work of the CCFH and therefore the Committee decided to consider this issue under Agenda Item 15.

**Guidelines for Obtaining Data of Interest for Microbiological Risk Assessment**

13. The Committee agreed to consider the subject of obtaining data of interest for microbiological risk assessment arising from the FAO/WHO Regional Coordinating Committee for Latin America and the Caribbean (ALINORM 01/36, paras 33-37) under Agenda Item 5.

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<sup>4</sup> CX/EXEC 00/47/7.

## **ENDORSEMENT OF HYGIENE PROVISIONS IN CODEX STANDARDS AND CODES OF PRACTICE: PROPOSED DRAFT CODEX CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (AGENDA ITEM 3)<sup>5</sup>**

14. In accordance with the provisions of the Codex Alimentarius Commission Procedural Manual and in consideration of the terms of reference of the Codex Committee on Food Hygiene, the Committee was invited to endorse the hygiene provisions of the proposed draft Codex Code of Practice for Fish and Fishery Products.

15. The Committee noted the difficulty in endorsing the hygiene provisions of the Code at the current meeting as various sections of the Code applicable to these provisions were at different steps of the Codex procedure. It was suggested that the endorsement of the hygiene provisions should await the Step 5 adoption of the Code in its entirety before considering the hygiene provisions for endorsement, especially since further modifications of the Code might have potential implications for these provisions.

16. The Delegation of Norway, as representative of the host government responsible for the Codex Committee on Fish and Fishery Products (CCFFP), indicated that the written comments addressing the hygiene provisions could be forwarded to the CCFFP for incorporation into the proposed draft Code but suggested that the Committee might wish to endorse these provisions generally. The Delegation noted that the written comment submitted by Finland concerning the traceability of products to the catch area had already been extensively discussed by the CCFFP and that this requirement was not incorporated into the Code as such a measure was impractical and difficult to control. However, the Committee also noted that this concept was important in the context of the Code since the catch area could be within contaminated waters or from areas where regulations concerning the use of veterinary drugs could differ from other areas. It was also noted that use of the terms fish and shellfish within the Code should be further clarified for consistency and to avoid potential confusion among the users of the Code.

17. Some delegations were of the view that the concept of defect action points, which applied to quality aspects, and critical control points, which applied to safety aspects, might be clearly differentiated within the Code for example through the use of a separate annex applicable to defect action points only in order to avoid potential confusion between these concepts.

### **Status of the Endorsement of the Hygiene Provision of the Codex Code of Practice for Fish and Fishery Products**

18. The Committee agreed to generally endorse the food hygiene provisions of the Codex Code of Practice for Fish and Fishery Products. It however requested the CCFFP to forward such provisions to the Committee for reconsideration once the Code had been preliminarily adopted in its entirety at Step 5. It also agreed to forward the above discussion as well as written comments submitted to the CCFFP for their consideration.

## **DRAFT CODE OF HYGIENIC PRACTICE FOR THE PRIMARY PRODUCTION AND PACKAGING OF FRESH FRUITS AND VEGETABLES (AGENDA ITEM 4)<sup>6</sup>**

19. The Committee recalled that at its thirty-third Session, in view of the many links between them, the Draft Code for Primary Production, Harvesting and Packaging of Fresh Fruits and Vegetables and its Annex on Sprout Production had been merged with the Draft Code for Pre-Cut Fruits and Vegetables.

20. The Delegation of Canada, which led the Drafting Group, stated that this amalgamation was expected to provide a general framework of recommendations that allowed for sufficient flexibility for the prevention and control of contamination of fresh fruits and vegetables.

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<sup>5</sup> Proposed Draft Code of Practice for Fish and Fishery Products (ALINORM 01/18, Appendix V) and comments submitted in response to CL 2001/15 on the Hygiene Provisions of the Proposed Draft Code of Practice from Canada, Finland, New Zealand, South Africa, USA (CX/FH 01/3) and Mexico (CRD 1).

<sup>6</sup> ALINORM 01/13A; CX/FH 01/4 (comments of Argentina, Canada, the United States of America and the European Community); CRD 2 (comments of Costa Rica); CRD 12 (comments of Brazil); CRD 14 (comments of Thailand).

21. The Committee reviewed the draft code section by section and made the following major changes based on the discussions summarized as follows. Other changes made were predominantly of editorial nature due to the combining of the codes as shown in Appendix II.
22. The Committee decided to change the title of the combined codes to “Draft Code of Hygienic Practice for Fresh Fruits and Vegetables” and rearranged the order of the two Annexes on Pre-Cut Fruits and Vegetables and Sprout Production.

### Section 2.1 Scope

23. The Committee amended the second paragraph to make necessary reference to the Annex on Pre-Cut Fruits and Vegetables. The Committee noted the comments submitted in writing by the Delegation of Costa Rica to include physical and chemical hazards at the end of the first paragraph. The word “wholesale” was inserted in the third paragraph.

### Section 2.2 Use

24. The section was amended to include a reference to the Annex on Pre-Cut Fruits and Vegetables.

### Section 2.3 Definitions

25. The Committee corrected the Spanish version of the text to use “cultivo”.
26. The Committee agreed to amend the definition of ‘*Agricultural worker*’ to clarify the activities undertaken because “packing” did not always take place in the field as stipulated in the definition of “*Packing*”.
27. The definitions of “*Biosolids*,” and “*Cultivation*” were amended. The term “*Microbial hazards*” was replaced by “*Hazard*” to cover not only biological but also chemical and physical agents as potential causes of foodborne illness.
28. The Committee deleted the definitions on water in square brackets and changed the subheading of this part to “*Types of Water*”.
29. The Committee had an extensive debate on the definition of “*Antimicrobial agents*”(used in 3.2.1.4 *Agricultural chemicals*) and decided to use the definition by WHO<sup>7</sup>. Regarding the questions raised by several delegations on which substances would be specifically included as “*Antimicrobial agents*”, the Representative of WHO clarified that if Member States considered certain substances inappropriate to be included as antimicrobial agents, that could be debated and reviewed but it was not appropriate to change the WHO definition itself.

## Section 3 Primary Production

30. The word “good” was added to the last sentence of the first paragraph.
31. The Delegation of Thailand emphasized that it was important to include a reference on water supply sources from different geographical areas such as the tropics where the water obtained through the tropical rain forests was cloudy and could contain large quantities of organic substances. The Committee therefore agreed to amend the first sentence, inserting the words “and diverse geographical” between “climate” and “conditions” to reflect this concern.
32. In Section 3.1, *Environmental Hygiene*, the first bullet, the Delegation of India sought clarification on whether “previous usage” was limited to the “immediate previous usage” as in the case of India land was often re-used by small farms for which records were difficult to obtain. The Committee noted that “immediate previous usage” could also be included and noted that in any case the provisions of this section were applied “where possible”.

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<sup>7</sup> WHO Global Principles for the Containment of Antimicrobial Resistance in Animals Intended for Food , June 2000 (WHO/CDS/CSR/APH/2000.4) : “*Antimicrobial agent*” is defined as “Any substance of natural, synthetic or semi-synthetic origin which at low concentrations kills or inhibits the growth of micro-organisms but causes little or no host damage.”

33. In the second bullet, the Committee discussed whether to modify the last sentence to make the requirement more practical by adding to it that “precaution should be taken to prevent access of domestic and wild animal to the fresh fruits and vegetables growing area during growing and harvesting season” as suggested by some delegations. However, the Committee concluded that there was a difference for this need depending on the pathogen, and the phrase “Where possible” at the beginning of the second paragraph preceding the bullets provided flexibility. The Representative of FAO drew attention to the fact that in some countries it was difficult to keep wild animals out of the cultivation areas. The word “risk” was changed to “likelihood”. The third bullet was amended to insert the term “leaching” between “leaking” and “or overflowing”.
34. In Section 3.2.1.1, the Committee discussed whether the term “contamination” in the Spanish version only included microbes or also included chemicals. It discussed whether the term “hazard” was more appropriate than “risk” in this case in the Spanish version. The Committee agreed to include the definition of “contaminant” and retained the original text. The last sentence of the second bullet was amended to replace “sufficient” with “suitable”.
35. In Section 3.2.1.1.1, the specific examples between round brackets in the first paragraph before the bullets were deleted in order to avoid making it too restrictive. In the first bullet of this section and in Section 3.2.1.1.3, the example of “sprinkler” in brackets was replaced by “sprayers”.
36. In Section 3.2.1.2, *Manure, Biosolids and Other Natural Fertilizers*, the provision of the third bullet was amended to provide more flexibility.
37. Section 3.2.1.3, *Soil*, was reworded for clarification.
38. In Section 3.2.1.4 *Agricultural Chemicals*, the Committee inserted a new bullet by separating the last two sentences in the first bullet concerning the provision on the use of antimicrobial agents from the first part of the bullet in order to strengthen the basic concept that they should not be used unless unavoidable.
39. In the seventh bullet, third line, the words “living areas” and “the inhabitants of the area” were inserted.
40. In Section 3.2.2.2 *Water Supply*, in the paragraph and first two bullets, the words “or clean” were inserted after the term “potable”.
41. In Section 3.2.2.3 *Drainage and Waste Disposal*, the second sentence was amended to replace “risk of contaminating” with “potential for contaminating of”.
42. In Section 3.2.3 *Personnel Health, Hygiene and Sanitary Facilities*, the Committee discussed whether or not indirect contacts with fresh fruits and vegetables during or after harvesting needed to be referred to. Some delegations were of the opinion that contamination was likely only through direct contact. The Committee agreed that the provision would be aligned with that of the Recommended international Code of Practice General Principles of Food Hygiene that uses the term “those who come directly or indirectly into contact with food” and the sentence was amended accordingly. In Section 3.2.3.1, the first two lines and the first bullet were amended.
43. In Section 3.2.3.4 *Personal Behaviour*, the term “fresh” after the phrase “unprotected fresh fruits and vegetables” was deleted.
44. In Section 3.3.1 *Prevention of Cross-Contamination*, in the first paragraph, last sentence, “risk” was substituted by “possibility”. The bullets were simplified to make them more readable.
45. In Section 3.3.2 *Storage and Transport from the Field to the Packing*, the bullets were amended for clarity.

### **Section 5.8 Recall Procedures and Traceback**

46. The Committee had an exchange of views on whether the use of the term “traceback” was appropriate in this context. While some delegations voiced their concern over its use in view of the ongoing discussions on “traceability” within Codex, others were of the view that “traceback” was an important component of the operation which did not necessarily lead to recalls. As a compromise, the term “traceback” was deleted from the title and consequential amendments were made to other sections of the text. Editorial changes were made to the first bullet.

## **Section 10 Training**

47. Section 10.1, *Awareness and Responsibilities*, a new sentence was added to increase clarity of the aim of the provision. In Section 10.2 "*Training Programmes*," the fourth bullet was amended.

## **PROPOSED DRAFT ANNEX FOR SPROUT PRODUCTION**

48. The Table of Contents was amended for consistency with the other texts in the code.

### **Introduction**

49. In the second paragraph third sentence, the term "field planting" was replaced by "forage or animal grazing" and the underlining was removed.

### **Section 1 Objectives**

50. Editorial changes were made.

### **Section 2 Scope, Use and Definition**

51. Section 2.1 *Scope and Use* was rearranged to form two separate sections, 2.1 *Scope* and 2.2 *Use*.

### **Section 3.2 Hygienic Production of Seeds**

52. The Committee agreed to use the terminology "production of spouts for human consumption" in place of "sprout production" and replaced this terminology throughout the text to ensure consistency. The words "wild or domestic" were inserted before animals.

### **Section 3.3 Handling, Storage and Transport**

53. The first paragraph was reworded.

### **Section 3.6 Tracebacks and Recalls**

54. The title of this section was amended in order to ensure consistency with the main body of the code, and the bullets were amended for clarity as indicated in the Appendix.

### **Section 4.2. Establishment for Sprout Production**

55. In Section 4.2.1 *Design and Layout*, the Committee discussed whether the term "disinfection" included antimicrobial agents referred to in Section 3.2.1.4 *Agricultural Chemicals* of the code. Some delegations particularly raised the question of whether propionic acids and lactic acids and active chlorides were considered as antimicrobial agents in this context. The Committee noted that it was necessary to differentiate between the use of antimicrobial agents and disinfection and agreed that the definition of "disinfectant" in the *General Principles of Food Hygiene* was applicable to microorganisms in the environment and thereby applicable to surface treatments of facilities, establishments and equipment for sprout production but not to sprouts themselves. The Committee decided to adhere to the WHO's definition of antimicrobial agents where relevant.

56. Regarding disinfection/decontamination the Committee decided that the term "decontamination" includes more than microbiological decontamination, therefore the text was revised to use the expression "microbiological decontamination" instead of "disinfection" with respect to seeds.

#### **Section 5.2.2.1 Water Use during Sprout Production**

57. In the last sentence, the word "preferably" was inserted. After some debate the phrase "or at least clean water" was retained and the same was done for Section 5.2.2.5 *Pre-Germination Soak* to ensure consistency.

### **Section 5.2.2.3 Seed Disinfection**

58. A new bullet was added at the beginning of the section. The second sentence was amended and the use of lactic acid bacteria was cited as an example of “other options”.

### **Section 5.2.2.8 Final Rinse and Cooking**

59. The third bullet was modified as indicated in Appendix II.

### **Section 5.2.3.2 Testing Irrigation Water and/or Sprouts**

60. The title of the section was amended to insert “of sprouts and/or spent” after “Testing”. In the first paragraph second sentence, the word “disinfection” was inserted for clarity.

## **PROPOSED DRAFT ANNEX FOR READY-TO-EAT FRESH PRE-CUT FRUITS AND VEGETABLES**

61. In order to harmonize terminology with the main texts and the other Annex, the Committee reworded the introduction to better reflect the content of the Annex.

### **Section 4.4.2 Drainage and Waste Disposal**

62. The phrase “so it does not become a source of product contamination” was added to the end of the last sentence to reinforce the provision.

### **Section 5.2.2.1 Receipt and Inspection of Raw Materials**

63. The section was divided into two: “Receipt and Inspection of Raw Material” and “Preparation of Raw Material Before processing” with the texts presented in the Appendix.

### **Section 5.2.2.5 Washing After Cutting, Shredding and Similar Pre-Cut Processes**

64. A bullet was added between the first and the second bullets and the last bullet was amended to stress the importance of this step. In the last bullet, the words “may be” were replaced by “is”.

### **Status of the Draft Code of Hygienic Practice for Fresh Fruits and Vegetables**

65. The Committee agreed to advance the above Draft Code to the 25<sup>th</sup> Session of the Codex Alimentarius Commission for adoption at Step 8 (see Appendix II).

## **REPORTS OF THE AD HOC EXPERT CONSULTATIONS ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS IN FOOD AND RELATED MATTERS (AGENDA ITEM 5)<sup>8</sup>**

### **Introduction**

66. The Representatives of FAO and WHO informed the Committee of progress made to date under the various initiatives jointly undertaken by the organizations on the risk assessment of microbiological hazards in foods, which were implemented in part in response to the request of the 32<sup>nd</sup> CCFH (ALINORM 01/13). In the past two years, FAO and WHO had undertaken risk assessments on *Listeria monocytogenes* in ready-to-eat foods, *Salmonella* Enteritidis in eggs and *Salmonella* spp. in broiler chickens. New work on *Campylobacter* spp. in poultry and *Vibrio* spp. in seafood was also initiated in 2001. The Committee was also informed of an information session held immediately prior to the

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<sup>8</sup> Report of the *Ad Hoc* Expert Consultations on Risk Assessment of Microbiological Hazards in Foods (CX/FH 01/5), Proposal for a Process by Which the Codex Committee on Food Hygiene Could Undertake its Work in Microbiological Risk Assessment/Risk Management (CX/FH 01/5-Add.2), Note Submitted by FAO and WHO (CX/FH 01/5-Add. 3), comments submitted by Malaysia, Uruguay (CRD 7) and Brazil (CRD 12).

current Session of the CCFH which discussed the results of these risk assessments as well as the process of interaction between risk assessors and risk managers.

67. The FAO and WHO Representatives outlined the lessons learned to date, including the need to take a multidisciplinary approach to risk assessment; the importance of clearly defining the scope of a risk assessment; the need for interaction between the risk assessors and the risk managers; the difficulty in generating global risk estimates; the possibility of generating risk assessment tools that can be used in the evaluation of risk management options; and, the identification of data gaps and research areas.

68. The Committee agreed that there was a need to clearly define the Scope of risk assessment through the development of risk profiles, to provide for interaction between risk assessors and risk managers, and to consider how the risk assessments could be used in the risk management activities of the Committee, and agreed to establish drafting groups as appropriate, and to consider the issue further (see also paras 73, 77, 78, 97). Some delegations mentioned that it was not always necessary to have a full risk assessment before risk management actions are taken

69. The Representatives of FAO and WHO thanked those Member Governments that had supported them in these activities and expressed the need for countries to continue to provide resources to sustain the risk assessment work. The Committee expressed its appreciation to FAO, WHO and the risk assessment groups for their excellent work and in view of the various initiatives undertaken in the area of risk assessment, discussed the results of the consultations and other related matters as follows:

#### **Risk Assessments on *Salmonella* and *Listeria***

70. The Committee was informed that a summary of the progress to date of the risk assessments on *Listeria* and *Salmonella* were available in the Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk Characterization of *Salmonella* spp. in Eggs and Broiler Chickens and *Listeria monocytogenes* in Ready-to-Eat Foods (Rome, 30 April - 4 May 2001). It was noted that the risk assessors were finalizing these risk assessments for publication by FAO and WHO following peer review.

71. In considering the Consultation responses to the questions posed by the Committee, it was firstly noted that the lack of data in some areas and the incompleteness of the risk assessment had prevented the provision of complete answers. Some concerns were expressed regarding the dose-response model for *Salmonella* in that it did not reflect the reality in some countries. However, it was noted that the model itself may not necessarily be problematic and such concerns may be satisfied if additional data were made available to FAO and WHO for the risk assessment and in this regard, countries were asked to submit any relevant data as soon as possible. It was also noted that the model was unable to effectively evaluate the risk from pathogenic *Salmonella* for various susceptible population groups (e.g., immunocompromised). For *Listeria*, the questions regarding the risk when the number of organisms ranges from absence in 25 g to 1000 cfu per gram has not yet been clearly answered.

72. The Committee recommended that the results of the risk assessment on *Listeria monocytogenes* in ready-to-eat foods be utilized in the further development of the work on the "Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods" (see Agenda Item 6). The Committee also recommended that the results of the risk assessment on *Salmonella* Enteritidis in eggs be taken into consideration in the Proposed Draft Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983, see Agenda Item 11).

73. It was noted that there was currently no work underway in the Committee on *Salmonella* spp. in poultry. Therefore, in order to better utilize this risk assessment the Committee agreed that a drafting group led by Sweden, with the assistance of Australia, Canada, China, Czech Republic, Denmark, France, Germany, Netherlands, New Zealand, Thailand, USA and the European Commission (CEC), would develop a Discussion Paper on Risk Management Strategies for *Salmonella* spp. in poultry. The Committee noted that the discussion paper would be considered at its next Session with a view towards developing risk management strategies for *Salmonella* spp. in poultry.

74. The Committee also suggested that their discussions on *Salmonella* spp. in eggs and poultry as well as the report of the Consultation should be considered by the Codex Committee on Meat and Poultry Hygiene in the context of their work related to the elaboration of codes of hygienic practice.

#### **Risk Assessment of *Campylobacter* and *Vibrio***

75. The Committee noted the work completed to date on risk assessments of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood as contained in the Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Hazard Identification, Exposure Assessment, and Hazard Characterization of *Campylobacter* spp. in Broiler Chickens and *Vibrio* spp. in Seafood (Geneva, 23 - 27 July 2001).

76. It was noted that there was no work underway in the Committee on *Campylobacter* spp. in broiler chickens or *Vibrio* spp. in seafood and therefore, clear guidance regarding the risk management goals for these pathogen-commodity combinations were needed so that the risk assessments could better serve the requirements of the CCFH and other parties.

77. The Committee therefore agreed that a drafting group led by the Netherlands, with the assistance of Australia, Belgium, Canada, China, Denmark, Finland, Japan, New Zealand, Norway, Philippines, Thailand, the United Kingdom, the United States and the European Commission (EC), would develop a Discussion Paper on Risk Management Strategies for *Campylobacter* spp. in Poultry with a view towards defining questions to be addressed in the risk assessment. The Committee also suggested that their discussions on *Campylobacter* spp. in poultry as well as the report of the *ad hoc* Expert Consultation<sup>9</sup> should be considered by the Codex Committee on Meat and Poultry Hygiene in the context of their work related to the elaboration of codes of hygienic practice. It was also suggested that the issue of fluoroquinolone resistant *Campylobacter* in poultry should be considered by the drafting group for possible evaluation by risk assessors and in developing risk management strategies (see also para. 159).

78. The Committee also agreed that a drafting group led by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand, would develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood with a view towards defining specific questions to be addressed in the risk assessment. It was suggested that the initial focus would be *Vibrio parahaemolyticus* in fish and shellfish as these risk assessments are the most advanced. The representative of Consumers International advised the Committee to take global public health concerns into consideration. The need to continue the work on *Vibrio cholerae* especially in view of its public health importance for developing countries.

79. The Committee stressed that in view of the current ongoing risk assessments being undertaken in FAO and WHO for these pathogen/commodity combinations, the drafting groups were given the mandate to formulate specific questions for the risk assessors as soon as possible. The Working Groups should also develop discussion papers to be circulated for comments and consideration by the Committee. The Committee also suggested that the papers could provide guidance to FAO and WHO in their continued elaboration of the risk assessment on *Vibrio* spp. in seafood and *Campylobacter* spp. in broiler chickens. The Committee also requested that countries which already had control programs in place for the pathogens under consideration to provide this information to the leaders of the drafting groups as soon as possible.

80. The Committee also noted the importance of developing well focused risk management questions to be addressed by the risk assessment, to clearly communicate the desired results, to take the farm-to-table continuum into account when developing risk management options and to take the needs of global health concerns for all countries into account.

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<sup>9</sup> Hazard identification, exposure assessment and hazard characterization of *Campylobacter* spp. in broiler chickens and *Vibrio* spp. in seafood, WHO Headquarters, Geneva, 23-27 July, 2001.



### **Interaction Between Risk Assessors and Risk Managers**

81. A central theme of this discussion was the importance of improving risk communication, including and in particular interaction between assessors and managers and the need to define the scope and goals of any risk analysis activity to help frame risk management questions around an understanding of the outputs required. It was noted that to date the risk management questions put forward by the Committee had not been subject to the systematic application of a framework for managing risk that was appropriate to the overall work of CCFH and therefore, this issue needed to be addressed by the Committee in detail. The Committee noted that the completion of the Principles and Guidelines for the Conduct of Microbiological Risk Management would greatly assist the CCFH in the development of risk management strategies and the utilization of the risk assessment results.

82. In view of this discussion, the Committee requested the United States to revise its proposal concerning CCFH work related to risk management (Proposal for a Process by which the Codex Committee on Food Hygiene Could Undertake its Work in Microbiological Risk Assessment/Risk Management, CX/FH 01/5-Add. 2). The Committee requested that the paper take account of the risk profile template provided by FAO and WHO (CX/FH 01/5-Add. 3) and that the process be as simple, short and flexible as possible, and to skip steps that are not functional as to avoid delay in process in order to meet the different needs of the Committee. It was agreed that the paper would be circulated for comments and further consideration at the 35<sup>th</sup> CCFH and that depending on the outcome of these discussions, might eventually be considered for inclusion in the Codex Alimentarius Procedural Manual.

83. In view of the need of the Committee to achieve a better understanding on how to integrate risk assessment results into the development of standards, guidelines and other management documents, the Committee requested FAO and WHO to convene an expert consultation to address this point. The German Delegation informed the Committee that they would be willing to host and fund this expert consultation in 2002 on the principles and guidelines for incorporating quantitative microbiological risk assessment in the development of national and international food safety policy as follow-up to the consultation on the interaction between risk assessors and risk managers that was organized by WHO with the collaboration of FAO in Kiel in 2000.

84. In view of the usefulness of the information session held prior to the current session of the CCFH, FAO and WHO agreed to organize a similar seminar for information /communication purposes prior to the 35<sup>th</sup> CCFH if resources were available to do so in order to ensure that a two way of information between risk assessors and risk managers would occur. It was pointed out that the risk assessment information presented in the seminar should be an explanation of that which is published literature so that participants could get clarification on various aspects of the risk assessment.

### **Guidelines for the Obtaining of Data of Interest for Microbiological Risk Assessment**

85. The Committee agreed that one of the main problems faced in the development of the risk assessments was the lack of data. Therefore, it was agreed that the paper (CX/FH 01/15) submitted by Brazil at the current Session on "Guidelines for the Obtaining of Data of Interest for Microbiological Risk Assessment" was relevant for all countries and not just developing countries. The Chairperson of the Committee suggested that this paper be forwarded to FAO and WHO for consideration. The Delegation of Brazil requested that the results of this consideration should be reported to the CCFH in the form of discussion paper. The Representative from FAO informed the Committee that an expert consultation would be convened in November to address the issue of surveillance data and its use in risk assessment.

### **Future Work**

86. The Committee confirmed that Enterohemorrhagic *Escherichia coli* remained as a priority item of work for the CCFH. However, several delegations noted that in addition to sprouts and ground beef, this pathogen was also a concern in other products such as pork. The Committee therefore agreed that the United States, with the assistance of Austria, Australia, Canada, China, France, Germany, Japan and the EC would prepare a risk profile for enterohemorrhagic *E. coli* including the identification of the commodities of concern, including sprouts, ground beef and pork. The Committee also agreed that the

paper should take account of the recently completed code of Hygienic Practice for Fresh Fruits and Vegetables as related to sprouts (see Appendix II of this report).

### **Status of the Joint FAO/WHO *ad hoc* Expert Consultations**

87. In order to further enhance the risk assessment work being undertaken by FAO and WHO and to support the risk management work of this Committee and better facilitate risk communication, the Committee suggested that the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods be given permanent status. However, the delegation from the United Kingdom found it too early to support this recommendation on the basis that uncertainties remain over the present utility of the risk assessment outputs to the risk management activities of the Committee. The delegation indicated that further reflection was necessary on this issue in the light of future developments, including the outcome of the FAO/WHO review of expert bodies concerning the quantity, quality and timeliness of scientific advice to Codex. There was no explicit support for the UK position in this matter.

### **Application of Microbiological Risk Assessment by Member Governments**

88. A number of delegations, particularly those from developing countries, expressed their concerns regarding the lack of expertise in their countries to understand and apply risk assessment. They stressed the need for FAO and WHO to provide assistance to countries to strengthen their technical capabilities for the application of risk assessment and address the emerging need for risk assessors in many countries. It was recommended that the network of FAO and WHO Collaboration Centres be strengthened and expanded to provide regional expertise in risk assessment and risk management, with the understanding that this would facilitate training and the development of regional risk analysis expertise and activities.

### **PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF LISTERIA MONOCYTOGENES IN FOODS (AGENDA ITEM 6)<sup>10</sup>**

89. The 33rd session of the Committee had agreed that Germany, with the assistance of the drafting group, would prepare a revised version of the proposed draft Guidelines for the Control of *Listeria monocytogenes* in Foods on the basis of written comments submitted and the results of the risk characterization to be finalized by the Joint FAO/WHO Expert Consultation.<sup>11</sup> The 49th Session of the Executive Committee approved the elaboration of the Guidelines as new work.<sup>12</sup>

90. The Delegation of Germany indicated that various aspects of control of *L. monocytogenes* in foods had been discussed since the 23rd Session of CCFH in 1989. The Delegation indicated that the outcome of the FAO/WHO Expert Consultation on Risk Assessment<sup>13</sup> was taken into consideration in revising the present document and that the risk assessment had provided various risk management options for the control of *L. monocytogenes* in foods in international trade. It was suggested that the Expert Consultation could be used as a pilot study to show how consultation results could be incorporated into the decisions of the Committee.

91. The Delegation noted that the scope gave guidance for the control of *L. monocytogenes* in foods based on the risk assessment and listed a number of risk management options. It was indicated that although the risk assessment for *L. monocytogenes* had demonstrated that, in relation to the likelihood of illness, there was a negligible difference when consuming foods with levels of *L. monocytogenes* ranging from 0-1000/g, the drafting group kept the original proposed level of less than 100 *L. monocytogenes* per gram at the time of consumption. This decision of the drafting group was taken in order to proceed with the elaboration of control measures, in particular the establishment of microbiological criteria, and highlighted the need for levels which were appropriate for Codex purposes.

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<sup>10</sup> CX/FH 01/6; CRD 7 (comments of ICMSF)

<sup>11</sup> ALINORM 01/13A, paras. 111-119.

<sup>12</sup> ALINORM 03/3, Appendix III.

<sup>13</sup> Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. Rome, 30 April- 4 May 2001.

92. The Delegation of United States expressed the view that specific consideration of this document would be limited until the report of the Joint FAO/WHO Expert Consultation was completed. The Delegation of Belgium, speaking on the behalf of the Member States of the European Union present at the current Session, pointed out that the new annexes should be considered carefully in order to ensure coherence with the body of the text.

93. The Observer from the IDF pointed out that more clarification was needed regarding terminology, including relationship between Accepted Levels of Protection (ALOPs), risk management goals, microbiological criteria and Food Safety Objectives (FSOs) and stressed the need for ensuring consistency with other texts developed by the Committee. The Delegation of France emphasized the need for initiating risk management activity at the primary production level and stressed the need for the Delegation of Germany to take into account the results of the risk assessment of *Listeria monocytogenes* in order to consolidate the microbiological criteria proposed in their document

94. Other delegations indicated that the risks associated with the establishment of specific limits in foods had not been estimated by the risk assessors and therefore, they urged caution in interpretation of results and the establishment of specific numerical microbiological criteria at this stage. It was also stated that the information contained in Annex 2 needed more examples related to milk and that the provisions of the Annex might be incorporated into the main body of the text. The Observer of ICMSF pointed out that further clarification on the scope was necessary; i.e., its application to ready-to-eat or all foods.

95. While the importance of taking a farm to table approach was highlighted, the report of the FAO/WHO Expert Consultation on Risk Assessment indicated that the foods most often associated with human listeriosis were ready-to-eat products that supported growth of *L. monocytogenes*.

96. The Delegation of Germany clarified that further integration of the results of the risk assessment into risk management options was necessary. However, it was not clear as to how these results might be used in establishing such options as the risk assessment of *L. monocytogenes* only addressed ready-to-eat foods.

97. The Committee expressed its appreciation to the Delegation of Germany and the drafting group for their valuable work and the progress made on the document.

#### **Status of the Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods**

98. Due to the fact that comments on the document were not solicited prior to the current meeting, the Committee agreed to attach the Guidelines to its report for additional comments to be sent to Germany by 1 February 2002 (see Appendix IV) and revision by Germany with assistance of its drafting partners Austria, Canada, Czech Republic, China, Denmark, France, Hungary, Japan, Norway, Phillipines, United Kingdom, United States, Commission of the European Community and ICMSF on the basis of the comments submitted and the results of the risk assessment. It was agreed that the revised Guidelines would be circulated for additional comments and further consideration at Step 4 at the next Session, including a full discussion on the scope of the Guidelines.

#### **PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (AGENDA ITEM 7)<sup>14</sup>**

99. The 33<sup>rd</sup> session of the CCFH had returned the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management to Step 3 for revision by a drafting group led by France, with the assistance of Argentina, Australia, Canada, Denmark, Germany, Netherlands, New Zealand, Norway, Sweden, United Kingdom, United States, Consumers International and ICMSF.<sup>15</sup>

100. In presenting the document, the delegation of France noted that the Guidelines were revised by a working group held in Paris from 7-8 June 2001 and as instructed by the Committee, took account of discussions and comments submitted at the 33<sup>rd</sup> CCFH, comments received in response to CL 2000/37-FH in regard to food safety objectives and the report of the WHO Expert Consultation on the Interaction Between Assessors and Managers of Microbiological Hazards (Kiel, Germany, 21-23 March 2000).

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<sup>14</sup> CX/FH 01/7 and comments submitted by Argentina, Mexico, New Zealand, United States, Consumers International, International Federation for Health (CX/FH 01/7-Add. 1); Canada, Malaysia (CRD 4); European Community (CRD 9), and; Brazil (CRD 12).

<sup>15</sup> ALINORM 01/13A, paras. 83-95.

101. The Committee discussed the proposed draft Guidelines section by section and agreed to the following revisions:

### General Comments

102. The delegation of India, in noting discussions concerning Principles of Risk Analysis at the 23<sup>rd</sup> Session of the Commission, stated that the Guidelines needed to be further refined so that they more adequately took account of the economic consequences and the feasibility of risk management options in developing countries<sup>16</sup>. It was also noted that the Guidelines needed to more thoroughly address other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

103. The delegation of Belgium, speaking on behalf of the EU Member States present at the Session, noted that the concept of food safety objective and their connection to ALR needed further development and discussion and that other aspects related to the conduct of microbiological risk management should also be considered in the light of progress in other Codex committees. The Committee also noted that the drafting group should take account of the new additions to the terms of reference for the CCFH adopted at the 24<sup>th</sup> Session of the Commission, namely, “to suggest and prioritize areas where there is a need for microbiological risk assessment at the international level and to develop questions to be addressed by the risk assessors” and “to consider microbiological risk management matters in relation to food hygiene and in relation to risk assessment of FAO and WHO”.

### Section 2 – Definitions

104. The Committee noted that the term and definition for Acceptable Level of Risk (ALR), which had been superseded by the term and definition for Appropriate Level of Protection (ALOP), was temporarily included in the Guidelines for reference purposes only and would be removed from the text prior to its finalization. The Committee also agreed to delete the terms Microbiological Hazard and Microbiological Risk from the list, and incorporated the definitions for these terms as subsets of the definitions for Hazard and Risk, respectively. The Committee also agreed to elaborate a definition for the term Risk Manager in a future revision to the Guidelines, with the understanding that risk management could be undertaken at the national, regional or international level.

### Section 3 – General Principles

105. The Committee decided to divide Principle 4 into two separate principles addressing risk assessment and risk assessment policy for clarity and conciseness by indicating, “The establishment of risk assessment policy is a responsibility of the risk managers. The objective of risk assessment should be clearly defined before risk assessment begins” (Principle 4) and “The scientific integrity of the risk assessment process should maintain the functional separation of risk management and risk assessment, while ensuring transparent and appropriate interaction between them” (Principle 5).

106. The Committee agreed in principle that the drafting group should take account of decisions made at the 24<sup>th</sup> Session of the Commission in regard to the consideration of precaution and the finalization of criteria for the consideration of other factors in revising Principles 6 and 8 as well as other relevant sections of the Guidelines.

107. The Committee agreed to revise and simplify Principle 9 to state that “Risk managers should ensure that any control measures that are to be implemented should be feasible, effective and proportionate to the risks identified” with the understanding that taking account of the economic and technical feasibility and effectiveness of such control measures would be addressed under Section 5.2.3.

108. The Committee agreed to revise Principle 10 to read, “Risk management decisions should always be open to review.” It further agreed that the remainder of the text should remain as explanatory material in a new paragraph under Principle 10 to read, “*Risk management decisions should be open to review when new*

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<sup>16</sup> Comment submitted by India on the “Need for Risk Analysis in the Elaboration of Standards and Codex by Various Codex Committees” (CRD 13).

*information becomes available that substantively alters the conclusions of risk assessment or its associated degree of uncertainty, or as new risk management options become available.”*

109. The Committee agreed to amend the phrase “public health concern” to “public health risk” in Principle 12. The Delegation of United Kingdom suggested that the Drafting Group might consider a stronger formulation, so that risk management decisions would be reviewed when a risk assessment is substantially altered.

#### **Section 4 – Involvement of Stakeholders**

110. The delegation of Mexico expressed the opinion that the ALOP and FSOs should not necessarily reflect the values of society. The Committee agreed to modify the 5<sup>th</sup> bullet of this Section to state that stakeholders should be involved in various aspects of risk management, as appropriate, for example: “Identification of the ALOP and establishing FSOs”.

#### **Section 5.1.3 – Risk Profile**

111. The Committee agreed to modify the 5<sup>th</sup> bullet of this section to indicate that the risk profile might also describe *to what extent* populations may be affected. As the Committee could not reach agreement on the inclusion of an additional bullet concerning trade impact implications as an example of a risk profile description, it decided to include this example in square brackets.

#### **Section 5.1.4 – Defining Goals**

112. For consistency with Principle 4 of the Guidelines, the Committee clarified the first sentence of this Section to indicate that the goals for a microbiological risk management activity should be identified *before a risk assessment begins*.

#### **Section 5.1.6 – Commissioning of Microbiological Risk Assessment**

113. In regard to the information required by the risk manager, the Committee agreed that the assessment may be needed to attain a *appropriate level of protection* as opposed to a “pre-specified level of protection with a high level of confidence”. Decision makers has been changed to risk managers.

#### **Section 5.1.7 – Consideration of the Process and the Results of the Microbiological Risk Assessment**

114. The Committee agreed in principle that the Guidelines needed to be examined, in particular at Section 5.1.5, to afford the opportunity for risk managers to resolve differences in risk assessments through a peer review process and in this regard, the Committee emphasized that this Section should be consistent with the Principles and Guidelines for the conduct of Microbiological Risk Assessment. The Committee therefore modified the 4<sup>th</sup> bullet of this section to indicate, “The risk assessment should be subject to a peer review. Any possible differences in the conclusions should be solved by the risk managers, with input from the risk assessors and stakeholders as appropriate” and left the text in square brackets.

#### **Section 5.1.8 – Regional Considerations**

115. The second bullet of this section was modified to read “Risk management should take into account the existence of regional differences such as the prevalence of foodborne pathogens in the food chain”.

#### **Section 5.2.1 – Identification of Available Options**

116. The Committee modified the second sentence of paragraph 2 to indicate that microbiological risk management options assessment is aimed at the option or options that achieve the *appropriate* as opposed to chosen level of public health protection.

### Section 5.2.1.1 – Identifying the Acceptable Level of Risk (ALR – refers to ALOP)

117. The Committee noted that it was not always possible to express an ALOP as a maximum permitted prevalence of a pathogen in food and therefore, replaced the penultimate sentence in the third paragraph of this section with the statement, “[Since in some cases it will be impossible to give exact estimates of the ALOP, an ALOP could also be expressed as an aim of reducing the number of cases in a population associated with a hazard in food]” in square brackets.

118. As the Committee could not reach an agreement as to whether or not all factors (e.g., public values, economic factors) associated with an ALOP/ALR were always scientifically justified, it decided to leave the 4<sup>th</sup> paragraph of this Section to read, “The ALOP/ALR applies equally to both domestic and imported food. The ALOP/ALR should be [scientifically justifiable and] clearly conveyed to the exporting country.” Pending further consideration by the drafting group.

### Section 5.2.1.2 – Food Safety Objectives (FSOs)

119. The Committee supported the concept of FSOs, and noted the importance of clearly defining the term FSO so that it was understandable and could be used in a transparent and consistent manner. This was felt to be especially important as the establishment of different FSOs at different points in the foodchain might actually introduce barriers to trade. Although the Committee generally agreed that the FSOs should cover the entire food production chain could be considered, there was no general agreement on the appropriate place for the establishment of FSOs.

120. In this regard, it was noted by some delegations that the critical point for the establishment of FSO was at the point of consumption since this was the stage at which detrimental effects occurred. However, it was noted that the establishment of FSO at the point of consumption could be problematic for producers as it might hold them responsible for issues outside of their control and would be difficult and impractical to enforce.

121. Other delegations were of the opinion that microbiological risk management applied at all points of the food chain and that in the interest in arriving at a logical point of application of FSOs the most relevant point of application could be earlier in the food chain including at the level of primary production.

122. However, it was also recognized that in both cases (paras 118, 119) this would require the establishment of performance criteria and other criteria at appropriate points of the food chain.

123. As a temporary compromise solution, the Committee decided that the drafting group should use the following definition proposed by the ICMSF as a basis for its discussions:

- a. **Food Safety Objective:** The maximum frequency and/or concentration of a [microbiological] hazard in a food at the time of consumption that provides the appropriate level of health protection [(ALOP)].

The Committee further recognised that FSOs will need to be used in conjunction with performance criteria to establish the level of control needed at other points in the food chain. The Committee also requested the Drafting Group to draw up on the table expanding the differences and relationship between these terms.

124. The Committee also confirmed that the bulleted list of considerations to be undertaken when determining the ALOP/ALR were presented as examples only and were therefore subject to further debate.

### Section 5.2.1.3 – Precaution in Risk Management

125. The Committee decided to include the following text adopted at the 24<sup>th</sup> Session of the Commission within the text, with the understanding that this addition as well as the current text would be subject to further consideration by the drafting group, notably because this text is relevant to Codex activities, while Risk management principles and Guidelines will have wider application:

- a. *“When there is evidence that a risk to human health exists but scientific data are insufficient of incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.”*

126. The Committee also directed the drafting group to take account of discussions held at the Codex Committee on General Principles in this regard, and to consider advice to national governments as well as recommendations for Codex. Some delegations proposed to change the title to “Precaution in Risk Management” from “Precautionary Principle”.

## **Section 6 – Guidelines for Implementation of Microbiological Risk Management Decisions and Section 7 – Monitoring and Review**

127. The Committee noted that these sections would require extensive revision by the drafting group and in this regard, it was suggested that consideration should be given to balancing aspects of the sections related to food safety objectives and risk management options.

## **Status of the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management**

128. The Committee requested the drafting group led by France to revise the proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management based on the above discussions, and written comments submitted for circulation and comment, especially on Sections 6 and 7 well before the 35<sup>th</sup> Session of the CCFH.

## **PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (AGENDA ITEM 8)<sup>17</sup>**

129. The 33<sup>rd</sup> Session of the CCFH had agreed to return the Proposed Draft Code to Step 3 for redrafting by the United States with the assistance of a drafting group and to circulate the revised draft for government comments prior to the next Session of the Committee. The Committee complemented the USA for their efforts in revising the Proposed Draft Code.

130. The United States summarized the major changes and discussions that had taken place in the drafting group, and noted that further work was still needed. In particular, the drafting group sought guidance on a number of issues arising from the comments submitted. These included issues related to validation of control measures, food safety objectives and their relationship with performance criteria, the structure and the presentation of base document, and content of the Primary Production Annex; and how to address raw milk for drinking. Due to the time constraints and recognizing that further redrafting was necessary, the Committee considered only general comments.

131. Some delegations indicated that a clearer hierarchy of principles was desirable to add more coherence to the Proposed Draft Code. Other delegations stated that the three primary production Annexes should be combined into a single Annex as they contained duplicative information. Some delegations also stated that the Annexes should contain information that supplemented the main text in order to avoid duplication.

132. The Delegation of India, supported by South Africa, expressed concern over combining the Annexes into a single Annex as they could not accommodate the diverse situations of small and large producers, therefore they were in favour of the present structure.

133. The Committee was in general agreement with the direction and much of the content of the Proposed Draft Code, and agreed with the need for further developing, among others, the concepts of “validation of control measures”, “food safety objectives”, and “performance criteria” on a horizontal basis. Further some delegations recommended to avoid duplications and to ensure consistency with the General Principles of Food Hygiene, the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management and other Codex standards. The Committee also noted that more work was required to ensure a coherent structure of the Proposed Draft Code and its Annexes.

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<sup>17</sup> CX/FH 01/8; CX/FH 01/8-Add.1 (comments of Argentina, Canada, Mexico, New Zealand, the United States of America, Uruguay, International Dairy Federation (IDF); CRD 3 (comments of Australia, Canada, Denmark); CRD 8 (comments of the European Community).

**Status of the Proposed Draft Code of Hygienic Practice for Milk and Milk Products**

134. The Committee agreed to return the Proposed Draft Code to Step 2 for revision by the drafting group led by the United States, with the assistance of Argentina, Australia, Canada, France, Germany, India, Netherlands, New Zealand, Spain, Switzerland, United Kingdom, Uruguay, and the International Dairy Federation, taking into account written comments submitted and the above discussion. The revised code will be circulated for further comments at Step 3 in advance before the next Session of the Committee

**PROPOSED DRAFT GUIDELINES FOR THE HYGIENIC REUSE OF PROCESSING WATER IN FOOD PLANTS (AGENDA ITEM 9)<sup>18</sup>**

135. The Committee was reminded that the 49<sup>th</sup> Session of the Executive Committee approved all of the proposals for new work submitted by the Codex Committee on Food Hygiene, but had expressed concern at the heavy workload of the Committee and recommended that its work should be prioritized<sup>19</sup>.

136. In view of this recommendation and the heavy workload devoted to microbiological risk assessment, the Committee, acting upon a suggestion of the US, recognized both the importance of this work as well as the Committees need to prioritize its work decided to discontinue the consideration of this subject for the time being, with the understanding that this decision would be reviewed at its 36<sup>th</sup> Session.

**PROPOSED DRAFT REVISED GUIDELINES FOR THE APPLICATION OF HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESSES (SLDBS) (AGENDA ITEM 10)<sup>20</sup>**

137. The Delegation of the Netherlands introduced the document and indicated that barriers to implementing HACCP in SLDBs had been considered by the CCFH since 1997. The Delegation recalled the request of the last session of the Committee to assist governments and businesses, particularly in SLDBs, to over-come the identified burdens and to provide additional guidance to facilitate HACCP implementation by SLDBs. Consequently the drafting group revised the document which currently contained two differently oriented Annexes. The Delegation indicated that the revised Annex I containing changes to the existing HACCP Guidelines currently provided guidance on how to apply the seven principles of HACCP in any size of business including SLDBs and that Annex II presented the discussions on the obstacles to implementing HACCP and provided additional recommendations to help to over come those obstacles. The Delegation indicated that the development and use of sector specific codes by governments and industry could be of great importance.

138. The Committee discussed the proposed draft Guidelines section by section and agreed to the following changes:

**General comments**

139. Some delegations were of the opinion that the amended Annex I provided flexible guidance in implementing HACCP in SLDBs, while a number of other delegations, especially from some developing countries, were of the view that still more flexibility was needed and that clarification of the term SLDBs as well as more detailed classification of the SLDBs was necessary.

140. The Delegation of the United Kingdom, as a member of the Drafting Group, confirmed that Annex II was intended as a possible basis for the development of more detailed guidance by bodies outside of the Codex framework, and this was clear from the second recommendation to the Committee contained in document CX/FH 01/10.

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<sup>18</sup> CX/FH 01/9; CX/FH 01/9-Add.1 (comments of Canada, France, Mexico, New Zealand and the United States of America); CRD 6 (comments of Australia and Malaysia), CRD 8 (comments of the European Community); CRD 12 (comments of Brazil).

<sup>19</sup> ALINORM 03/3, paras. 23.

<sup>20</sup> CX/FH 01/10; CX/FH 01/10-Add.1 (comments of Argentina, Canada, Mexico, New Zealand, the United States of America and Consumers International); CRD 5 (comments of Australia, Malaysia); CRD 8 (comments of the European Community).



141. The Committee had an extensive debate regarding future work and the use of Annex II. The Committee agreed that Annex II contained important data on obstacles and could be very valuable, however there were contrary opinions expressed regarding its intended use. While some delegations were of the view that Annex II should be used, especially by FAO and WHO for training purposes as an information paper in developing guidance materials for governments and industry in order to provide additional assistance in the implementation of HACCP by SLDBs, some other delegations favored incorporating Annex II into the main body of Annex I.

142. Some delegations indicated that the implementation of the content of Annex II be left to national governments for the decision on its intended use.

#### **Paragraph 8 of the Proposed Draft Revised Guidelines for the Application of the HACCP System**

143. The 8<sup>th</sup> paragraph was amended in order to emphasize the importance of appropriate ongoing training for all levels of food employees and managers.

#### **Section 4. Construct flow diagram**

144. The second sentence of the underlined text was amended to clarify the use of the flow diagram.

#### **Section 6. List of all potential hazards**

145. The wording “according to the scope” was inserted after “at each step” to emphasize intended use.

#### **Section 8. Establish critical limits for each CCP**

146. Next to the last sentence of this Section was amended to clarify products under consideration.

#### **Section 11. Establish verification procedures**

147. Square brackets were deleted from the wording “where appropriate” to make the application of validation more flexible.

#### **Section 12. Establish documentation and record keeping**

148. The third sentence of this Section was amended to clarify the purpose of documentation and record keeping.

149. Many delegations proposed to advance the proposed draft revised Guidelines on for the Application of the HACCP System in Small and/or Less Developed Businesses (SLDBs) for final adoption at Step 8 with omission of Steps 6 and 7. However, some delegations from developing countries opposed this and indicated that it was too premature to adopt it and more time was necessary to fully evaluate the implications of revised Guidelines.

#### **Status of the Proposed Draft Revised Guidelines for the Application of the HACCP System**

150. The Committee agreed to forward the Proposed Draft Revised Guidelines for the Application of the HACCP System for adoption at Step 5 by the 50<sup>th</sup> Session of the Executive Committee (Appendix III). The Committee clarified that the text of Annex I was intended to replace the current Guidelines for the Application of the HACCP System in the context of SLDBs, which formed an integral part of the Hazard Analysis and Critical Control Point System and Guidelines for its Application (Annex to CAC/RCP 1-1969, rev. 3 1997); i.e., the revised text was not intended to be adopted as a separate document but included in the Proposed Draft Guidelines for the Application of the HACCP System.

151. The Committee agreed to request comments on Annex II. Since some delegations expressed the need for consideration of the paper in its totality, the Committee also agreed that written comments and the above discussion in relation to Annex II (Obstacles to the Application of HACCP, Particularly in SLDBs and Approaches to Overcome Them) should be forwarded to the Netherlands for preparation of an up-dated version of the Annex II for consideration at the next Session of the Committee.

**PROPOSED DRAFT REVISION OF THE CODE OF HYGIENIC PRACTICE FOR EGG PRODUCTS (AGENDA ITEM 11)<sup>21</sup>**

152. The 33<sup>rd</sup> Session agreed to revise the Code of Hygienic Practice for Egg and Egg Products, pending the approval of the Commission, generally recognizing the necessity for its revision due to the important public health aspects of the Code and the long period of time that had passed since its original development (CAC/RCP 15-1976, Amended 1978, 1985). It was noted that the microbiological risk assessment on Salmonella in eggs and poultry to be finalized by FAO and WHO would be useful for the revision of the code. It was agreed that Australia, with the assistance of the United States and Association Latino Americana de Avicultura (ALA) would prepare an initial document for consideration at the next Session. The 49<sup>th</sup> Session of the Executive Committee approved the revision as new work.
153. The Committee recognized that different types of Salmonella needed to be addressed and that the ongoing risk assessment work on Salmonella might be useful in addressing this issue.
154. There was general agreement that the scope of the code should also cover eggs in shell, and some delegations pointed out the need to change the title of the code to include these products in addition to egg products. It was also noted that the Drafting Group might wish to address the agricultural chemicals, mycotoxins and contaminants in poultry production as it strictly related to hygienic practices.
155. Some delegations pointed out the importance of including provisions relevant to management strategies, production systems and measures in breeding that were of importance in preventing the spread of disease.
156. The Observer of Consumers International was of the view that the procedures for egg disposal should be addressed, since discarded eggs of questionable safety were sometimes sold at a reduced price to consumers. The Observer also suggested that definitions for inedible eggs and restricted eggs be included in the definitions section.

**Status of the Proposed Draft Revision of the Code of Hygienic Practice for Egg Products**

157. The Committee agreed to return the proposed draft revision of the Code to Step 2 for revision by the drafting group led by Australia, with the assistance of Canada, Italy, Netherlands, United Kingdom and the United States and ALA, taking into account written comments submitted and the above discussion. The revised version of the code would be circulated for comments and further discussions at the next Session of the Committee well in advance before the next Session.

**DISCUSSION PAPER ON THE RISK PROFILE FOR ANTIMICROBIAL-RESISTANT BACTERIA IN FOOD (AGENDA ITEM 12)<sup>22</sup>**

158. The 33<sup>rd</sup> CCFH requested Denmark to revise the discussion paper on the basis of comments submitted, and with the understanding that the advice of the Executive Committee would be sought on the coordination of the work in this area between the various Committees concerned.<sup>23</sup> The 48<sup>th</sup> Session of the Executive Committee agreed that consideration should be given to the consideration of antimicrobial resistant microorganisms in food within a risk analysis framework on a case-by-case basis as microorganism/food combinations were being assessed. The Executive Committee also recommended that FAO and WHO should give consideration to convening a multidisciplinary expert consultation, in cooperation with Office International des Epizooties (OIE) and if required the IPPC, to advise the Commission on possible directions to be taken including the establishment of a new task force if necessary.<sup>24</sup>
159. The Committee generally supported the conclusions of the Executive Committee, especially as related to convening a multidisciplinary expert consultation to address antimicrobial resistance. It noted that

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<sup>21</sup> CX/FH 0/11; CRD 7 (comments of New Zealand); CRD 8 (comments of European Community); CRD 12 (comments of Brazil).

<sup>22</sup> CX/FH 01/12 and unsolicited comments submitted by the EC (CRD 8).

<sup>23</sup> ALINORM 01/13A, paras. 134-142.

<sup>24</sup> ALINORM 01/4, paras. 36-37.

regardless of whether or not an *Ad Hoc* Task Force was established, a comprehensive and multidisciplinary approach to these risk assessments would be required. The Committee agreed that the emergence of pathogen-specific antimicrobial resistance such as fluoroquinolone-resistant *Campylobacter* in poultry be examined as data are available for future risk assessments. The Committee also supported the first two recommendations in the document (CX/FH 01/12) but decided to amend the last recommendation as follows: “The principles of ‘reservation for human medicine’ of certain antimicrobial substances need international consideration”.

160. The Representative of the WHO informed the Committee that the recommendations of a number of expert consultations held over the past few years might also be examined by the Committee and/or the drafting groups. The Representative noted that the convening of an additional future consultation would depend on the availability of funding.

161. The Observer of the Office International des Epizooties (OIE) noted that the organization strongly favored a coordinated approach to the consideration of antimicrobial resistance and was taking steps towards this end. These strategies included the immediate implementation of measures to contain and reduce antimicrobial resistance through the prudent and responsible use of antimicrobials; the development of tools to assess and manage the risks to animal health; and, to increase worldwide knowledge of antimicrobial resistance and information gathering. The representative also highlighted the results of the recently held OIE Working Group on Antimicrobial Resistance which considered issues related to risk analysis methodology, responsible use, monitoring, standardization and surveillance of antimicrobial uses.

162. The Committee thanked Denmark for its efforts and agreed that the relevant drafting groups examining pathogen/commodity combinations might wish to take the document as well as the above discussions into account. The Committee also agreed to inform the Executive Committee of its discussions.

#### **DISCUSSION PAPER ON THE PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (AGENDA ITEM 13)<sup>25</sup>**

163. The 33<sup>rd</sup> Session of the CCFH requested the United States, with the assistance of its drafting partners, to revise the Discussion Paper on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures for further consideration at the current meeting<sup>26</sup>.

164. The Delegation of the United States noted that in the current environment of outcome based codes of hygienic practice that provide flexibility with the selection of control measures, the concept of validation of food hygiene of control measures had acquired increased importance since it is through validation that one is able to demonstrate that the selected control measures actually achieve the desired goal of controlling the food hazard.

165. The Delegation of Belgium, speaking on behalf of European Union member states present at the current session, emphasized the need for having clear guidance on validation and noted the need to give careful consideration describing the various concepts, such as FSOs or performance criteria, that appeared in the document. It was also noted that it was not clear as to the type of document to be developed.

166. Several delegations and the representative of Consumers International pointed out that the concept of validation was fundamental in the development/revision of codes in risk based environment and therefore supported further elaboration of the document as an annex to the International Code of Practice-General Principles of Food Hygiene. The Delegation of Thailand, supported by Kenya, noted that it was not clear as to whether every food hygiene measure required validation and that the application of validation to each and every case would be impractical.

#### **Status of the Discussion Paper of the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures**

167. The Committee requested the United States, with the assistance of Australia, Canada, France, Italy, New Zealand, Thailand, Sweden, IDF and ICMSF, to elaborate proposed draft Guidelines for the Validation of Food Hygiene Control Measures as an Annex to the International Code of Practice-

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<sup>25</sup> CX/FH 01/13; CRD 7 (comments from Malaysia); CRD 8 (comments from the European Community).

<sup>26</sup> ALINORM 01/13A, paras. 143-145.

General Principles of Food Hygiene. The Committee agreed to circulate the proposed draft Guidelines for comment and further consideration at its next session, pending the approval of this initiative as new work by the Executive Committee.

### **DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR EVALUATING OBJECTIONABLE MATTER IN FOOD (AGENDA ITEM 14)<sup>27</sup>**

168. The Committee was reminded that the 49<sup>th</sup> Session of the Executive Committee approved all of the proposals for new work submitted by the Codex Committee on Food Hygiene, but had expressed concern at the heavy workload of the Committee and recommended that its work should be prioritised<sup>28</sup>.

169. In view of this recommendation and the heavy workload devoted to microbiological risk assessment, the Committee, acting upon a suggestion of the US, recognized both the importance of this work as well as the Committees need to prioritise its work decided to discontinue the consideration of this subject for the time being, with the understanding that this decision would be reviewed at its 36<sup>th</sup> Session.

### **OTHER BUSINESS AND FUTURE WORK (AGENDA ITEM 15)**

#### **Traceability**

170. The 49<sup>th</sup> Session of the Executive Committee agreed that it should be for the Committees concerned (including the Codex Committees on General Principles, Food Import and Export Inspection and Certification Systems, Food Hygiene and Food Labelling) to undertake work on traceability as they deemed appropriate, within their respective mandates<sup>29</sup>. In this regard, the CCFH noted its previous decision that traceability would be considered in the context of its work on the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management.

171. The delegations of Mexico, Thailand and the Observer of the EC were of the opinion that the concept of traceability should be addressed in a specific discussion paper and volunteered to draft it, however the Committee was of the opinion that specific work on traceability as related to food hygiene was premature. The Committee therefore reiterated its request to the drafting group that the concept of traceability should be taken into account in the further elaboration of the Principles and Guidelines for the Conduct of Microbiological Risk Management.

#### **Risk Analysis in the Context of Codex Standards and Codex of Practice<sup>30</sup>**

172. The Committee agreed that India would present a document on Risk Analysis in the Elaboration of Standards and Codes by Various Codex Committees at the 35<sup>th</sup> CCFH.

### **DATE AND PLACE OF NEXT SESSION (AGENDA ITEM 16)**

173. The Committee noted that the 35<sup>th</sup> Session of the Codex Committee on Food Hygiene was tentatively scheduled to be held in the United States from 21 – 26 October 2002, subject to further discussions between the Codex and U.S. Secretariats.

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<sup>27</sup> CX/FH 01/14; CRD 7 (comments of Malaysia), CRD 12 (comments of Brazil).

<sup>28</sup> ALINORM 03/3, paras. 23.

<sup>29</sup> ALINORM 03/3, paras. 29-33.

<sup>30</sup> Need for Risk Analysis in Elaboration of Standards and Codes by Various Codex Committees (CRD 13, prepared by India)

## SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 03/13
Draft Code of Hygienic Practice for Fresh Fruits and Vegetables	8	<b>Governments</b> , 25 <sup>th</sup> Session of the CAC	paras 19-65 and Appendix II
Proposed Draft Revised Guidelines for the Application of HACCP System	5	<b>Governments</b> , 35 <sup>th</sup> CCFH	paras 137-151
Proposed Draft Guidelines for the Hygienic Reuse of Processing Water in Food Plants	4	Hold at Step 4 until 36 <sup>th</sup> CCFH	paras 135-136
Proposed Draft Guidelines for the Control of <i>Listeria monocytogenes</i> in Foods	2	<b>Governments</b> , Germany and drafting partners, 25 <sup>th</sup> CCFH	paras 89-98 and Appendix IV
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	2	<b>Governments</b> , France, 35 <sup>th</sup> CCFH	paras 99-128
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	2	<b>US</b> , 35 <sup>th</sup> CCFH	paras 129-134
Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures	1/2/3	<b>50<sup>th</sup> Session of the CCEXEC</b> , US, 35 <sup>th</sup> CCFH	paras 163-167
Proposed Draft Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983)	1/2/3	<b>Australia</b> , 35 <sup>th</sup> CCFH	paras 152-157
Discussion Paper Risk Profile on the Antimicrobial Resistant Bacteria in Food		<b>FAO/WHO</b>	paras 158-162
Discussion Paper on Proposed Draft Guidelines for Evaluating Objectionable Matter in Food		Hold until 36 <sup>th</sup> CCFH	paras 168-169
Discussion Paper on Risk Management Strategies for <i>Salmonella</i> spp. in Poultry		<b>Sweden</b> and drafting partners	para. 73
Discussion Paper on Risk Management Strategies for <i>Campylobacter</i> spp. in Poultry		<b>Netherlands</b> and drafting partners	para. 77
Discussion Paper on Risk Management Strategies for <i>Vibrio</i> spp.		<b>United States</b> and drafting partners	para. 78
Risk Profile for Enterohemorrhagic <i>E. coli</i> Including the Identification of the Commodities of Concern, Including Sprouts, Ground Beef and Pork		<b>United States</b> and drafting partners	para. 86

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## Appendix II

**DRAFT CODE OF HYGIENIC PRACTICE FOR FRESH FRUITS AND VEGETABLES  
(AT STEP 8 OF THE PROCEDURE)**

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## INTRODUCTION

Scientific research over the last decades has shown that a diet rich in fruits and vegetables is protective against many cancers and lowers the occurrence of coronary heart disease. This recognition of the importance of routine consumption of fresh fruits and vegetables, together with a marked increase in the year-round availability of fresh fruits and vegetables from a global market, has contributed to the substantial increase in consumption of fresh fruits and vegetables over the past two decades. However, the recent increase in reports of food borne illness associated with fresh fruits and vegetables has raised concerns from public health agencies and consumers about the safety of these products.

### 1. OBJECTIVES OF THE CODE

This code addresses Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) that will help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables from primary production to packing. Particular attention is given to minimizing microbial hazards. The code provides a general framework of recommendations to allow uniform adoption by this sector rather than providing detailed recommendations for specific agricultural practices, operations or commodities. The fresh fruit and vegetable industry is very complex. Fresh fruits and vegetables are produced and packed under diverse environmental conditions. It is recognized that some of the provisions in this code may be difficult to implement in areas where primary production is conducted in small holdings, in both developed and developing countries and also in areas where traditional farming is practised. Therefore, the code is, of necessity, a flexible one to allow for different systems of control and prevention of contamination for different groups of commodities.

### 2. SCOPE, USE AND DEFINITIONS

#### 2.1 SCOPE

This code of practice covers general hygienic practices for the primary production and packing of fresh fruits and vegetables cultivated for human consumption in order to produce a safe and wholesome product: particularly for those intended to be consumed raw. Specifically, this code is applicable to fresh fruits and vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses). It concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GAPs and GMPs.

The *Annex for Ready –to-eat Fresh Pre-cut Fruits and Vegetables* (Annex I) and the *Annex for Sprout Production* (Annex II) are supplements to this code and include additional recommendations to cover, respectively, the hygienic practices for the processing of ready-to-eat fresh pre-cut fruits and vegetables, and the hygienic practices that are specific for the primary production of seeds for sprouting and the production of sprouts for human consumption

The code does not provide recommendations for handling practices to maintain the safety of fresh fruits and vegetables at wholesale, retail, food services or in the home. It excludes food products for which there is a specific Codex Alimentarius Code of Hygienic Practices.

#### 2.2 USE

This code follows the format of the Codex *Recommended International Code of Practice - General Principles of Food Hygiene*- CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with it. This code focuses upon hygienic issues that are specific to the primary production and packing of fresh fruits and vegetables. The major issues are covered in Section 3. In other sections, the *General Principles of Food Hygiene* have been expanded where there are issues specific to primary production

and packing. The *Annex for Ready-to-Eat Fresh Pre-Cut Fruits and Vegetables* provides additional recommendations specific for the processing of ready-to-eat fresh pre-cut fruits and vegetables and the *Annex for Sprout Production* provides additional recommendations specific for the primary production of seeds for sprouting and the production of sprouts for human consumption

### 2.3 DEFINITIONS

Definitions of general expressions are included in the General Principles of Food Hygiene. For the purpose of this code, the following terms have the definition stated:

*Agricultural inputs* - any incoming material (e.g. seeds, fertilizers, water, agricultural chemicals, plant support, etc.) used for the primary production of fresh fruits and vegetables.

*Agricultural worker* - any person that undertakes one or more of the following: cultivation, harvesting and packing of fresh fruits and vegetables.

*Antimicrobial agents*- any substance of natural, synthetic or semi-synthetic origin which at low concentrations kills or inhibits the growth of microorganisms but causes little or no host damage.

*Biological control* - the use of competing biologicals (such as insects, microorganisms and/or microbial metabolites) for the control of mites, pests, plant pathogens and spoilage organisms.

*Biosolids* - Sludge and other residue deposits obtained from sewage treatment plants and from treatment applied to urban and industrial wastes (food industries or other types of industry).

*Composting* - a managed process in which organic materials are digested aerobically or anaerobically by microbial action.

*Cultivation*- any agricultural action or practise used by growers to allow and improve the growing conditions of fresh fruits or vegetables grown in the field (with or without cover) or in protected facilities (hydroponic systems, greenhouses).

*Farm* - any premise or establishment in which fresh fruits and/or vegetables are grown and harvested and the surroundings under the control of the same management.

*Grower* - the person responsible for the management of the primary production of fresh fruits and vegetables.

*Harvester* - the person responsible for the management of the harvesting of fresh fruits and vegetables.

*Hazard* – a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

*Hazardous material* - any compound which, at specific levels, has the potential to cause adverse health effects.  
*Hydroponics* - a general term for the production of plants without soil in a water medium.

*Manure* - Animal excrement which may be mixed with litter or other material, and which may be fermented or otherwise treated.

*Microorganisms* -include yeasts, moulds, bacteria, viruses and parasites. When used as an adjective, the term "microbial" is used.

*Packer* - the person responsible for the management of post-harvest processing and packing of fresh fruits and vegetables.

*Packing* -the action of putting fresh fruits and vegetables in a package. This may take place in a field or in an establishment.

*Packing establishment* - any indoor establishment in which fresh fruits and vegetables receive post-harvest treatment and are packaged.

*Primary production* - those steps involved in the growing and harvesting of fresh fruits and vegetables such as planting, irrigation, application of fertilizers, application of agricultural chemicals, etc.

Types of Water:

*Clean water* - water that does not compromise food safety in the circumstances of its use.

*Potable water* - water which meets the quality standards of drinking water such as described in the WHO Guidelines for Drinking Water Quality.

### **3. PRIMARY PRODUCTION**

Fresh fruits and vegetables are grown and harvested under a wide range of climatic and diverse geographical conditions, using various agricultural inputs and technologies, and on farms of varying sizes. Biological, chemical and physical hazards may therefore vary significantly from one type of production to another. In each primary production area, it is necessary to consider the particular agricultural practices that promote the production of safe fresh fruits and vegetables, taking into account the conditions specific to the primary production area, type of products, and methods used. Procedures associated with primary production should be conducted under good hygienic conditions and should minimize potential hazards to health due to the contamination of fresh fruits and vegetables.

#### **3.1 ENVIRONMENTAL HYGIENE**

Where possible, potential sources of contamination from the environment should be identified. In particular, primary production should not be carried out in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in or on fresh fruits and vegetables after harvest.

Where possible, growers should evaluate the previous uses of the sites (indoor and outdoor) as well as adjoining sites in order to identify potential microbial, chemical and physical hazards. The potential for other types of contamination (e.g., from agricultural chemicals, hazardous wastes, etc.) should also be considered. The evaluation process should include the following:

- Previous and present usage of the primary production area and the adjoining sites (e.g. crop grown, feed lot, animal production, hazardous waste site, sewage treatment site, mining extraction site) to identify potential microbial hazards including faecal contamination and contamination by organic waste and potential environmental hazards that could be carried to the growing site.
- The access of farm and wild animals to the site and to water sources used in primary production to identify potential faecal contamination of the soils and water and the likelihood of contaminating crop. Existing practices should be reviewed to assess the prevalence and likelihood of uncontrolled deposits of animal faeces coming into contact with crops. Considering this potential source of contamination, efforts should be made to protect fresh produce growing areas from animals. As far as possible, domestic and wild animal should be excluded from the area.
- Potential for contaminating produce fields from leaking, leaching or overflowing manure storage sites and flooding from polluted surface waters.

If previous uses cannot be identified, or the examination of the growing or adjoining sites leads to the conclusion that potential hazards exist, the sites should be analysed for contaminants of concern. If the contaminants are at excessive levels and corrective or preventative actions have not been taken to minimize potential hazards, the sites should not be used until correction/control measures are applied.

## **3.2 HYGIENIC PRIMARY PRODUCTION OF FRESH FRUITS AND VEGETABLES**

### **3.2.1 Agricultural input requirements**

Agricultural inputs should not contain microbial or chemical contaminants (as defined under the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev 3 (1997) at levels that may adversely affect the safety of fresh fruits and vegetables and taking into consideration the WHO guidelines on the safe use of wastewater and excreta in agriculture and aquaculture as appropriate.

#### **3.2.1.1 Water for primary production**

- Growers should identify the sources of water used on the farm (municipality, re-used irrigation water, well, open canal, reservoir, rivers, lakes, farm ponds etc.). They should assess its microbial and chemical quality, and its suitability for intended use, and identify corrective actions to prevent or minimize contamination (e.g. from livestock, sewage treatment, human habitation).
- Where necessary, growers should have the water they use tested for microbial and chemical contaminants. The frequency of testing will depend on the water source and the risks of environmental contamination including intermittent or temporary contamination (e.g. heavy rain, flooding, etc.). If the water source is found to be contaminated corrective actions should be taken to ensure that the water is suitable for its intended use.

##### 3.2.1.1.1 Water for irrigation and harvesting

Water used for agricultural purposes should be of suitable quality for its intended use. Special attention to water quality should be considered for the following situations:

- Irrigation by water delivery techniques that expose the edible portion of fresh fruits and vegetables directly to water (e.g. sprayers ) especially close to harvest time.
- Irrigation of fruits and vegetables that have physical characteristics such as leaves and rough surfaces which can trap water.
- Irrigation of fruits and vegetables that will receive little or no post-harvest wash treatments prior to packing, such as field-packed produce.

##### 3.2.1.1.2 Water for fertilizers, pest control and other agricultural chemicals

Water used for the application of water-soluble fertilizers and agricultural chemicals in the field and indoors should not contain microbial contaminants at levels that may adversely affect the safety of fresh fruits and vegetables. Special attention to the water quality should be considered when using fertilizer and agricultural chemical delivery techniques (e.g. sprayers) that expose the edible portion of fresh fruits and vegetables directly to water especially close to harvest time.

##### 3.2.1.1.3 Hydroponic water

Plants grown in hydroponic systems absorb nutrients and water at varying rates, constantly changing the composition of the re-circulated nutrient solution. Because of this:

- Water used in hydroponic culture should be changed frequently, or if recycled, should be treated to minimize microbial and chemical contamination.
- Water delivery systems should be maintained and cleaned, as appropriate, to prevent microbial contamination of water.



### **3.2.1.2 Manure, biosolids and other natural fertilizers**

The use of manure, biosolids and other natural fertilizers in the production of fresh fruits and vegetables should be managed to limit the potential for microbial, chemical and physical contamination. Manure, biosolids and other natural fertilizers contaminated with heavy metals or other chemicals at levels that may affect the safety of fresh fruits and vegetables should not be used. Where necessary, in order to minimize microbial contamination the following practices should be considered:

- Adopt proper treatment procedures (e.g. composting, pasteurization, heat drying, UV irradiation, alkali digestion, sun drying or combinations of these) that are designed to reduce or eliminate pathogens in manure, biosolids and other natural fertilizers. The level of pathogen reduction achieved by different treatments should be taken into account when considering suitability for different applications.
- Manure, biosolids and other natural fertilizers which are untreated or partially treated may be used only if appropriate corrective actions are being adopted to reduce microbial contaminants such as maximizing the time between application and harvest of fresh fruits and vegetables.
- Growers who are purchasing manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants, should, where possible, obtain documentation from the supplier that identifies the origin, treatment used, tests performed and the results thereof.
- Minimize direct or indirect contact between manure, biosolids and other natural fertilizers, and fresh fruits and vegetables, especially close to harvest.
- Minimize contamination by manure, biosolids and other natural fertilizers from adjoining fields. If the potential for contamination from the adjoining fields is identified, preventative actions (e.g. care during application and run-off controls) should be implemented to minimize the risk.
- Avoid locating treatment or storage sites in proximity to fresh fruit and vegetable production areas. Prevent cross-contamination from runoff or leaching by securing areas where manure, biosolids and other natural fertilizers are treated and stored.

### **3.2.1.3 Soil**

Soils should be evaluated for hazards. If the evaluation concludes that such hazards are at levels that may compromise the safety of crops, control measures should be implemented to reduce hazards to acceptable levels. If this cannot be achieved by available control measures, growers should not use these soils for primary production.

### **3.2.1.4 Agricultural chemicals**

- Growers should use only agricultural chemicals which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose. Residues should not exceed levels as established by the Codex Alimentarius Commission.
- In order to minimize and contain the emergence of microbial resistance:
- the use of antimicrobial agents significant to human and animal therapy should be avoided.
- Antimicrobial agents not significant to human and animal therapy should be used only when unavoidable and in accordance with good agricultural practices and in a manner that achieves this objective.
- Agricultural workers who apply agricultural chemicals should be trained in proper application procedures.

- Growers should keep records of agricultural chemical applications. Records should include information on the date of application, the chemical used, the crop sprayed, the pest or disease against which it was used, the concentration, method and frequency of application, and records on harvesting to verify that the time between application and harvesting is appropriate.
- Agricultural chemical sprayers should be calibrated, as necessary, to control the accuracy of the rate of application.
- The mixing of agricultural chemicals should be carried out in such a way as to avoid contamination of water and land in the surrounding areas and to protect employees involved in this activity from potential hazards.
- Sprayers and mixing containers should be thoroughly washed after use, especially when used with different agricultural chemicals on different crops, to avoid contaminating fruits and vegetables.
- Agricultural chemicals should be kept in their original containers, labelled with the name of the chemical and the instructions for application. Agricultural chemicals should be stored in a safe, well ventilated place, away from production areas, living areas and harvested fruits or vegetables, and disposed of in a manner that does not pose a risk of contaminating crops, the inhabitants of the area, or the environment of the primary production.
- Empty containers should be disposed of as indicated by the manufacturer. They should not be used for other food-related purposes.

#### **3.2.1.5 Biological control**

Environmental and consumer safety should be considered when using competing biological organisms and/or their metabolites applied for the control of pests, mites, plant pathogens and spoilage organisms in fresh fruits and vegetables.

Growers should use only biological controls which are authorized for the cultivation of the specific fruit or vegetable and should use them according to the manufacturer's instructions for the intended purpose.

#### **3.2.2 Indoor facilities associated with growing and harvesting**

For operations where fresh fruits and vegetables are grown indoors (greenhouses, hydroponic culture, etc.) suitable premises should be used.

##### **3.2.2.1 Location, design and layout**

- Premises and structures should be located, designed and constructed to avoid contaminating fresh fruits and vegetables and harboring pests such as insects, rodents and birds.
- Where appropriate, the internal design and layout should permit compliance with good hygienic practices for the primary production of fresh fruits and vegetables indoors, including protection against cross-contamination between and during operations. Each establishment should be evaluated individually in order to identify specific hygienic requirements for each product.

##### **3.2.2.2 Water supply**

Where appropriate an adequate supply of potable or clean water with appropriate facilities for its storage and distribution should be available in indoor primary production facilities. Non-potable water should have a separate system. Non-potable water systems should be identified and should not connect with, or allow reflux into, potable water systems.

- Avoid contaminating potable and clean water supplies by exposure to agricultural inputs used for growing fresh produce.

- Clean and disinfect potable and clean water storage facilities on a regular basis.
- Control the quality of the water supply.

### **3.2.2.3 Drainage and waste disposal**

Adequate drainage and waste disposal systems and facilities should be provided. These systems should be designed and constructed so that the potential for contamination of fresh fruits and vegetables, agricultural inputs or the potable water supply is avoided.

### **3.2.3 Personnel health, hygiene and sanitary facilities**

Hygiene and health requirements should be followed to ensure that personnel who come directly or indirectly into contact with fresh fruits and vegetables during or after harvesting are not likely to contaminate them. Visitors should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

#### **3.2.3.1 Personnel hygiene and sanitary facilities**

Hygienic and sanitary facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained. As far as possible, such facilities should:

- Be located in close proximity to the fields and indoor premises, and in sufficient number to accommodate personnel.
- Be of appropriate design to ensure hygienic removal of wastes and avoid contamination of growing sites, fresh fruits and vegetables or agricultural inputs.
- Have adequate means of hygienically washing and drying hands.
- Be maintained under sanitary conditions and good repair.

#### **3.2.3.2 Health status**

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through fresh fruits and vegetables, should not be allowed to enter any food handling area if there is a likelihood of their contaminating fresh fruits and vegetables. Any person so affected should immediately report illness or symptoms of illness to the management.

#### **3.2.3.3 Personal cleanliness**

Agricultural workers who have direct contact with fresh fruits and vegetables should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing and footwear. Cuts and wounds should be covered by suitable waterproof dressings when personnel are permitted to continue working.

Personnel should wash their hands when handling fresh fruits and vegetables or other material that comes in contact with them. Personnel should wash their hands before starting work involving the handling of fruits and vegetables, each time they return to handling areas after a break, immediately after using the toilet or after handling any contaminated material where this could result in contamination of fresh fruits and vegetables.

#### **3.2.3.4 Personal behaviour**

Agricultural workers should refrain from behaviour which could result in the contamination of food, for example: smoking, spitting, chewing gum or eating, or sneezing or coughing over unprotected fresh fruits and vegetables.

Personal effects such as jewellery, watches, or other items should not be worn or brought into fresh fruit and vegetable production areas if they pose a threat to the safety and suitability of the food.

### **3.2.4 Equipment associated with growing and harvesting**

As required, growers and harvesters should follow the technical specifications recommended by the equipment manufacturers for their proper usage and maintenance. Growers and harvesters should adopt the following sanitary practices:

- Equipment and containers coming into contact with fresh fruits and vegetables should be made of materials that are non-toxic. They should be designed and constructed to ensure that, when necessary, they can be cleaned, disinfected and maintained to avoid the contamination of fresh fruit and vegetables. Specific hygienic and maintenance requirements should be identified for each piece of equipment that is used and the type of fruit or vegetable associated with it.
- Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Where appropriate, such containers should be lockable to prevent malicious or accidental contamination of fresh fruits and vegetables or agricultural inputs. Such containers should be segregated or otherwise identified to prevent their use as harvesting containers.
- Containers that can no longer be kept in a hygienic condition should be discarded.
- Equipment and tools should function according to the use for which they are designed without damaging the produce. Such equipment should be maintained in good order.

## **3.3 HANDLING, STORAGE AND TRANSPORT**

### **3.3.1 Prevention of cross-contamination**

During the primary production and post-harvest activities, effective measures should be taken to prevent cross-contamination of fresh fruits and vegetables from agricultural inputs or personnel who come directly or indirectly into contact with fresh fruits and vegetables. To prevent the potential of cross-contaminating fresh fruits and vegetables, growers, harvesters and their employees should adhere to the recommendations presented elsewhere in section 3 of this code and the following:

- At the time of harvest, consideration should be given to the need for additional management action where any local factor, for example adverse weather conditions, may increase the opportunity for contamination of the crop.
- Fresh fruits and vegetables unfit for human consumption should be segregated during harvesting. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.
- Agricultural workers should not use harvesting containers for carrying materials (e.g. lunches, tools, fuel, etc.) other than harvested fruits and vegetables.
- Equipment and containers previously used for potentially hazardous materials (e.g. garbage, manure, etc.) should not be used for holding fresh fruits or vegetables or have contact with packaging material that is used for fresh fruits and vegetables without adequate cleaning and disinfecting.
- Care must be taken when packing fresh fruits and vegetables in the field to avoid contaminating containers or bins by exposure to , manure or animal/human faeces.

### **3.3.2 Storage and transport from the field to the packing facility**

Fresh fruits and vegetables should be stored and transported under conditions which will minimize the potential for microbial, chemical or physical contamination. The following practices should be adopted:

- Storage facilities and vehicles for transporting the harvested crops should be built in a manner to minimize damage to fresh fruits and vegetables and to avoid access by pests. They should be made of non-toxic materials that permit easy and thorough cleaning. They should be constructed in a manner to reduce the opportunity for potential contamination from physical objects such as glass, wood, plastic, etc.
- Fresh fruits and vegetables unfit for human consumption should be segregated before storage or transport. Those which cannot be made safe by further processing should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.
- Agricultural workers should remove as much soil as possible from fresh fruits and vegetables before they are stored or transported. Care should be taken to minimize physical damage to crop during this process.
- Transport vehicles should not be used for the transport of hazardous substances unless they are adequately cleaned, and where necessary disinfected, to avoid cross-contamination.

### **3.4 CLEANING, MAINTENANCE AND SANITATION**

Premises and harvesting equipment should be kept in an appropriate state of repair and condition to facilitate cleaning and disinfection. Equipment should function as intended to prevent contamination of fresh fruits and vegetables. Cleaning materials and hazardous substances such as agricultural chemicals should be specifically identifiable and kept or stored separately in secure storage facilities. Cleaning materials and agricultural chemicals should be used according to manufacturer's instructions for their intended purpose.

#### **3.4.1 Cleaning programs**

Cleaning and disinfection programs should be in place to ensure that any necessary cleaning and maintenance is carried out effectively and appropriately. Cleaning and disinfection systems should be monitored for effectiveness and should be regularly reviewed and adapted to reflect changing circumstances. Specific recommendations are as follows:

- Harvesting equipment and re-usable containers that come in contact with fresh fruits and vegetables should be cleaned, and, where appropriate, disinfected on a regular basis.
- Harvesting equipment and re-usable containers used for fresh fruits and vegetables that are not washed prior to packing should be cleaned and disinfected as necessary.

#### **3.4.2 Cleaning procedures and methods**

The appropriate cleaning methods and materials will depend on the type of equipment and the nature of the fruit or vegetable. The following procedure should be adopted:

- Cleaning procedures should include the removal of debris from equipment surfaces, application of a detergent solution, rinsing with water, and, where appropriate, disinfection.

#### **3.4.3 Pest control systems**

When primary production is carried out in indoor establishments (e.g. greenhouses), the recommendations of the *General Principles of Food Hygiene*, section 6.3 should be followed with respect to pest control.

### **3.4.4 Waste management**

Suitable provision must be made for the storage and removal of waste. Waste must not be allowed to accumulate in fresh fruit and vegetable handling and storage areas or the adjoining environment. Storage areas for waste should be kept clean.

## **4. PACKING ESTABLISHMENT: DESIGN AND FACILITIES**

Refer to the General Principles of Food Hygiene.

## **5. CONTROL OF OPERATION**

### **5.1 CONTROL OF FOOD HAZARDS**

Refer to the General Principles of Food Hygiene.

### **5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS**

#### **5.2.1 Time and temperature control**

Refer to the General Principles of Food Hygiene.

#### **5.2.2 Specific process steps**

##### **5.2.2.1 *Post-harvest water use***

Water quality management will vary throughout all operations. Packers should follow GMPs to prevent or minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should be dependent on the stage of the operation. For example, clean water could be used for initial washing stages, whereas water used for final rinses should be of potable quality.

- Post-harvest systems that use water should be designed in a manner to minimize places where product lodges and dirt builds up.
- Antimicrobial agents should only be used where absolutely necessary to minimize cross-contamination during post-harvest and where their use is in line with good hygienic practices. The antimicrobial agents levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.
- Where appropriate, the temperature of the post-harvest water should be controlled and monitored.
- Recycled water should be treated and maintained in conditions that do not constitute a risk to the safety of fresh fruits and vegetables. The treatment process should be effectively monitored and controlled.
- Recycled water may be used with no further treatment provided its use does not constitute a risk to the safety of fresh fruits and vegetables (e.g. use of water recovered from the final wash for the first wash).
- Ice should be made from potable water. Ice should be produced, handled and stored to protect it from contamination.

### **5.2.2.2 Chemical treatments**

- Packers should only use chemicals for post-harvest treatments (e.g. waxes, fungicides) in accordance with the General Standards on Food Additives or with the Codex Pesticide Guidelines. These treatments should be carried out in accordance with the manufacturer's instructions for the intended purpose.
- Sprayers for post-harvest treatments should be calibrated regularly to control the accuracy of the rate of application. They should be thoroughly washed in safe areas when used with different chemicals and on different fruits or vegetables to avoid contaminating the produce.

### **5.2.2.3 Cooling of fresh fruits and vegetables**

- Condensate and defrost water from evaporator type cooling systems (e.g. vacuum cooling, cold rooms) should not drip onto fresh fruits and vegetables. The inside of the cooling systems should be maintained clean.
- Potable water should be used in cooling systems where water or ice is in direct contact with fresh fruits and vegetables (e.g. hydro cooling, ice cooling). The water quality in these systems should be controlled and maintained.
- Forced-air cooling is the use of rapid movement of refrigerated air over fresh fruits and vegetables in cold rooms. Air cooling systems should be appropriately designed and maintained to avoid contaminating fresh produce.

### **5.2.2.4 Cold storage**

- When appropriate, fresh fruits and vegetables should be maintained at low temperatures after cooling to minimize microbial growth. The temperature of the cold storage should be controlled and monitored.
- Condensate and defrost water from the cooling system in cold storage areas should not drip on to fresh fruits and vegetables. The inside of the cooling systems should be maintained in a clean and sanitary condition.

## **5.2.3 Microbiological and other specifications**

Refer to the General Principles of Food Hygiene.

## **5.2.4 Microbial cross-contamination**

Refer to the General Principles of Food Hygiene.

## **5.2.5 Physical and chemical contamination**

Refer to the General Principles of Food Hygiene.

## **5.3 INCOMING MATERIAL REQUIREMENTS**

Refer to the General Principles of Food Hygiene.

## **5.4 PACKING**

Refer to the General Principles of Food Hygiene.

## **5.5 WATER USED IN THE PACKING ESTABLISHMENT**

Refer to the General Principles of Food Hygiene.

## **5.6 MANAGEMENT AND SUPERVISION**

Refer to the General Principles of Food Hygiene.

## **5.7 DOCUMENTATION AND RECORDS**

Where appropriate, records of processing, production and distribution should be kept long enough to facilitate a recall and food borne illness investigation, if required. This period could be much longer than the shelf life of fresh fruits and vegetables. Documentation can enhance the credibility and effectiveness of the food safety control system.

- Growers should keep current all relevant information on agricultural activities such as the site of production, suppliers' information on agricultural inputs, lot numbers of agricultural inputs, irrigation practices, use of agricultural chemicals, water quality data, pest control and cleaning schedules for indoor establishments, premises, facilities, equipment and containers.
- Packers should keep current all information concerning each lot such as information on incoming materials (e.g. information from growers, lot numbers), data on the quality of processing water, pest control programmes, cooling and storage temperatures, chemicals used in post-harvest treatments, and cleaning schedules for premises, facilities, equipment and containers, etc.

## **5.8 RECALL PROCEDURES**

Refer to the General Principles of Food Hygiene.

In addition, where appropriate:

- Growers and packers should have programs to ensure effective lot identification. These programs should be able to trace the sites and agricultural inputs involved in primary production and the origin of incoming material at the packing establishment in case of suspected contamination.
- Growers information should be linked with packers' information so that the system can trace products from the distributor to the field. Information that should be included are the date of harvest, farm identification, and, where possible, the persons who handled the fresh fruits or vegetables from the primary production site to the packing establishment.

## **6. PACKING ESTABLISHMENT: MAINTENANCE AND SANITATION**

Refer to the General principles of Food Hygiene.

## **7. PACKING ESTABLISHMENT: PERSONAL HYGIENE**

Refer to the General Principles of Food Hygiene.

## **8. TRANSPORTATION**

Refer to the General Principles of Food Hygiene and to the Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food.

## **9. PRODUCT INFORMATION AND CONSUMER AWARENESS**

Refer to the General Principles of Food Hygiene.



## **10. TRAINING**

Refer to the General Principles of Food Hygiene except for section 10.1 and 10.2.

### **10.1 AWARENESS AND RESPONSIBILITIES**

Personnel associated with growing and harvesting should be aware of GAPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Agricultural workers should have the necessary knowledge and skills to enable them to carry out agricultural activities and to handle fresh fruits and vegetables and agricultural inputs hygienically.

Personnel associated with packing should be aware of GMPs, good hygienic practices and their role and responsibility in protecting fresh fruits and vegetables from contamination or deterioration. Packers should have the necessary knowledge and skills to enable them to perform packing operations and to handle fresh fruits and vegetables in a way that minimizes the potential for microbial, chemical, or physical contamination.

All personnel who handle cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques. They should be aware of their role and responsibility in protecting fresh fruit and vegetables from contamination during cleaning and maintenance.

### **10.2 TRAINING PROGRAMMES**

Factors to take into account in assessing the level of training required in growing, harvesting and packing activities include:

- The nature of the fruit or vegetable, in particular its ability to sustain growth of pathogenic microorganisms.
- The agricultural techniques and the agricultural inputs used in the primary production including the probability of microbial, chemical and physical contamination.
- The task the employee is likely to perform and the hazards and controls associated with those tasks.
- The manner in which fresh fruits and vegetables are processed and packaged including the probability of contamination or microbial growth.
- The conditions under which fresh fruits and vegetables will be stored.
- The extent and nature of processing or further preparation by the consumer before final consumption.

Topics to be considered for training programmes include, but are not limited to, the following:

- The importance of good health and hygiene for personal health and food safety.
- The importance of hand washing for food safety and the importance of proper hand washing techniques.
- The importance of using sanitary facilities to reduce the potential for contaminating fields, produce, other workers, and water supplies.
- Techniques for hygienic handling and storage of fresh fruits and vegetables by transporters, distributors, storage handlers and consumer.

## ANNEX I

## ANNEX FOR READY-TO-EAT FRESH PRE-CUT FRUITS AND VEGETABLES

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## INTRODUCTION

The health benefits associated with fresh fruits and vegetables combined with the on-going consumer interest in the availability of a variety of ready-to-eat foods have contributed to a substantial increase in the popularity of pre-cut fruits and vegetables. Because of the increased convenience and consumption of pre-cut fruits and vegetables in and away from the home, the preparation of these products has moved from the point of consumption to the food processor or retailer. The processing of fresh produce without proper sanitation procedures in place in the manufacturing environment may enhance the potential for contamination by microbiological pathogens. The potential for pathogens to survive or grow may be enhanced by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process to eliminate them, and the potential for temperature abuse during processing, storage, transport, and retail display.

Some of the microbiological pathogens associated with fresh fruits and vegetables include *Salmonella* spp., *Shigella* spp., pathogenic strains of *Escherichia coli*, *Listeria monocytogenes*, Norwalk-like virus and hepatitis A virus and parasites such as Cyclospora. Some of these pathogens are associated with the agricultural environment, whereas others are associated with infected workers or contaminated water.

Because of the ability for pathogens to survive and grow on fresh produce, it is important for the pre-cut industry to follow good hygienic practices to ensure the microbiological safety of its products.

## **1. OBJECTIVE**

Hygienic recommendations for the primary production of fresh fruits and vegetables are covered under the *Code of Practice for Fresh Fruits and Vegetables*. This Annex recommends the application of Good Manufacturing Practices (GMPs) for all stages involved in the production of ready-to-eat fresh pre-cut fruits and vegetables, from receipt of raw materials to distribution of finished products.

The primary objective of this Annex is to identify GMPs that will help control microbiological, physical, and chemical hazards associated with the processing of fresh pre-cut fruits and vegetables. Particular attention is given to minimizing microbiological hazards. This Annex provides elements that should be taken into account in the production, processing and distribution of these foods.

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

### **2.1 SCOPE**

This Annex specifically applies to ready-to-eat fresh fruit and vegetables that have been peeled, cut or otherwise physically altered from their original form but remain in the fresh state and particularly those that are intended to be consumed raw. This Annex applies irrespective of where the operations take place (e.g. in the field, at the farm, at the retailer, at the wholesaler, at the processing establishment, etc.).

For some establishments that process fresh pre-cut fruit and vegetables, this Annex will cover all operations from receipt of raw material to the distribution of the final product. For other establishments, (e.g. those that use ready-to-eat pre-cut fresh fruit and vegetables in combination with other products, such as sauces, meat, cheese, etc.) only the specific sections that relate to the processing of the fresh pre-cut fruit and vegetable components will apply.

This Annex does not directly apply to fresh fruit and vegetables that have been trimmed leaving the food intact. Nor does it apply to other fresh fruit and vegetables that are pre-cut but are destined for further processing that would be expected to eliminate any pathogen that may be present (e.g. cooking, juice processing, fermentation) nor to fresh fruit or vegetable juices. However, some of the basic principles of the Annex could still be applicable to such products.

Packaging includes single serving containers (e.g., sealed pouches or plastic trays), larger consumer or institutional size packages and bulk containers. This Annex concentrates on microbial hazards and addresses physical and chemical hazards only in so far as these relate to GMPs.

### **2.2 USE**

This document follows the format of the Recommended International Code of Practice -- General Principles of Food Hygiene CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruits and Vegetables.

### **2.3 DEFINITIONS**

*Processor* - the person responsible for the management of the activities associated with the production of ready-to-eat fresh pre-cut fruits and vegetables.

## **3. PRIMARY PRODUCTION**

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

## **4. ESTABLISHMENT: DESIGN AND FACILITIES**

Refer to the *General Principles of Food Hygiene*. In addition:

## 4.4 FACILITIES

### 4.4.2 Drainage and Waste Disposal

The processing of products covered by this Annex generates a large quantity of waste that can serve as food and shelter for pests. It is therefore very important to plan an effective waste disposal system. This system should always be maintained in good condition so it does not become a source of product contamination.

## 5. CONTROL OF OPERATIONS

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

### 5.1 CONTROL OF FOOD HAZARDS

For the products covered by this Annex it should be recognised that while processing may reduce the level of contamination initially present on the raw materials, it will not be able to guarantee elimination of such contamination. Consequently, the processor should ensure that steps are taken by their suppliers (growers, harvesters, packers and distributors) to minimise contamination of the raw materials during primary production. It is recommended that processors ensure that their suppliers have adopted the principles outlined in the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

There are certain pathogens, *Listeria monocytogenes* and *Clostridium botulinum*, which present specific concern in relation to ready to eat fresh pre-cut vegetables packaged in a modified atmosphere. Processors should ensure that they have addressed all relevant safety issues relating to the use of such packaging.

### 5.2 KEY ASPECTS OF CONTROL SYSTEMS

#### 5.2.2 Specific Process Steps

##### 5.2.2.1 Receipt and inspection of raw materials

During unloading of raw material, verify the cleanliness of the food transportation unit and raw materials for evidence of contamination and deterioration

##### 5.2.2.2 Preparation of raw material before processing

Physical hazards (such as the presence of animal and plant debris, metal, and other foreign material) should be removed through manual sorting or the use of detectors, such as metal detectors. Raw materials should be trimmed to remove any damaged, rotten or mouldy material.

##### 5.2.2.3 Washing and microbiological decontamination

Refer to section 5.2.2.1 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

- Water used for final rinses should be of potable quality, particularly for these products as they are not likely to be washed before consumption.

##### 5.2.2.4 Pre-cooling Fresh Fruits and Vegetables

Refer to section 5.2.2.3 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

##### 5.2.2.5 Cutting, slicing, shredding, and similar pre-cut processes

Procedures should be in place to minimize contamination with physical (e.g. metal) and microbiological contaminants during cutting, slicing, shredding or similar pre-cut processes.

##### 5.2.2.6 Washing after cutting, slicing, shredding, and similar pre-cut processes

Washing cut produce with potable water may reduce microbiological contamination. In addition, it removes some of the cellular fluids that were released during the cutting process thereby reducing the level of available nutrients for microbiological growth. The following should be considered:

- Water should be replaced at sufficient frequency to prevent the build-up of organic material and prevent cross-contamination.
- Antimicrobial agents should be used, where necessary, to minimize cross-contamination during washing and where their use is in line with good hygienic practices. The antimicrobial agents levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of antimicrobial agents, followed by a wash as necessary, should be done to ensure that chemical residues do not exceed levels as recommended by the Codex Alimentarius Commission.
- Drying or draining to remove water after washing is important to minimize microbiological growth.

#### 5.2.2.7 Cold Storage

Refer to section 5.2.2.4 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

- Pre-cut fresh fruits and vegetables should be maintained at low temperatures at all stages, from cutting through distribution to minimise microbiological growth.

### 5.7 DOCUMENTATION AND RECORDS

Where appropriate, records should be maintained to adequately reflect product information, such as product formulations or specifications and operational controls. Maintaining adequate documentation and records of processing operations is important in the event of recall of with fresh pre-cut fruits and vegetables. Records should be kept long enough to facilitate recalls and foodborne illness investigations, if required. This period will likely be much longer than the shelf life of the product. Some examples of records to keep are the following:

- Fresh fruit and vegetable supplier records
- Water quality and supply records
- Equipment monitoring and maintenance records
- Equipment calibration records
- Sanitation records
- Product processing records
- Pest control records
- Distribution records

### 5.8 RECALL PROCEDURES

Refer to the *General Principles of Food Hygiene*.

## 6. ESTABLISHMENT: MAINTENANCE AND SANITATION

Refer to the *General Principles of Food Hygiene*.

## 7. ESTABLISHMENT: PERSONAL HYGIENE

Refer to the *General Principles of Food Hygiene*.

## 8. TRANSPORTATION

Refer to the *General Principles of Food Hygiene* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

## 9. PRODUCT INFORMATION AND CONSUMER AWARENESS

Refer to the *General Principles of Food Hygiene*.

## **10. TRAINING**

Refer to the *General Principles of Food Hygiene* and the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

### **10.2 TRAINING PROGRAMS**

To evaluate the level of training required of persons responsible for the production of fresh pre-cut fruits and vegetables, the additional following factors should be taken into account:

- the packaging systems used for fresh pre-cut fruits and vegetables, including the risks of contamination or microbiological growth involved in this method;
- the importance of temperature control and GMPs.

**Annex for Sprout Production****Content**

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## INTRODUCTION

In recent years the popularity of sprouted seeds has increased dramatically and are favoured by many for their nutritional value. However, the recent increase in reports of food borne illness associated with raw sprouts has raised concerns from public health agencies and consumers about the safety of these products.

The microbial pathogens associated with sprouted seeds are for example *Salmonella* spp, pathogenic *E. coli*, *Listeria monocytogenes*, and *Shigella* spp. Outbreak investigations have indicated that microorganisms found on sprouts most likely originate from the seeds. Most seeds supplied to sprout producers are produced primarily for forage or animal grazing where the Good Agricultural Practices (GAPs) necessary to prevent microbial contamination of seeds intended for sprouting are not followed, especially through the misuse of natural fertilizers or contaminated irrigation water. As a result, the seeds may be contaminated in the field or during harvesting, storage or transportation. Typically, the germination process in sprout production involves keeping seeds warm and moist for two to ten days. In these conditions, if low levels of microbial contaminants are present on seeds, they can quickly reach levels high enough to cause illness.

The scientific literature proposes microbiological decontamination of seeds treatments which can achieve different levels of pathogen reduction. There is currently no treatment available that can guarantee pathogen free seeds. Research is in progress to find efficient microbiological decontamination treatments which would provide sufficient pathogen reduction on seeds especially if pathogens are internalized.

### 1. OBJECTIVES

This annex recommends control measures to occur in two areas: during seed production and during sprout production. During seed production, conditioning and storage, the application of Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs) are aimed at preventing microbial pathogen contamination of seeds. During sprout production, the microbiological decontamination of seeds step is aimed at reducing potential contaminants and the good hygienic practices at preventing the introduction of microbial pathogens and minimizing their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.

### 2. SCOPE, USE AND DEFINITION

#### 2.1 SCOPE

This annex covers the hygienic practices that are specific for the primary production of seeds for sprouting and the production of sprouts for human consumption in order to produce a safe and wholesome product.

#### 2.2 USE

This annex follows the format of the Recommended International Code of Practice – General Principles of Food Hygiene CAC/RCP 1-1969, Rev 3 (1997) and should be used in conjunction with the General Principles of Food Hygiene and the Code of Hygienic Practice for Fresh Fruit and Vegetables.

#### 2.3 DEFINITIONS

*Seed producer* - any person responsible for the management of activities associated with the primary production of seeds including post-harvest practices.

*Seed distributor* - any person responsible for the distribution of seeds (handling, storage and transportation) to sprout producers. Seed distributors may deal with single or multiple seed producers and can be producers themselves.



*Sprout producer* - any person responsible for the management of the activities associated with the production of sprouted seeds.

*Spent irrigation water* - water that has been in contact with sprouts during the sprouting process.

### **3. PRIMARY PRODUCTION OF SEEDS**

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

#### **3.2 HYGIENIC PRODUCTION OF SEEDS**

##### **3.2.1.2 Manure and biosolids**

When seeds are destined for the production of sprouts for human consumption, wild or domestic animals should not be allowed to graze in the fields where seeds are grown (e.g., employing sheep for spring clip back of alfalfa).

It is particularly important to prevent microbial contamination during the production of seeds which will be used to produce sprouts for human consumption because of the potential for pathogens to grow during the sprouting process. Consequently, manure, biosolids and other natural fertilizers should only be used when they have undergone treatments which achieve a high level of pathogen reduction.

##### **3.2.1.4 Agricultural chemicals**

Seed producers should only use chemicals (e.g., pesticides, desiccants) which are acceptable for seeds intended for the production of sprouts for human consumption .

##### **3.2.4 EQUIPMENT ASSOCIATED WITH GROWING AND HARVESTING**

Prior to harvest, harvesting equipment should be adjusted to minimize soil intake and seed damage and should be cleaned from any debris or earth. Diseased or damaged seeds, which could be susceptible to microbial contamination, should not be used for the production of sprouts for human consumption.

### **3.3 HANDLING, STORAGE AND TRANSPORT**

Seeds produced for the production of sprouts for human consumption should be segregated from product to be seeded or planted for animal feed (e.g., for forage or animal grazing) and clearly labelled.

Recognising that seeds are vulnerable to microbial pathogens during thrashing and drying, adequate care is needed to maintain sanitation in drying yards, and exposure of seeds to mist, high humidity and fog should be avoided.

### **3.4 ANALYSES**

Seed producers, distributors, and sprout producers should test lots of seeds for microbial pathogens using internationally accepted analytical methods. Sprouting seeds before testing increases the possibility of finding pathogens that may be present. If lots of seeds are found to be contaminated, they should not be sold or used for the production of sprouts for human consumption. Because of the limitations associated with sampling methods and analytical tests, failure to find contamination does not guarantee that the seeds are pathogen free. However, if contamination is found at this stage, it allows seeds to be diverted or destroyed before entering sprout production for human consumption. Seed producers, distributors and sprout producers should refer to the *Principles for the Establishment and Application of Microbiological Criteria for Foods*, CAC/GL 21-1977, for guidance on establishing a sampling plan.

### **3.5 RECALL PROCEDURES**

Seed producers for the production of sprouts for human consumption should ensure that records and recall procedures are in place to effectively respond to health risk situations. Procedures should enable the complete and rapid recall of any implicated seed. The procedures should also assist in providing

detailed information for the identification and investigation of any contaminated seeds and sprouts. The following should be adopted:

- Seed production and distribution practices should be in place to minimize the quantity of seed identified as a single lot and avoid the mixing of multiple lots that would complicate recalls and provide greater opportunity for cross-contamination. Seed producers and distributors and sprout producers should maintain records for each lot. The lot number, producer and country of origin should be indicated on each container.
- Seed producers should have a system to: effectively identify lots, trace the production sites and agricultural inputs associated with the lots, and allow physical retrieval of the seeds in case of a suspected hazard.
- Where a lot has been recalled because of a health hazard, other lots that were produced under similar conditions (e.g., on the same production sites or with the same agricultural inputs) and which may present a similar hazard should be evaluated for safety. Any lot presenting a similar risk should be recalled. Blends containing potentially contaminated seeds must also be recalled.
- Seeds which may present a hazard must be held and detained until they are disposed of properly.

#### **4. ESTABLISHMENT FOR SPROUT PRODUCTION**

Refer to the General Principles of Food Hygiene. In addition:

##### **4.2.1 DESIGN AND LAYOUT**

Where appropriate, the internal design and layout of sprout establishments should permit Good Hygiene Practices, including protection against cross-contamination between and during operations. Storage, seed rinsing and microbiological decontamination, germination and packaging areas should be physically separated from each other.

#### **5. CONTROL OF OPERATION**

Refer to the General Principles of Food Hygiene. In addition:

##### **5.2.2 SPECIFIC PROCESS STEPS IN SPROUT PRODUCTION**

###### **5.2.2.1 *Water use during sprout production***

Water quality management will vary throughout all operations. Sprout producers should follow GMPs to minimize the potential for the introduction or spread of pathogens in processing water. The quality of water used should be dependent on the stage of the operation. Because of the potential for pathogen proliferation during the sprouting process, clean water could be used for initial washing stages, whereas water used later in the sprout production process (i.e., for the rinse following the microbiological decontamination of seed, and subsequent operations) should be preferably of potable quality or at least clean water.

###### **5.2.2.2 *Initial rinse***

The seeds should be rinsed thoroughly before the microbiological decontamination treatment to remove dirt and increase the efficiency of this treatment.

- Seeds should be rinsed and thoroughly agitated in large volumes of clean water, in such a way to maximize surface contact. The process should be repeated until most of the dirt is removed and rinse water remains clear.

### **5.2.2.3 Microbiological decontamination of seeds**

Due to the difficulty of obtaining seeds which can be guaranteed as pathogen free, it is recommended that seeds be treated prior to the sprouting process. Although there are other options like the use of lactic acid bacteria, liquid microbiological decontamination treatment is generally used. During this treatment sprout producers should adhere to the following:

- All containers used for microbiological decontamination of seeds should be cleaned and disinfected prior to use.
- Seeds should be well agitated in large volumes of antimicrobial agent to maximise surface contact.
- The duration of treatment and the concentration of antimicrobial agent used should be accurately measured and recorded.
- Strict measures should be in place to prevent re-contamination of seeds after the microbiological decontamination treatment.
- Antimicrobial agent should be used according to manufacturer's instructions for their intended use.

### **5.2.2.4 Rinse after seed treatment**

As appropriate, seeds should be thoroughly rinsed after the microbiological decontamination treatment with potable water or at least clean water. Rinsing should be repeated sufficiently to eliminate antimicrobial agent.

### **5.2.2.5 Pre-germination soak**

Soaking is often necessary to improve germination. When soaking, the sprout producer should adhere to the following:

- All containers used for soaking should be cleaned and disinfected prior to use.
- Seeds should be soaked in cleaned water for the shortest possible time to minimize microbial growth.
- This step may also employ antimicrobial agents.
- After soaking, seeds should be rinsed thoroughly with potable water or at least clean water.

### **5.2.2.6 Germination**

During germination, keep the environment and equipment clean to avoid potential contamination. All equipment should be cleaned and disinfected before each new batch.

- Only potable water should be used.
- Where necessary and when used, soils or other matrices should be treated (e.g., pasteurized) to achieve a high degree of microbial reduction.

### **5.2.2.7 Harvesting**

All equipment should be cleaned and disinfected before each new batch. Harvesting should be done with cleaned and disinfected tools dedicated for this use.

### **5.2.2.8 Final rinse and cooling**

A final water rinse will remove hulls, cool product, and may reduce microbial contamination on sprouts. The following should be adopted:

- As appropriate, sprouts should be rinsed in cold potable water to lower sprout temperature and slow down microbial growth.
- Water should be changed, as needed (e.g., between batches), to prevent cross-contamination.

- Sprouts should be drained using appropriate equipment ( e.g. food grade centrifugal dryer) that is clean and disinfected prior to use.
- If additional cooling time is necessary, steps should be taken to facilitate rapid cooling (e.g., placed in smaller containers with adequate air flow between containers).

#### **5.2.2.9 Storage of finished product**

- Where appropriate, sprouts should be kept under cold temperature (e.g. 5<sup>0</sup>C) that will minimize microbial growth for the intended shelf life of the product. Regular and effective monitoring of temperature of storage areas and transport vehicles should be carried out.

### **5.2.3 MICROBIOLOGICAL AND OTHER SPECIFICATIONS**

It is recommended that seed and sprouts or spent irrigation water be tested for the presence of pathogens.

#### **5.2.3.1 Testing of seed lots before entering production**

It is recommended that each new lot of seeds received at the sprouting facility is tested before entering production (i.e. before the microbiological decontamination of seeds ).

- The seed sample selected for testing should be sprouted prior to analysis to increase the potential to detect pathogens if present. Analysis may be performed on the sprouted seeds or the water used to sprout the sample.
- Seed samples for microbial analysis should not be subject to any microbiological decontamination treatment at the sprouting facility.

#### **5.2.3.2 Testing of sprouts and/or spent irrigation water**

Current seed treatments cannot guarantee total elimination of pathogens. Further, if even a few pathogens survive the microbiological decontamination treatment, they can grow to high numbers during sprouting. Therefore, producers should have in place a sampling/testing plan to regularly monitor for pathogens at one or more stages after the start of germination.

- Analyses can be performed during the germination process (e.g., spent irrigation water or sprouts) and/or finished product may be analysed after harvest.
- Testing spent irrigation water is a good indicator of microbial conditions of sprouts. It is homogeneous and is simpler to analyse. Further, sampling spent irrigation water (or sprouts) during germination allows earlier results compared to testing finished product.
- Because of the sporadic nature of seed contamination, it is recommended that producers test every production lot.

### **5.2.4 MICROBIOLOGICAL CROSS-CONTAMINATION**

Sprout producers should adhere to the following:

- The traffic pattern of employees should prevent cross-contamination of sprouts. For example: the employees should avoid going back and forth to various areas of production. The employees should not go from a potentially contaminated area to the germination and/or packaging area unless they have washed their hands and changed to clean protective clothing.

## **5.3 INCOMING MATERIAL REQUIREMENTS**

### **5.3.1 SPECIFICATIONS FOR INCOMING SEEDS**

- Sprout producers should recommend that seed producers adopt good agricultural practices and provide evidence that the product was grown according to section 3 of this Annex and the *Code of Hygienic Practice for Fresh Fruits and Vegetables*.

- Seed and sprout producers should obtain assurance from seed producers or distributors that chemical residues of each incoming lot are within the limits established by the Codex Alimentarius Commission and, where appropriate, they should obtain certificates of analysis for microbial pathogens of concern.

### **5.3.2 CONTROL OF INCOMING SEEDS**

Seed containers should be examined at their arrival to minimize the potential for introducing obvious contaminants in the establishment.

- Seed containers should be examined for physical damage (e.g., holes from rodents) and signs of contamination (e.g., stains, rodent, insects, faeces, urine, foreign material, etc.). If found to be damaged, contaminated or potentially contaminated, its contents should not be used for the production of sprouts for human consumption.
- If seed lots are analysed for the presence of microbial pathogens of concern, these should not be used until results of analysis are available.

### **5.3.3 SEED STORAGE**

Seeds should be handled and stored in a manner that will prevent damage and contamination.

- Seeds should be stored off the floor, away from walls and in proper storage conditions to prevent mould and bacterial growth and facilitate pest control inspection.
- Open containers should be stored in such a way that they are protected from pests and other sources of contamination.

## **5.7 DOCUMENTATION AND RECORDS**

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

Written records that accurately reflect product information and operational controls should be available to demonstrate the adequacy of the production activities.

- Upon receipt of seeds, records should be maintained of the seed supplier, the lot number and the country of origin to facilitate recall procedures.
- Records should be legible, permanent and accurate. Records should include written procedures, controls, limits, monitoring results and subsequent follow-up documents. Records must include: seed sources and lot numbers, water analysis results, sanitation checks, pest control monitoring, sprout lot codes, analysis results, production volumes, storage temperature monitoring, product distribution and consumer complaints.
- Records should be kept long enough to facilitate recalls and food borne illness investigation, if required. This period will likely be much longer than the shelf life of the product.

## **6. ESTABLISHMENT: MAINTENANCE AND SANITATION**

Refer to the *General Principles of Food Hygiene*.

## **7. ESTABLISHMENT: PERSONAL HYGIENE**

Refer to the *General Principles of Food Hygiene*.

## **8. TRANSPORTATION**

Refer to the *General Principles of Food Hygiene*.

## **9. PRODUCT INFORMATION AND CONSUMER AWARENESS**

Refer to the *General Principles of Food Hygiene*.

## **10. TRAINING**

Refer to the *General Principles of Food Hygiene*. In addition:

### **10.1 AWARENESS AND RESPONSIBILITIES**

Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables*. In addition:

The producer should have a written training program that is routinely reviewed and updated. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety of sprouts.

## Appendix III

**PROPOSED DRAFT REVISED GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM*****(At Step 5 of the Procedure)*****RECOMMENDED ENHANCEMENTS INCLUDED (UNDERLINED)**

Prior to application of HACCP to any sector of the food chain, that sector should be operating under good hygienic practices according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. These prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system.

For all types of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

All seven principles must be applied in the HACCP system. It is important when applying HACCP to be flexible. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints. The application of the HACCP principles should be the responsibility of each individual business. However, it is recognised that there may be obstacles hindering the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses.

Specific obstacles, particularly for small and/or less developed businesses, are not always having the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. Expertly developed HACCP guidance relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration.

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

## **APPLICATION**

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

### **1. Assemble HACCP team**

The food operation should assure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources, such as, trade and industry associations, independent experts, regulatory authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house.

### **2. Describe product**

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including  $A_w$ , pH, etc), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan.

### **3. Identify intended use**

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

### **4. Construct flow diagram**

The flow diagram should be constructed by the HACCP team (see also paragraph 1 above). The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

### **5. On-site confirmation of flow diagram**

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

### **6. List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards**



**(SEE PRINCIPLE 1)**

The HACCP team (see also paragraph 1 above) should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team (see also paragraph 1 above) should next conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents; and,
- conditions leading to the above.

Consideration should be given to what control measures, if any exist, can be applied to each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

**7. *Determine Critical Control Points*****(SEE PRINCIPLE 2)<sup>1</sup>**

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

**8. *Establish critical limits for each CCP*****(SEE PRINCIPLE 3)**

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<sup>1</sup> Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g., slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

Critical limits must be specified and validated for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH,  $A_w$ , available chlorine, and sensory parameters such as visual appearance and texture.

Where expertly developed HACCP guidance has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, **product or groups of products** under consideration. These critical limits should be measurable.

**9. *Establish a monitoring system for each CCP***

**(SEE PRINCIPLE 4)**

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product.

All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

**10. *Establish corrective actions***

**(SEE PRINCIPLE 5)**

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

**11. *Establish verification procedures***

**(SEE PRINCIPLE 6)**

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively.

Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where verification can not be performed in house, verification should be performed on behalf of the business by external experts.

Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where appropriate, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

## **12. Establish Documentation and Record Keeping**

### **(SEE PRINCIPLE 7)**

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

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Verification procedures performed;
- Modifications to the HACCP plan;
- Modifications to the HACCP system.

An example of a HACCP worksheet is attached as Diagram 3.

A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

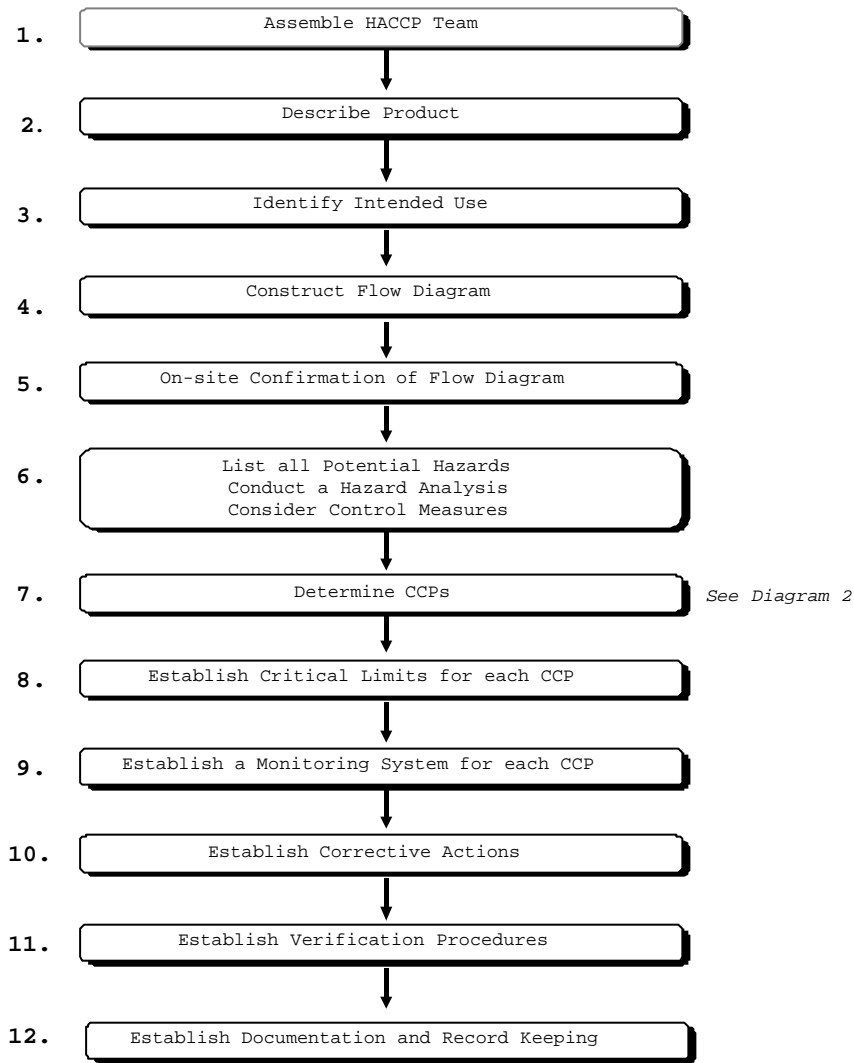
## **TRAINING**

Training of personnel in industry, government and academia in HACCP principles and applications and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As

an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

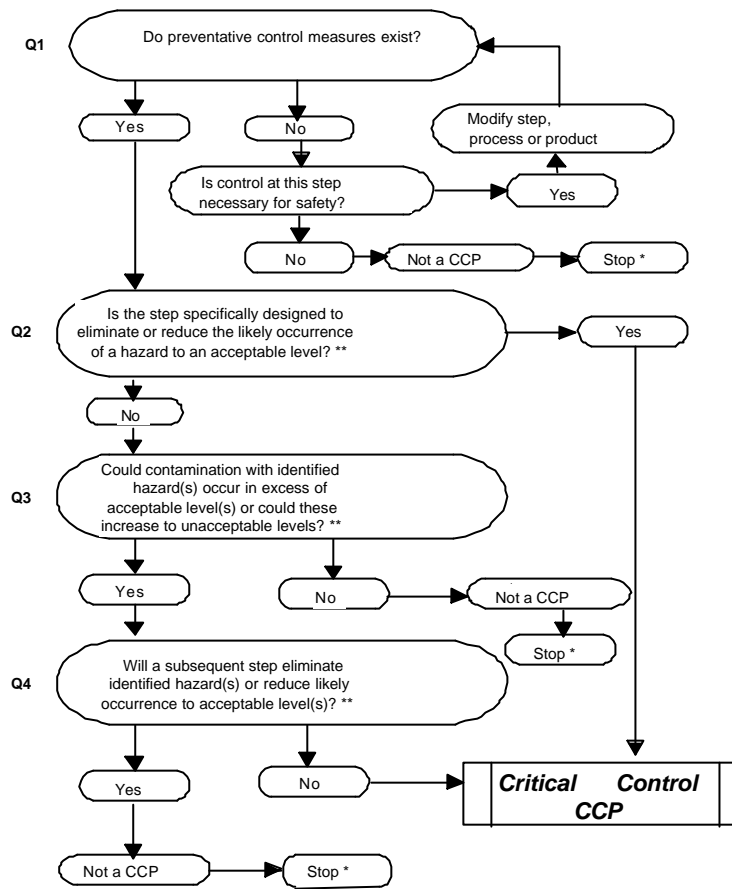
Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is of vital important. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

**DIAGRAM 1**



**LOGIC SEQUENCE FOR THE APPLICATION OF HACCP**

**DIAGRAM 2**  
**EXAMPLE OF DECISION TREE TO IDENTIFY CCPs**  
 (answer questions in sequence)



\* Proceed to the next identified hazard in the described process

\*\* Acceptable and unacceptable levels need to be determined within the overall objectives in identifying the CCPs of the HACCP plan

**DIAGRAM 3**

**EXAMPLE OF A HACCP WORKSHEET**

1. 

Describe Product
------------------

2. 

Diagram Process Flow
----------------------

3. 

List							
Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limit(s)	Monitoring Procedure(s)	Corrective Action(s)	Record(s)

4. 

Verification
--------------

## Appendix IV

**PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *Listeria monocytogenes* IN  
FOODS:(at Step 2 of the Procedure)**

**Prepared by Germany with assistance of Austria, Denmark, France, Japan, Norway, the  
United Kingdom, the European Commission and the International Commission on  
Microbiological Specifications for Foods (ICMSF)**

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## INTRODUCTION

*Listeria monocytogenes* (*L. monocytogenes*) is a bacterium that occurs widely in both the agricultural (soil, plants and water) and food processing environment. The bacterium is resistant to various environmental conditions such as high salt or acidity (Ryser and Marth, 1991). *L. monocytogenes* grows at low oxygen conditions and refrigeration temperatures, and survives for long periods in the environment, on foods, in the processing plant, and in the household refrigerator. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods due to post-processing contamination. *L. monocytogenes* has been isolated in such foods as raw and pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw-meat sausages, raw and cooked poultry, raw meats (all types) and raw and smoked fish. Even when *L. monocytogenes* is initially present at a low level in a contaminated food, the organism can multiply during storage, including storage at refrigeration temperatures when the food supports growth.

Available epidemiological data show single cases and outbreaks of listeriosis. During recent years, the incidence of listeriosis in most countries has not increased, and in a number of countries the incidence appears to have decreased. In most countries, the reported incidence is 2 to 7 cases per million inhabitants. Transitory increases in incidence rates have been noted in several countries. These have been associated typically to foodborne outbreaks attributed to specific foods, often from specific manufacturers. Even at the height of such outbreaks, listeriosis is still a relative rare disease, having an attack rate of 0.8 to 2 cases per 100,000 people. The incidence rates for listeriosis returned to prior baseline values after the causative food was removed from the market and consumers received effective public health information pertaining to appropriate food choices and handling practices.

Apparent reductions in the baseline levels of listeriosis have been observed during the past several years. This likely reflects the efforts of industry and governments (a) to implement Good Hygiene Practice (GHP) and apply HACCP to reduce the frequency and extent of *Listeria* in industrially processed foods, (b) to improve the integrity of the cold chain to reduce the incidence of temperature abuse conditions that foster the growth of *L. monocytogenes*, and (c) to enhance risk communication, particularly for consumers at increased risk of listeriosis (ICMSF, 1996).

However, further actions shall be taken to lower the risk of human listeriosis from food consumption world wide. Based upon the known characteristics of the microorganism and the disease some countries maintain a policy of „zero tolerance“ for *L. monocytogenes* in ready-to-eat foods. Several countries have concluded that while a complete absence of *L. monocytogenes* (zero tolerance) may be a commendable goal, for certain foods it is an unrealistic and unattainable requirement, that limits trade without having a positive impact on public health. The levels of *L. monocytogenes* associated with “unavoidable” contamination of these products are typically low, and the risks are minimal if multiplication does not, or cannot, occur during storage, distribution and preparation. Therefore, a slightly different approach to *L. monocytogenes* contamination was taken.

These different approaches towards the management of *L. monocytogenes* may lead to trade barriers that can and should be avoided, if the foods do not endanger a country's appropriate level of protection. This document provides data on which the CCFH and countries or regions can decide whether the presence of low numbers of *L. monocytogenes* in certain categories of food would be tolerable (acceptable) and proposes Microbiological Criteria that should prevent in the context of the WTO/SPS Agreement the establishment of unnecessary or unjustified trade barriers.

## 1 SCOPE

The document gives guidelines for the control of *L. monocytogenes* in foods in [international] trade based on considerations of risk assessment and lists a number of risk management options. One option may be the establishment of Microbiological Criteria and recommendations for them are given.

## 2 DOCUMENTS USED

During the elaboration of these guidelines for the control of *L. monocytogenes* in foods the following documents were considered:

- (a) Documents of the Codex Committee on Food Hygiene:
  - Report of the 32<sup>nd</sup> Session of the Codex Committee on Food Hygiene (ALINORM 01/13)
  - Principles and Guidelines for the Conduct of Microbiological Risk Assessment (ALINORM 99/13A, Appendix II)
  - Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)
  - Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (Annex to CAC/RCP 1-1969, Rev. 3 1997).
  - Danish Government: Discussion paper for the Codex Committee on Food Hygiene on „The Control of *Listeria monocytogenes* in Foods“ (28th August 1998)
  - Proposed Draft Principles and Guidelines for the conduct of microbiological risk management, CX/FH 00/6 July 2000
  - „Establishment of sampling plans for microbiological safety criteria for foods in international trade“. Document prepared by the ICMSF for the Codex Food Hygiene Committee (September 1996)
  - Annex to Codex document on Establishment of sampling plans for *Listeria monocytogenes* in international trade (submitted by the ICMSF secretariat to the Codex FH Committee, September 1996)
- (b) „Risk management and food safety“. Report of a joint FAO/WHO Consultation, Rome, Italy, 27 to 31 January 1997. FAO Food Nutrition Paper 65, Rome 1997
- (c) Report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods. Rome, 17-21 July 2000.

## 3. DEFINITIONS

**Microbiological Food Safety Objective** –A statement [based on risk analysis] expressing the level of microbiological hazard in a food that is tolerable in relation to an appropriate level of protection 1 .

**Risk Management** – The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed selecting appropriate prevention and control options 2 .

[**Management Options** - different approaches to managing microbiological risks.]

**Microbiological Criterion** – A microbiological criterion for food defines the acceptability of a product or a lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot 3 .

## 4 INVOLVEMENT OF STAKEHOLDERS

The management of *L. monocytogenes* in foods needs to involve parties along the whole food chain, i.e. food producers, processors, distributors, retailers, people in food service and consumers.

The degree to which a single party gets involved depends on the steps to consider in the Risk Assessment of *L. monocytogenes* in foods of concern. If there is a listericidal step within the production process, the control of *L. monocytogenes* is focussed at the processing level and food processors are mainly involved. When no listericidal step is included several control measures may need to be taken to achieve the appropriate level of protection, and thus more parties have to be involved in the

management process. Within CCFH, governments and interested parties have the possibility to participate, however, sometimes participation of particular stakeholders may be specifically encouraged.

<sup>1</sup> This definition is taken from the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management, CX/FH 00/6

<sup>2</sup> This definition is taken from the Procedural Manual of the Codex Alimentarius Commission, Eleventh Edition.

<sup>3</sup> This definition is taken from CAC/GL 21 – 1997

## **5 GUIDELINES FOR THE CONTROL OF *Listeria monocytogenes* IN FOODS**

### **5.1 INITIAL RISK MANAGEMENT ACTIVITIES**

*Explanation:*

*The CCFH has been discussing since 1989 how to manage *Listeria monocytogenes* in foods. Several documents were prepared, the one presented to the Committee in 1997 was asked to be put in line with the Codex document on Microbiological Risk Management. For this reason, the previous version of the current document followed closely the outline of the Risk Management. All initial risk management activities were dealt with; including those performed prior to commissioning a risk assessment. In this revised version of the current document these activities are included in Annex 1. The drafting group felt that this was necessary because the information, for instance presented in the section risk profile, was written in 1997 and is not up-to-date anymore. Information that is more recent can be found in the report of the Risk Assessment performed by the FAO/WHO. The headings of this section were kept in the text, in order to remain in line with the Risk Management document.*

#### **5.1.1 Identification of Risk Managers (see Annex 1)**

#### **5.1.2 Identification of the problem (see Annex 1)**

#### **5.1.3 Risk Profile (see Annex 1)**

#### **5.1.4 Defining Goals**

The first aim of controlling *L. monocytogenes* in food is to maintain or improve the protection of human health. There are several control measures that can be taken at national or international level, this document lists some of them.

The second aim is to facilitate international trade without compromising the protection of human health. The WTO/SPS agreement specifies that Codex standards, Codes or Guidelines have to be applied, whenever necessary. This document gives guidance on the management of *L. monocytogenes* by applying appropriate control measures at the various levels of the food chain and by the establishment of microbiological criteria.

#### **5.1.5 Scope, range and risk assessment policy**

Microbiological risk assessment policy setting is a management responsibility. It serves to protect the essential scientific independence and integrity of the microbiological risk assessment. It should be carried out in full collaboration between risk managers and risk assessors and other interested parties.

### 5.1.6 Commissioning of microbiological risk assessment

After several meetings of expert drafting groups FAO and WHO convened an expert consultation on risk assessment for *Listeria monocytogenes* in ready-to-eat foods<sup>1</sup>. The objectives were to critically review the assumptions on which risk assessment were based and to use the risk assessment to provide a science-based response to the specific risk management questions posed by the 33<sup>rd</sup> Session of the CCFH:

- i. Estimate the risk for consumers in different susceptible population groups (elderly, infants, pregnant women, and immunocompromised patients) relative to the general population.
- ii. Estimate the risk from *L. monocytogenes* in food when the number of organisms ranges from absence in 25 g to 1000 colony-forming units (cfu) per gram, or does not exceed specified levels at the point of consumption.
- iii. Estimate the risk from *L. monocytogenes* in foods that support growth and foods that do not support growth under specific storage and shelf life conditions.
- iv. Estimate the change in risk likely to occur from specific interventions and evaluate the effect of strain variation of *L. monocytogenes* on the risk estimates.

As the data basis is still too small the latter question was not considered by the expert consultation. The report of the expert consultation was published in August 2001 and made available through the internet.

### 5.1.7 Consideration of the process and results of the microbiological risk assessment

The expert consultation concluded that questions pertaining to international food safety issues can be addressed by expanding and/or adapting components of risk assessment done at a national level. They showed also that pre-existing models and data sets can serve as a basis for a quantitative risk assessment efforts. The group identified also a number of areas where data gaps exist and indicated the need for improved data acquisition for prevalence and growth of *Listeria monocytogenes* in foods and the incidence of foodborne listeriosis. The risk characterization was based on exposure assessment for six ready-to-eat foods from initial prevalence and concentration at the retail level to final concentration in contaminated servings. Risk characterizations based on the exposure profile of *Listeria monocytogenes* at consumption and dose-response models were used to attempt to estimate-predicted cases of listeriosis per serving for each of the six foods.

The expert group identified problems related to the statistical basis applied in the exposure assessment, specifically in relation to the representation of events with very low probability that could have a very large impact on human health. Despite gaps in data and various caveats the consultation gave valuable conclusions that should suffice to advance this document.

In summary, the questions posed by the 33<sup>rd</sup> CCFH meeting were answered as follows:

- i. Based on epidemiological data from France and the US the relative susceptibility was calculated. Setting the susceptibility of non-immunocompromised population to 1 those people having received organ transplants are 2584fold more susceptible when they are challenged with a infective dose of log 7.5. Elderly people (above 60 years) may be 1.6-7.5 fold more susceptible than younger, non-immunocompromised people. Based on these data specific precautionary management measures and requirements can be justified for foods specifically intended for

---

<sup>1</sup> Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, Risk characterization of *Salmonella* spp. in eggs and broiler chickens and *Listeria monocytogenes* in ready-to-eat foods. FAO Headquarters, Rome, Italy, 30 April – 4 May 2001.

consumption by clearly identifiable vulnerable groups (e.g., geriatric foods, baby foods, enteral foods).

- ii. The experts tried to answer question (ii) by using the dose-response relationship derived in the hazard characterization in conjunction with a “global contamination distribution”. By using the most conservative dose-response curve the total predicted number of cases/year in the United States is 2,130. By making the model even more conservative the group provides the following calculations.

Maximum log dose at consumption (log cfu/serving)	Predicted number of cases
Baseline distribution (log 10 <sup>7.5</sup> cfu/serving)	2130
4.5	24.9
3.5	5.3
2.5	1.1
1.5	0.2
0.5	0.06
-0.5	0.02
-1.5	0.01

The group concluded that it would be obvious that by eliminating higher dose levels (>10<sup>3.5</sup>) the number of predicted cases would be reduced by more than 99%.

- iii. The expert group reports: “The question concerning the relative risk associated with foods that do and do not support growth can also be considered broadly by using the example above. The key consideration is whether a correction factor needs to be applied when comparing levels at time of retail versus at time of consumption. For foods that support growth, increases in *L. monocytogenes* cell numbers between retail and consumption would have to be assumed and there is a significant likelihood that the hypothetical criteria analyzed above would be exceeded. However, this would not be the case for foods that do not support growth. Thus, for foods that do not support growth of *L. monocytogenes*, the predicted number of cases in relation to maximum dose level at retail would be the same as those depicted above for doses at time of consumption. Again, more rigorous modeling of other factors that could influence the differential in risk of severe listeriosis between foods that do and do not support the growth of *L. monocytogenes* are currently underway and the results of that activity are expected shortly. However, these are not likely to alter the large differential in risk between food that do and do not support the growth of *L. monocytogenes* to high levels that is suggested by the current “best-case” analysis.”

In summary the group give a basis for the management of the Listeria/food problem. Combined with the empirical knowledge the conclusion for the management is that there is little evidence that consumption of low levels (<100/g) of the microorganism in foods cause listeriosis. Products that may support the growth above this level may pose a certain risk when growth has occurred above a level of at least 10<sup>3</sup>. Further, estimates based on available data indicate that the risks associated with such products are low, even for the immunosuppressed segments of the population.

#### [5.1.8 Identifying of Tolerable Level of Risk (TLR)]

*The issue of tolerable level of risk is not discussed in the context of this document. It is a managerial decision to be discussed and decided by the CCFH.*

### 5.1.9 Regional considerations

Data made available to the FAO/WHO Risk Assessors showed that *L. monocytogenes* is distributed in nature and is found in a variety of products around the world. The effect of the exposure to *L. monocytogenes* is depending on predisposing factors, such as age and immunological status. The size of the population having such predisposing factors may differ from region to region. Moreover, the conditions during distribution, storage and sale may differ. Consequently, risk estimates may vary. However, there is no evidence that the problem in other regions of the world is more prominent than in those from where the data were provided for the risk assessment.

## 5.2 RISK MANAGEMENT OPTIONS

### 5.2.1 Identification of options

There are many different approaches to control *L. monocytogenes* at the various stages of the food chain. Most of the time a combination of measures will be more effective in reducing risks. Some of these control options are listed in section 5.2.2.

The risk assessment for *L. monocytogenes* has demonstrated that, in relation to the likelihood of illness, there is a negligible difference when consuming foods with levels of *L. monocytogenes* ranging from 0-1000/g. As such control measures based on a assumed maximum level of *L. monocytogenes* in food at the time of consumption can be set. It may guide the selection of the most efficient control measures assuring that this level is not exceeded.

*Explanation:*

*It should be noted that a tolerable level of risk has not yet been set for Listeria monocytogenes, however, this should not prevent risk management options being put in place. Regardless of any decision on the TLR the drafting group believes that the options suggested will lead to a reduction in the likelihood of illness due to L. monocytogenes.*

### Microbiological Food Safety Objective (FSO)

Based on the risk assessment report the maximum contamination level in food at consumption should be less than 100/g *L. monocytogenes*.

*Explanation:*

*Based on the information from the Risk Assessment report CCFH should decide which level would be appropriate for Codex purposes. The drafting group kept the original proposed level of less than 100 L. monocytogenes per gram at the moment of consumption in order to proceed with the elaboration of control measures, in particular the establishment of microbiological criteria.*

#### [5.2.1.2 Precaution in risk management]

*The issue of precaution is not discussed in the context of this document. It is a topic of another CODEX committee meeting.*

### 5.2.2 Preferred microbiological risk management options

In order to control *L. monocytogenes* and hence to prevent listeriosis the application of General Principles of Food Hygiene" (CAC/RCP 1-1969, Rev. 3, 1997) and in particular the HACCP principles "from farm to fork" (Annex to CAC/RCP 1-1969, Rev. 3, 1997) and the food specific Codes of

Hygienic Practices are important. In addition, apart from the usual hygienic measures some specific guidelines focusing on *L. monocytogenes* are recommended below.

#### **5.2.2.1 Primary production and food harvesting**

The management for preventing contamination and/or introduction of *L. monocytogenes* should start at primary production level with approaches such as:

- introducing measures to reduce the level of specific *L. monocytogenes* in specific kinds of primary production;
- specific hygienic measures related to harvesting of fish and fishery products, meat, milk, salads, sprouts

#### **5.2.2.2 Food processing and distribution**

*L. monocytogenes* can cause problems that should be managed by using hygienic measures. Thus, health authorities and industry should base control of *L. monocytogenes* on the proper application and verification of GHP and HACCP.

As examples, specific aspects of management *Listeria monocytogenes* in meat and poultry, fish and cheese processing are given in **Annex 2**.

Some general approaches for managing *L. monocytogenes* are:

- Selecting raw materials and ingredients (e.g. the use of ingredients, which received a listericidal treatment), if necessary use of microbiological criteria and testing to accept or reject incoming material.
- Preventing contamination and/or introduction of *L. monocytogenes* into the food processing plant
- Combating multiplication, and spread of *L. monocytogenes* in the food processing plant, use of an environment management and monitoring program;
- Inactivation of *L. monocytogenes* (e.g. pasteurization, sterilization, cooking, high pressure etc.);
- Preventing recontamination between cooking and packaging e.g. separation of raw from cooked product;
- Reducing the levels in cooked products after packaging e.g. applying a commercially feasible in-pack pasteurization.
- Preventing an increase in levels between packaging and preparation for serving. Controlling the increase of *L. monocytogenes* during storage and distribution that may occur when food was recontaminated. Examples are. the use of adding safe, accepted additives, the use of improved chill chain management or freezing of the product; and furthermore the implementation of code-dating practices
- Removing *L. monocytogenes* from products e.g. the use of validated washing regimes on fresh-cut salads and vegetables as a pathogen reduction step;
- Establishing regulatory requirements and/or creating incentives for changes in attitude that will contribute to risk reduction, for instance by developing food safety assurance systems (e.g. HACCP), by allowing operators to establish themselves the stringency of such schemes and the microbiological quality of the products they buy or sell;

- Establishing microbiological standards, performance<sup>2</sup>, process<sup>3</sup>, product<sup>4</sup> or other criteria and enforcing compliance (see **Annex 3**);

Timely action, taken in case of a deviation at a critical control point (CCP) will reduce the risk that defective products reach the consumer. Analyzing samples of end-products may provide information concerning the microbiological status of the product. However, analysis of samples taken from the line and line-environment is a more useful tool to check the effectiveness of control measures.

### 5.2.2.3 Use of Microbiological Criteria

The safety of products should be assured by application and implementation of the HACCP principles and GHP in the country of origin. Moreover, codes developed for regulating the import and export of foods should be adhered to the documents elaborated by the CCFICS<sup>5</sup>. However, when there is no assurance that the HACCP principles and GHP were correctly applied and implemented, inspection and analysis of imported lots may be indicated. In this instance Microbiological Criteria could be applied. Imported foods should be treated in the same manner as those produced in the domestic market.

The proposed Microbiological Criteria were developed according to the "Principles for the Establishment and Application of Microbiological Criteria for Foods" (CAC/GL 21 - 1997). Based on the deliberation of the risk assessment group and [decision of the CCFH], a concentration of *L. monocytogenes* not exceeding 100/g of food at the point of consumption is the microbiological limit for the use in a sampling plan. In order not to exceed these levels at the point of consumption, lower levels may need to be applied at the port of entry for those foods in which growth can occur. In order to establish such levels, knowledge of the behavior of *L. monocytogenes* in the food at the prevailing storage and distribution conditions is needed; the use of predictive models may be helpful.

However, the proposed microbiological criteria are not intended to be used for clearly identifiable food, specifically intended for consumption by clearly identifiable vulnerable groups (high risk groups) e.g. geriatric foods, baby foods, enteral foods.

In order to determine the number of sample units within a lot that should comply with these limits, the recommendations prepared by ICMSF (1997) for Codex purposes have been applied (see Annex XX). These considerations have been used to construct a decision tree (**Figure 1**). The criteria proposed should be achievable by products produced according to good hygienic practices (GHP) and under a system for control based on HACCP.

When analyzing foods it is important to adhere to adequate quality assurance procedures in the laboratories and the use of validated methods of detection and enumeration of *L. monocytogenes* (e.g. ISO 11290-1:1996 and ISO 11290 -2:1998).

### 5.2.2.4 Consumer education

Communication programs should be implemented to inform consumers about potential risks and how to avoid foodborne listeriosis to lower the risk of human listeriosis from food consumption such as:

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<sup>2</sup> Performance Criterion: The required outcome of a step, or combination of steps, that contribute to assuring that a food safety objective is met.

<sup>3</sup> Process Criteria : The control parameters of a step, or combination of steps, that can be applied to achieve a performance criterion.

<sup>4</sup> Product Criterion: A parameter of a food that can contribute to assuring that a food safety objective is met.

<sup>5</sup> Principles for Food Import and Export Inspection and Certification (CAC/GL 20-1195); Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CAC/GL 26-1997); Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CAC/GL 34-1999); Guidelines for the Exchange of information in Food control Emergency Situations (CAC/GL 19-1995 and Guidelines for the Exchange of Information Between Countries on Rejections of Imported Food (CAC/GL 25-1997).



- Informing the affected sub-groups, by all appropriate means, notably by properly trained health professions (e.g. general practitioner, public or private hospitals, local or general health services), about categories of avoiding foods and their specific denomination;
- Using all appropriate and available means (e.g. mass media, distribution of informative cards by retailers, supermarkets or consumer associations) for these sub-groups to be able to recognize these avoiding foods when seeing their denomination on the packaging and to help them to distinguish these specific products from the other categories of foods.
- Educating the population about food hygiene bases the soonest as possible, in particular at school. For example, beyond basic measures as “cleaning hands”, following points could be included in implemented training:
  - respect for preserving conditions written on food labeling, in particular for cold preserving temperatures,
  - respect for dates written on food labeling (in particular the use-by-date),
  - appropriate management of leftovers food,
  - rules for handling of foods,
  - all other appropriate points.

### 5.2.3 Final management decisions

*At a national or regional level, Food Control authorities have to decide whether the decisions made are appropriate for the protection of the consumers under their jurisdiction. If not, they have to perform a risk assessment and justify their deviation from the Codex recommendation(s) in order to be in line with the WTO/SPS Agreement.*

## 6 GUIDELINES FOR IMPLEMENTATION OF RISK MANAGEMENT DECISIONS FOR CONTROL OF *LISTERIA MONOCYTOGENES*

The implementation of microbiological risk management decisions can be by both governmental officials and by representatives of the food industry. Implementation will take different forms depending upon the options that have been decided.

In some situations, it may be preferable to utilise historical regulatory approaches. These approaches may be most successful in ensuring that fundamental good manufacturing practices are maintained. The most traditional tools for implementing microbiological risk management decision have been regulatory command and control or periodic inspection/end product testing that is enforced through penalties for non-compliance. While this system has resulted in significant reduction to the contamination levels in foods, it presents certain limitations. These systems place the burden of compliance with the regulatory authority rather than with the food manufacturer. Where a substantial pathogen level reduction has already been achieved, the rigidity of existing systems cannot provide the flexibility for tailoring remedies to individual situations in a cost-effective manner.

In most cases, however, an integrated systems approach to ensuring the safety of foods is preferable. Risk management decisions should address the entire farm to table continuum. HACCP, in combination with prerequisite programmes, is one such system. Such an approach places the responsibility for ensuring safe foods with the producer, the manufacturer, the distributor and the retailer, effectively using regulatory resources to provide the necessary oversight.

FSOs may function as important management tools in the implementation of risk management decisions. FSOs communicate to food producers the level of safety that should be achieved and facilitates the optimal use of limited regulatory resources.

In the field of food microbiology, microbiological testing against microbiological criteria (whether included in regulations as standards or only advisory) has been widely used as a management tool to determine the acceptability of products in trade. Microbiological criteria retain their value as a possible implementation tool of microbiological risk management decisions. However, end product testing is limited in its ability to assess the safety of food and cannot adequately assure the absence of pathogens. The inherent low prevalence of most foodborne pathogens makes it statistically impossible for end product testing to ensure the safety of foods. Microbiological testing is more properly utilised to verify the proper implementation of HACCP, to validate control measures and to assess problems either where HACCP has not been employed or where access to HACCP verification information is limited or unavailable. When microbiological criteria are used, reference should be made to the Codex document *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

## **7 MONITORING AND REVIEW**

Listeriosis in humans presents in three main clinical forms: septicemia, meningitis, and maternofetal infection. All have a considerable mortality.

In order to follow the effect of any measures to control *Listeria monocytogenes* in food (including microbiological criteria) and to establish the basis for a valid risk analysis it is crucial that data on the incidence of listeriosis in humans are reliable and comparable between countries. Because of the seriousness of the disease most cases will probably be diagnosed.

To create such reliable and comparable data on the incidences of listeriosis, all cases of listeriosis with isolation of *Listeria monocytogenes* from the blood or cerebrospinal fluid from any patient, or from any site in any newborn or pregnant woman should be made notifiable at the national level.

It is also crucial that all human isolates are characterized by at least one discriminatory typing method, i.e., PFGE or a similar method, on a real-time basis at least on the national level to point out related isolates indicative of an outbreak.. This requires the establishment of a reference laboratory to collect the isolates and to do the typing in each country.

## ANNEXES

### Annex 1: Initial Risk Management Activities

#### 1.1 Identification of Risk Managers

The primary responsibility for the production of safe food production is with the food operator. He may, however, need to be guided regarding the level of safety to be achieved. Within the context of Codex Alimentarius it is the CCFH who has the responsibility to establish such levels, as an Appropriate Level of Protection (or Tolerable Level of Risk), a Microbiological Food Safety Objective (MFSO) or a Microbiological Criterion. The CCFH has in the past developed, and will in the future develop, Codes of Practice, which contain many control measures that will be helpful to ensure the safety of a product.

At the national level, the national food authorities act as Risk Managers. They hold a pivotal position in management of *L. monocytogenes* in the whole food chain "from farm to fork" (primary production, food-processing establishments, food distribution, retail and professional preparation). In order to arrive at effective risk management decisions frequent and transparent interactions between governmental risk managers and responsible business managers along the food chain as well as consumers is needed. When food choice, storage, handling and preparation of the food by the consumer are important control measures, the public should be aware of this and be involved in the decision making process.

#### 1.2 Identification of the problem

Many of the foods on the market (such as those containing raw ingredients or which are subjects to some form of portioning or maturation process after processing) will, from time to time, contain low numbers of *L. monocytogenes*. Many such foods will be cooked during preparation for consumption, so there will be no health concern. Moreover, epidemiological evidence indicates that the ingestion of low numbers of *L. monocytogenes* does not pose a significant health risk to the general public. High numbers may pose an unacceptable risk even to healthy persons.

Available epidemiological data show single cases and outbreaks of listeriosis (Table 1 and Table 2 of Annex 1). During recent years, the incidence of listeriosis in most countries has not increased, and in a number of countries the incidence appears to have decreased. In most countries, the reported incidence is 2 to 7 cases per million inhabitants. Transitory increases in incidence rates have been noted in several countries. These have been associated typically to foodborne outbreaks attributed to specific foods, often from specific manufacturers. Even at the height of such outbreaks, listeriosis is still a relative rare disease, having an attack rate of 0.8 to 2 cases per 100,000 people. The incidence rates for listeriosis returned to prior baseline values after the causative food was removed from the market and consumers received effective public health information pertaining to appropriate food choices and handling practices.

Apparent reductions in the baseline levels of listeriosis have been observed during the past several years. This likely reflects the world-wide efforts of industry and governments (a) to implement GHP and apply HACCP to reduce the frequency and extent of *Listeria* in industrially processed foods, (b) to improve the integrity of the cold chain to reduce the incidence of temperature abuse conditions that foster the growth of *L. monocytogenes*, and (c) to enhance risk communication, particularly for consumers at increased risk of listeriosis (ICMSF, 1996).

Listeriosis is recognized as a foodborne disease. The connection with consumption of food is well established. Several types of foods have been implicated in foodborne disease cases or outbreaks, such as packaged coleslaw mix (Canada, 1982), Mexican style cheese (USA, 1985), pate (United Kingdom, 1987-88), cheese (Switzerland, 1983-87), pork tongue delicatessen (France, 1992), pork „rillettes“ (France, 1993), smoked mussels (Australia, 1991, New Zealand, 1992) and hot dogs (USA, 1998).

Analyses accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases and outbreaks have typically had elevated levels of the pathogen due to the growth of the microorganism in the food at some time prior to the food being consumed (ICMSF, 1996). Public health agencies have concluded that the levels of *L. monocytogenes* consumed is an important factor affecting the incidence of listeriosis. Foods that do not support the growth of *L. monocytogenes* are unlikely to be a sources of listeriosis, whereas foods that support the growth to high levels, should be the target of risk management efforts (Pinner et al., 1992). There are very little data to suggest that low levels of *L. monocytogenes* in foods, particularly in foods that do not support its growth, cause listeriosis. The contention that foodborne listeriosis is associated with the consumption of foods with elevated levels of *L. monocytogenes* is supported by studies with animal models.

### **1.3 Risk Profile**

#### **1.3.1 Present information on hazard identification**

*L. monocytogenes* is a facultative intracellular bacterial pathogen of both human and animals. It causes listeriosis in humans, with a variety of symptoms including mild diarrhea, meningitis, and septicemia. Epidemiological evidence suggests that most exposure is foodborne. Although listeriosis occurs infrequently at somewhere between 2 and 7 cases per million of the population, between 20 and 30% of both epidemic and sporadic cases are fatal. The fatality rate is higher (up to 38-45%) in highly susceptible individuals, such as immunosuppressed people, including pregnant women, newborns, immunocompromised patients and the elderly people, whereas it is lower in persons without predisposing factors. In addition, *L. monocytogenes* is found in many different foods.

Serotyping distinguishes 13 serovars of *L. monocytogenes*, but cases of human listeriosis are caused mainly by only three serotypes (4b, 1/2a and 1/2b). Most outbreaks of human listeriosis and a great percentage of the sporadic cases have been caused by the serovar 4b. In contrast, serogroup 1/2 strains seem to be more often recovered from food.

This broad based prevalence in the food system, together with a high mortality rate of listeriosis, suggests that *L. monocytogenes* represents an important hazard to human health that needs to be controlled.

#### **1.3.2 Present information on hazard characterization**

Serious cases are manifested by septicemia and meningitis, and may result in death. The highest incidence is amongst individuals at increased risk due to alterations or deficiencies in the normal immune response as a result of immunosuppressive drugs, cancer, AIDS, etc. Data collected in France indicated that patients at higher risk among non-pregnancy related cases are organ-transplantation recipients (200 cases/100,000 recipients), patients suffering from cancer (13/100,000 patients) and individuals aged more than 65 years without known underlying diseases (14/100,000 individuals). Data of U.S.A. indicated incidence of listeriosis among HIV-infected patients with 52 cases per 100,000 and among AIDS-patients with 115 cases per 100,000 patients.

The very young and the very old human beings may also be affected, and the unborn child is particularly at risk, because listeriosis may lead to abortion, stillbirth, or septicemia and meningitis in the neonate. The incidence of pregnancy-related listeriosis has been reported as 4.7 to 30 cases per 100,000 live birth.

Cases of mild gastrointestinal illness following the ingestion have recently been documented. The actual number is unknown, but mild diarrhea-type episodes can occur, as evidenced by several recent outbreaks.

Virulent strains may invade the gastrointestinal epithelium and enter phagocytic host cells, where the bacteria are able to survive and multiply. Their intracellular presence permits access to the brain and probably to the fetus in pregnant women. The incubation period varies from about 2 days to 6 weeks.

The role of healthy carriers in the epidemiology of listeriosis has not been elucidated. It may be excreted by patients suffering from listeriosis during the long incubation period or by certain individuals where the pathogen may persist without clinical symptoms leading to continued risk of spread and infection. As noted, although the incidence of listeriosis is relatively low and the consequence of an infection may be severe, an estimated 2 to 6 percent of the healthy population harbors *L. monocytogenes* in their intestinal tract without signs of illness (Rocourt and Cossart, 1997).

All *L. monocytogenes* strains should be considered as potentially pathogenic for humans. No correlation between origin (human, animal, food, environment) or typing characteristics (serovar, lysotype, ribovar, DNA macrorestriction patterns etc.) and virulence has been established.

Differences in virulence are observed. Serotype 4b contains more virulent and the serotypes 1/2a and 1/2b contain less virulent strains. To date, nothing is known about changes in virulence of these pathogens due to interaction with the host and the environment or due to transfer of genetic material between microorganisms. Virulence factors like homeless gene are known but do not reflect the pathogenicity of *L. monocytogenes* conclusively. In addition, up to date virulence factors identified in animal models are not suitable to differentiate *L. monocytogenes* strains with respect to infectivity or severity of disease. Due to this unresolved problems all *L. monocytogenes* strains are assumed to be pathogenic, and the following calculations take account of this conclusion. Special food attributes that may alter the microbial pathogenicity of *L. monocytogenes* are not known.

### 1.3.3 Present information on dose-response assessment

There are no experimental dose response data for humans available, i.e., the minimum infective dose (MID) of *L. monocytogenes* for humans is unknown. However, analyses accompanying epidemiological investigations have indicated that foods implicated in both sporadic cases and outbreaks have typically had elevated levels of the pathogen in the food at some time prior to consumption (Table 1 and Table 3 of Annex 1). Furthermore, foods that have been implicated in human listeriosis outbreaks have always been foods in which the growth of *L. monocytogenes* during storage is supported.

In addition, widespread occurrence of *L. monocytogenes* in foods harboring low numbers of *L. monocytogenes* indicate that many people ingest frequently such food without getting ill.

There is no information, whether accumulating effects exist, when different contaminated foods are consumed.

Animal experiments show, that the *Listeria* infection is dose-dependent and that the ID<sub>50</sub> is rather high, above 10<sup>5</sup>, in different models for intragastral inoculation (Amstberg, 1980; Schlech et. al., 1993; Notermans, 1995). However, extrapolation of mouse data to the human situation is questionable.

New approaches using dose-response models based on probability distributions have been introduced, but it should be kept in mind that also such models are based on assumptions of infective dose and consumption patterns.

### 1.3.4 Present information on exposure assessment

*L. monocytogenes* is widespread in nature and can be found in soil, silage, sewage and the faces of humans and animals. It can survive and grow on food production lines and in the production environment, especially in difficult-to-clean equipment and production areas. In addition, microbiological surveys indicate that *L. monocytogenes* is present in a variety of foods, including meat

products, smoked fish products, milk, cheese and “Ready To Eat“ products. There is a high exposure of people with *L. monocytogenes* and other *Listeria spp.*.

*L. monocytogenes* can grow in the presence or absence of air and in foodstuffs at pH values between 4.5 and 9.2, at water activities above 0.92 and at temperatures between 0 and +45 degrees Celsius, when other conditions in the food are optimal for growth. *L. monocytogenes* is able to grow in the presence of high salt concentrations (up to 10% NaCl). It may also survive for long periods of time in frozen or dried foods. Conclusively, high numbers of *L. monocytogenes* occur after growth in certain foods during storage.

Exposure assessments of specific foods should comprise data about prevalence or levels of *L. monocytogenes* in foods and consumption data of these foods. Specific food consumption data bases should contain information on type and amounts of products eaten, gender, age etc. of the population and individuals depending on the depth of surveys. Surveys on the prevalence or levels of *L. monocytogenes* in foods should reveal products of concern in particular those, which promote the growth of *L. monocytogenes* during storage, distribution and sale. These data will be supplemented by general data on the potential fate of *L. monocytogenes* in a specific commodity.

The presently available data indicate that the population worldwide is frequently exposed to varying levels of *L. monocytogenes*. This is, for the moment, sufficient to consider which Risk Management Options are available to decrease the number of illnesses, or as a minimal requirement, keep it at the same level.

**Annex 1 Table 1: Foodborne outbreaks of human listeriosis**

Country	Year	Number of cases (deaths)	Food implicated	Level of L.m./g
USA	1976	20 (5)	?Raw salad*	
New Zealand	1980	20 (5)	?Shell or raw fish*	
Canada	1981	41 (18)	Coleslaw	
USA	1983	49 (14)	?Milk*	
USA	1985	142(48)	Soft cheese	10 <sup>3</sup> -10 <sup>4</sup> (R)
Switzerland	1983-7	122(34)	Soft cheese	10 <sup>4</sup> -10 <sup>6</sup> (R)
UK	1987-9	>350 (?)	Pâté	10 <sup>2</sup> -10 <sup>6</sup> (R)
Denmark	1989-0	26 (6)	Hard and Blue cheese	
Australia	1990	9 (6)	Pâté	10 <sup>3</sup> (R & P)
Australia	1991	4	Smoked mussels	10 <sup>7</sup> (R)
New Zealand	1992	4 (2)	Smoked mussels	
France	1992	279(85)	Pork tongue in aspic	10 <sup>4</sup> -10 <sup>6</sup> (R)
France	1993	33	Pork rillettes	10 <sup>2</sup> -10 <sup>4</sup> (R)
Italy	1993	18†	Rice salad	
USA	1994	45†	Chocolate milk	10 <sup>9</sup> (R)
Sweden	1994-5	8 (2)	Smoked fish	10 <sup>2</sup> -10 <sup>6</sup> (R)
France	1995	33 (4)	Soft cheese	
Australia	1996	4 (1)	Cooked chicken	
Italy	1997	748†	Corn meal	10 <sup>6</sup> (R)
USA	1998-9	100(>10)	Hot dogs and deli meats	
Finland	1998-9	18 (4)	Butter	10 <sup>1</sup> -10 <sup>4</sup> (R & P)

\* = Epidemiological association only, without recovery of the implicated strain from the specific food item

† = Predominantly pyrexial and gastrointestinal illness

R = Food from retailer, usually unopened

P = Food from patients home, usually opened

**Annex 1 Table 2: Sporadic cases of foodborne human listeriosis**

Country	Year	Patient died	Food implicated	Level of L.m./g
USA	1985	No	Turkey frankfurters	10 <sup>5</sup> (P)
England	1986	No	Soft cheese	'High' (P)
USA	1987	NK	Raw milk	
England	1988	No	Soft cheese	10 <sup>7</sup> (P)
England	1988	Yes	Cooked chicken	
England	1988	Yes	Rennet	
Canada	1989	Yes	Alfalfa tablets	
USA	1989	No	Sausage	
Finland	1989	No	Salted mushrooms	10 <sup>6</sup> (P)
Italy	1989	NK	Sausage	10 <sup>6</sup> (P)
Italy	1989	No	Fish	
Denmark	1989	NK	Smoked cod roe	
Canada	1989	No	Soft cheese	
Belgium	1989	No	Fresh and ice cream	10 <sup>3</sup> -10 <sup>6</sup> (P)
Sweden	1993	No	Mettwurst	
Italy	1994	NK	Pickled olives	

NK = Not known

P = Food from patients home, usually opened

**Annex 1 Table 3: Levels of *Listeria monocytogenes* in foods causing listeriosis (ICMSF, 1996)**

Country, year	No. of cases	Food	<i>L. monocytogenes</i> /g	Sampling point *
Switzerland, 1983-87	122	Cheese	10 <sup>4</sup> - 10 <sup>6</sup>	R
United States, 1985	142	Cheese	10 <sup>3</sup> - 10 <sup>4</sup>	R
United Kingdom, 1988	1	cheese	10 <sup>7</sup>	R
United Kingdom, 1987-88	> 300	paté	> 10 <sup>3</sup>	R
France, 1992	279	pork tongue, delicatessen	10 <sup>4</sup> - 10 <sup>6</sup> <10 <sup>2</sup> - 10 <sup>4</sup>	R R
France, 1993	39	pork "rillettes"	<10 <sup>2</sup> - 10 <sup>4</sup>	R
Finland, 1988	1	salted mushrooms	10 <sup>6</sup>	P
United States, 1988	1	turkey frank	> 10 <sup>3</sup>	P
Italy, 1988	1	sausage	10 <sup>6</sup>	P
Australia, 1991	2	smoked mussels	10 <sup>7</sup>	P
New Zealand, 1992	3	smoked mussels	10 <sup>3</sup>	P
United States, 1994	48	chocolate milk	10 <sup>8</sup>	P

\* R : food from retailer, P : food from patient's refrigerator

## **ANNEX 2: EXAMPLES OF MANAGING OF *Listeria monocytogenes* IN FOOD PRODUCTION**

### **ANNEX 2.1: GENERAL *LISTERIA* GUIDELINES FOR INDUSTRY (BASED ON A FSIS POLICY DOCUMENT<sup>6</sup>)**

#### **CURRENT THINKING ON BEST PRACTICES**

A number of trade associations have produced "Best Practice" or GMP documents that cover production practices such as sanitation, raw materials handling, and employee hygiene. These documents are listed in the bibliography; copies may be obtained from these organizations.

#### **SAMPLING PROGRAMS**

FSIS envisions two types of sampling programs that establishments may use: environmental and end product. Environmental sampling includes non-product contact surfaces, such as floors and drains, and product contact surfaces, such as conveyors, belts, slicers, and peelers. End product testing covers RTE product. Establishments with limited resources should establish end product sampling as their top priority, followed by product contact surface/non-product contact surface testing.

#### **ENVIRONMENTAL TESTING: A Commonly Used Tool**

##### **Sample Sites and Frequency**

Selection of sample sites and sampling frequency for non-product and product contact surfaces depends on establishment features such as plant layout, overhead structures, number of production lines/products, location of processing equipment, and product flow. A sampling protocol should include the sample sites, sample area size, sampling frequency and sample collection techniques. In general, sample sites should be selected randomly. However, some sites may be designated for sampling on a regular basis based on the hazard analysis. Sample size can be determined based on the nature of equipment or surfaces e.g. flat surfaces, inside of equipment, etc. The plan should also detail appropriate, progressive actions the establishment will take as positive samples are found.

##### **Methods**

Environmental samples, including swabs and sponges, should be placed in a neutralizing medium immediately after collection, in order to neutralize any residual disinfectants that may be picked up from equipment or other environmental sampling sites. Samples should be stored and shipped to laboratories using standardized procedures. A reputable laboratory should analyze samples. The establishment is responsible for determining the competency of the laboratory used. The laboratory conducting the sample analyses should have properly trained personnel, suitable facilities and equipment, a written quality assurance program that is available to all personnel, and reporting and record keeping capabilities. An establishment may choose to perform its own indicator organism testing using a screening test. Such tests are available but should be validated as part of the HACCP plan.

##### **Record Keeping**

The results of environmental sampling are not available until after products are produced. Therefore, adequate and accurate records are essential because the environmental sampling program is of retrospective value only. For example, identification of the site sampled (drain #1 in peeling room) and the visible condition of the site (clean, smooth surface) is necessary to effectively utilize the sampling results.

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<sup>6</sup> Food Safety and Inspection Service, United States Department of Agriculture, Washington, D.C., 20250-3700



**Results and Follow-up: Non-product contact surfaces**

If positive samples are found from non-product contact surfaces, follow-up actions should be taken, and may include thorough cleaning of suspect areas and equipment with subsequent intensified/expanded testing.

**Results and Follow-up: Product contact surfaces**

If positive samples are found on product contact surfaces, different follow up actions should be taken, including follow up sampling of product produced on that line, as follows:

1. Once the product contact surface is found to be positive for the number of samples indicated in the HACCP plan for *Listeria* spp., the next lot of product produced from the line should be sampled and tested for *L. monocytogenes*.
2. Minimum production time prior to sampling should be determined by the plant and followed. The time may depend on individual line configuration, clean up, and sanitizing procedures. The testing plan should include variations in the time of sampling to detect the increase in *Listeria* that could occur during the production shift.
3. After product sampling, the line may need to be cleaned and/or operational procedures reviewed, before production of the next lot.
4. The product lot sampled may be held, pending laboratory results.
5. If a sampled lot is found to be positive for *L. monocytogenes*, and is already in commerce, it will be subject to recall.
6. Product sampling may be intensified, such as testing several consecutive lots. All product produced on positive lines may be held pending laboratory results.
7. After the predetermined number of lots has tested negative for *L. monocytogenes*, the plant may resume its regular regime of environmental and product sampling.
8. The establishment should document the reason for contamination and steps taken to prevent future incidents.

**END PRODUCT TESTING: A Potential Verification Tool**

An end-product sampling program for RTE meat and poultry products may serve as verification of the HACCP plan. An end product testing program should include several elements, such as sampling frequency, sampling procedures, laboratory methods, follow-up actions, and record keeping.

**Sample Frequency and Procedures**

The frequency of end product sampling should take into consideration the number and types of different products produced, complexity of processing procedures, the amount of product produced, whether an environmental sampling program is in place, and establishment history. Establishments can base their sampling frequencies on any validated statistical sampling program that achieves their objectives.

Products that have direct exposure to the establishment's processing environment after a kill step is applied may be at greater risk from environmental contaminants than a product cooked and distributed in the same packaging. An establishment may want to increase the frequency of sampling of the former type of products. If no environmental sampling is taking place, more frequent product sampling may be advisable because the early warning of a potential *L. monocytogenes* problem that environmental sampling may provide will not be available. An establishment that has a prior history of *L. monocytogenes* findings by either FSIS or its own sampling program may also need to test more frequently.

Sampling should be done as randomly as possible, with all lines and shifts eligible for selection. From the selected lot, multiple sample packages should be collected from the beginning, various middle time points, and towards the end of the production to test a sample representative of the entire lot. Whenever practical, intact packages should be sent to the laboratory for analysis, as they will provide better control of aseptic sampling. Otherwise, an establishment should aseptically collect a portion of each package and place the sample into a sterile bag or other sterile container for shipment to the laboratory.

## Methods

Samples should be stored and shipped to laboratories using standardized procedures. A reputable laboratory should analyze samples. The establishment is responsible for determining the competency of the laboratory used. The laboratory conducting the sample analyses should have properly trained personnel, suitable facilities and equipment, a written quality assurance program that is available to all personnel, and reporting and record keeping capabilities. Laboratory methods employed should be AOAC approved or the FSIS *L. monocytogenes* method published in the Microbiology Laboratory Guidebook, 3<sup>rd</sup> edition (Chapter 8, Revision #1, 1/12/99).

## Results and Follow-up

If a sampled lot is found to be positive for *L. monocytogenes*, the establishment should take the appropriate actions.

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**ANNEX 2.2: MANAGING *LISTERIA MONOCYTOGENES* IN THE MEAT AND POULTRY PROCESSING ENVIRONMENT**

**(Based on a paper of R. B. Tompkin<sup>7</sup>)**

Experience over the past 10 –15 years points to recontamination as the primary source of *L. monocytogenes* in many commercially prepared ready-to-eat processed foods. This realization has led to significant changes in how the post-processing environment is managed. For example, modifications have been necessary in cleaning and disinfecting, plant layout, equipment design and personnel practices. Experience further indicates that *L. monocytogenes* will continue to be introduced into the cooked meat product environment. Under these circumstances it is possible to minimize, but not prevent, the risk of product contamination.

Knowledge concerning the microbial ecology of the food processing environment is important (ICMSF 2001). Several studies have demonstrated that certain strains become established in a food processing facility and can remain for extended periods of time (e.g., months, years). The risk of listeriosis appears to be highest when a highly virulent strain becomes established in the food processing environment, leading to contamination of the food, multiplication occurs in the food following packaging, and one or more members of the more highly susceptible population consumes the food.

Foodborne listeriosis appears to generally follow a pattern of three scenarios. Scenario 1 consists of isolated cases for which information about the food is seldom available due to the long incubation period (i.e., days to weeks). Scenario 2 consists of an outbreak or cluster of cases involving a single lot of contaminated food. These events typically involve errors in food handling that lead to a single lot of food becoming contaminated and an opportunity for multiplication before the food is consumed. Once the implicated quantity of food is eliminated further cases cease to occur. Scenario 3 consists of an outbreak involving a few cases to several hundred cases scattered by time and location. The outbreaks typically involve an unusually virulent strain that has become established in the environment and contaminates multiple lots of food over days or months of production (Table 1 of Annex 2.2).

Experience in cooked meat and poultry operations indicates that a niche is commonly involved. A niche is a site within the cooked product environment wherein *L. monocytogenes* becomes established and multiplies. The sites may be impossible to reach and clean with normal cleaning and sanitizing procedures. In fact, in operations with an effective *Listeria* control program the processing environment typically appears visually clean and acceptable. The sites serve as a reservoir from which the pathogen is dispersed during operation and contaminates food contact surfaces and food. In a controlled environment the niche usually affects only the food along one packaging line and not the product on a close adjacent line.

Microbiological testing is necessary to detect a niche. Examples of a niche include hollow rollers on conveyors, cracked tubular support rods on equipment, the space between close fitting metal-to-metal or metal-to-plastic parts, worn or cracked rubber seals around doors, on-off valves and switches for equipment, and saturated insulation. In all three scenarios, there is an opportunity for *L. monocytogenes* to multiply before the food is consumed. Food processors should establish control systems to prevent scenario 3 events and minimize the probability of scenarios 1 and 2. Compliance with local regulatory requirements and Codex Alimentarius documents should further ensure an acceptable level of consumer protection.

Two factors determine the effectiveness of a *Listeria* control program, i.e. environmental testing and the response to a positive finding. Without an environmental testing program it is not possible to assess

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control. In the event a positive product contact sample is detected, corrective actions should be initiated to identify and control the source of contamination, thereby minimizing the risk of product contamination. This means that a routine sampling program should be established to provide a continuing assessment of control. Experience has shown that the frequency of sampling the ready-to-eat environment in many operations should be weekly with emphasis on product contact surfaces. The need for sampling and frequency should depend on risk to consumers in the event the food becomes contaminated. There should be little, if any, need for an extensive sampling program if it is known that growth can not occur between when the food is produced and when it is consumed (e.g., frozen, dried, or acidified foods).

If sampling weekly, the results for the previous 7 samplings should be reviewed each week to detect patterns and trends. Ideally, the results also should be reviewed annually, if not quarterly, to obtain a longer-term perspective and identify problems that might otherwise go undetected. While it would be preferable to analyze and control directly for *L. monocytogenes*, regulatory and/or company policies may result in the analyses being limited to a finding of *Listeria*-like colonies on modified MOX agar or colonies that have been confirmed to be of the genus, *Listeria*.

An effective *Listeria* control program must take account of human nature as well as the scientific basis for control. While it is human nature to avoid problems, it is important to recognize that control of *Listeria* will periodically result in a positive finding. This should be viewed as a "success" because the monitoring program has been effective, the problem can be corrected and consumer protection can be ensured. Recrimination against plant management for the presence of this ubiquitous bacterium invariably proves counter-productive in the long term. The better response is to provide technical assistance and laboratory support to help restore control. The information gained can be used to reduce, perhaps prevent, additional positives. Under the best of circumstances sharing experiences among peers can prove very helpful.

Experience has shown that the most effective response to a positive finding of *Listeria* on a product contact surface is to help determine the source so it can be corrected. A simple map showing the layout of equipment can be beneficial. As positives are detected the sites should be marked on the layout map with the date (Figure 1). This procedure is useful for organizing results, identifying which sites are more positive and where the positives first occur. This information will help to identify the equipment that is harboring the bacterium. In general, contamination flows down along a packaging line much like a river.

When investigating the source of contamination it may be better to use an abbreviated method for *Listeria*. It is faster and much cheaper to stop the analysis following incubation of the modified Frazer broth tubes. By striving for no black tubes, more samples (e.g., more sites, different times during the day) can be processed and more information obtained.

When equipment has been identified as the likely source, the equipment should be dismantled (meanwhile sampling suspicious sites), cleaned and sanitized. Occasionally, the most extensive dismantling and cleaning will prove ineffective. In such cases sensitive electronics, oil and grease should be removed and the equipment subjected to steam heat. The equipment can be moved into an oven (e.g., smokehouse) or, if this is possible, the equipment should be shrouded with a heat resistant plastic tarp and steam introduced from the bottom. The target is to achieve an internal temperature of 70C. Thermocouples placed within the equipment can be used to verify the temperature.

Results over the past 12 years from a wide variety of operations indicate that *Listeria* can be controlled, but not eliminated, from the cooked product environment. Despite best efforts the bacterium will continue to be re-introduced to the environment. While failure to control *Listeria* on the floors increases risk to packaging lines, an effective means to control *Listeria* on floors has remained elusive.

Cleaning and sanitizing procedures should be directed toward *Listeria* control. Washing equipment more frequently during production (e.g., mid-shift, between shift) is detrimental to *Listeria* control and

must be avoided. Contrary to common opinion, random contamination from air, people, packaging materials, etc is minor. Workers hands/gloves, however, can serve as a vector in transferring contamination from unclean surfaces to product. In a facility with a controlled environment, growth within a niche is of greatest concern. Contamination is normally limited to a single packaging line, with adjacent lines not affected. Considering our growing knowledge of *Listeria* control, statements that *Listeria* contamination is due to poor sanitation indicates a lack of understanding of the issue.

Recognizing the continuing challenge faced by the food industry some future changes will likely occur. Better equipment design is needed for improved cleanability and to minimize the possibility of niches. More durable floors are needed to withstand the increased use of chemicals. There will likely be greater use of steam for sanitizing certain equipment at some routine frequency, as described above. Food additives that inhibit *L. monocytogenes* will become more widely used in those foods where growth can occur. As an alternative to inhibitors, there will be increased use of post packaging pasteurization when product quality will not be adversely affected.

#### Reference:

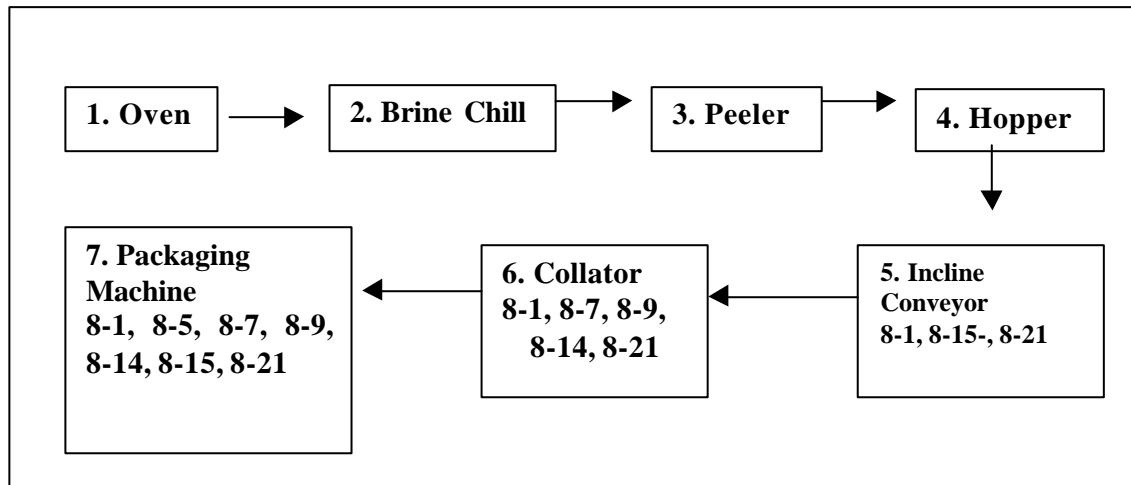
ICMSF (International Commission on Microbiological Specifications for Foods), 2001. Microorganisms in Foods 7: Microbiological testing in Food Safety Management. Aspen Publishers.

**Table 1 of Annex 2.2:** Examples of Scenario No. 3

<u>Country, year(s)</u>	<u>Implicated food</u>	<u>No. cases</u>
France, 1975-1976	Unknown	≤167
Switzerland, 1983-87	Cheese	122
USA, 1985	Mexican-style cheese	142
UK, 1987-88	Pate'	>300
France, 1992	Jellied pork tongue	279
France, 1993	Pork rillettes	39
USA, 1994	Chocolate milk	53
France, 1995	Brie cheese	36
Sweden, 1994-95	Cold smoked/gravad trout	6-8
USA, 1998-99	Franks (lunchmeat?)	~100
France, 2000	Jellied pork tongue	26
Finland, 1998-99	Butter	18

**Figure 1 of Annex 2.2:**

**Example showing how positive results for samples collected from August 1 to 21 from 7 steps along a frankfurter line could be mapped.**



## ANNEX 2.3. GUIDELINES FOR CONTROL OF *LISTERIA MONOCYTOGENES* IN SEAFOOD PROCESSING

(Based on documents from Denmark)

### Introduction

These guidelines are intended to provide practical advice for preventing contamination during production of ready-to-eat fish products that support growth of *Listeria monocytogenes*. This guideline will use cold smoked salmon as the most common example of such products. Although this document focuses on such products the guidelines may be applied to other products to minimize contamination. The controls for *L. monocytogenes* will be product, process and plant specific and should consequently be considered as guidelines. Furthermore this is “the state of art in June 2001” and may need to be adjusted in the future. The guidelines cover background information, general considerations, processing operations, equipment considerations, general plant sanitation, employee personnel hygiene and sampling to assess control of *L. monocytogenes* in the processing environment. Major parts of this document were inspired by the article “Guidelines to Prevent Post-Processing Contamination from *Listeria monocytogenes*” by R. Bruce Tompkin, V. N. Scott, D.T. Bernard, W H. Sveum and K. Sullivan Gombas, printed in Dairy, Food and Environmental Sanitation, Vol 19, No 8, pages 551-562.

### Background

Due to the halotolerant and psychrotrophic nature, *L. monocytogenes* tolerates the production parameters (salting, cold smoking, cooling, freezing) and preserving parameters (low temperature, salt and vacuum packaging) of cold smoked salmon and consequently there is no elimination step. As these products are not heat treated by the consumer and the organism may multiply to considerable numbers at refrigeration temperatures, the products must be considered high risk products with respect to *L. monocytogenes*. It should, however, be emphasized that only very few outbreaks of listeriosis have been linked to ready-to-eat seafood products.

Research over the last few years points to contamination during processing as the primary source of *L. monocytogenes* in many food products. Some investigations have also shown that a reservoir of *L. monocytogenes* can be established in the processing plant environment. The ways in which *L. monocytogenes* may be introduced in the cold-smoked salmon processing plants are numerous. The bacterium is a natural part of the general environment and the raw fish could be an important source for contaminating the processing equipment and environment. Because *L. monocytogenes* will continue to be introduced into a plant’s environment, control must be directed toward preventing its establishment and growth in the environment. Therefore an environmental sampling and testing program is the best measure of control. A total elimination of *L. monocytogenes* from the processing environment may be impossible, as reintroduction of the organism is likely to occur. Therefore it is possible to minimize, but not completely prevent, the risk of product contamination.

### General Considerations

The primary points of potential contamination with *L. monocytogenes* will potentially include all sites that come into direct contact with the unpacked product. Examples of such sites leading to product contamination include:

- Direct product contact surfaces (injection-, slicing- and packaging equipment, conveyors)
- Personnel who handle the product (hand tools, gloves, clothes)
- Items which may come into direct contact with product (brining solution, water or ice used in processing or storage)

The secondary sources of potential contamination with *L. monocytogenes* include the immediate processing environment. These areas may harbor the organism and under certain conditions lead to contamination of the product or product contact surfaces. Examples of such secondary sources include:

- Floors
- Drains
- Walls
- Ceilings
- Condense
- Other equipment which may be in the immediate area but are not intended for direct product contact (cleaning tools, trolleys, maintenance tools)

The tertiary level of concern is the potential for cross-contamination by *L. monocytogenes* brought into the clean environment. This may result from:

- Traffic in the processing and packaging areas (both people and equipment)
- Other areas that may have an impact on the environmental conditions in the exposed product areas (passageways, lunchrooms)

The stringency of *Listeria* control in those three zones varies and obviously must be stricter the closer to the product. Also, drains (secondary area) can be an important source of residing organisms spreading e.g. during cleaning. Therefore specific procedures (e.g. alkaline or citric acid treatment) may be used to eliminate the bacterium from drains. Obviously, care must be taken not to use procedures that corrode the material.

### **Processing operations**

Raw salmon may be contaminated with *L. monocytogenes*, although the presence of the organism and the levels of contamination vary widely. Because of this potential, raw fish should be managed as if they are contaminated. Thus, steps should be taken to prevent cross-contamination from raw fish to semi-finished and finished products, by separation the processes. In other words during the workday it is essential that potential contamination is not transferred from the tertiary level of concern to the secondary and/or primary points of potential contamination with *L. monocytogenes*.

- The flow of product through the operations from the raw fish to the finished product should be linear. It may be necessary to rearrange plants and/or practices to improve the flow. It is also desirable to establish positive airflow on the “product” side of the operation relative to the “raw material” side
- Traffic flow patterns between the raw fish area and the processed area must be controlled to prevent transfer of *L. monocytogenes*. Thus equipment, utensils and people in raw and processed areas should not be interchanged during the workday.
- Compartmentalize operations should be installed to enhance the separation of raw fish and processed products. In the processing plant of cold smoked salmon the raw fish area including processes such as filleting and salting should be separated from the smoking area, the slicing/product area, packaging and storage area. Preferably filleting should also be separated from for example the ice removing of the fish to reduce traffic. Likewise, it is also preferable that conveyer belts transport waste products from the filleting to another room to reduce traffic. In that way wet process areas are isolated from other production areas, which is important. Standing water for example at the floor should be removed as soon as possible because contaminated water on floors can become an aerosol and move about the plant and contaminate product and product contact surfaces. Separate utensils, carts, racks, totes, equipment, cleaning utensils, etc., color coded where practical, should be used for different areas.



## Equipment considerations

Proper design and maintenance of equipment is essential.

- Equipment must be designed to facilitate cleaning and to minimize sites where microbial multiplication can occur and a niche being developed. Acceptability of the design from a microbiological and sanitation standpoint should be reviewed before any new or replacement equipment is acquired.
- Several plants have found that elimination of a point source of *Listeria* contamination is difficult using normal cleaning and disinfecting procedures. In such cases, steam disinfection (an hour at 71°C) has proven very effective. This requires that the equipment can withstand the procedure and that any electronic parts can be removed.
- Equipment must be properly maintained. Damaged, pitted, corroded, or cracked equipment should be repaired or replaced. Regular maintenance should be adopted too minimize breakdowns and the attendant risk of contamination during repair.

## General plant sanitation

Sanitation procedures designed to control *L. monocytogenes* should be used. Visual inspection is very important in verifying equipment cleanliness. Routine microbiological testing for example detection of total aerobic counts allows to developing a baseline for comparison purposes and detect a developing sanitation problem. However environmental testing for *L. monocytogenes* is the best measure of control.

- Successful control of *L. monocytogenes* requires consistency and attention to detail performing the cleaning and sanitation procedures. The cleanup crew should receive special training in proper procedures to control *L. monocytogenes*, as well as close monitoring and correction to improve and maintain a high level of performance.
- Rotating sanitizers (for example chlorine, acid-anionic, peracid and iodophors) into the sanitation program may provide for greater effectiveness. Considerations should also be given to using peracetic acid and peroctanoic acid have been shown to be effective against biofilms containing *L. monocytogenes*.

## Employee personnel hygiene

The personnel must be trained to understand the problem, the potential sources of the organism, and the specific controls the plant is employing for control of *L. monocytogenes*. With regard to hygiene matters, the fish industry has to adhere to the fish hygiene directive and the food hygiene directive or their national counterparts.

- Employee must clearly understand that the purpose of wearing clean garments and disposable gloves is to protect the product from contamination, not to protect employees from getting dirty.
- If an unclean surface is touched, then hands should be washed and gloves changed. Thereby potential contamination is not transferred from the secondary level of concern to primary points of potential contamination with *L. monocytogenes*.

## Sampling to assess control of *L. monocytogenes* in the processing environment

The data from an effective environmental sampling program can be used to detect trends indicating potential loss of control and enable timely corrective actions. In practice, a time lapse is likely between when a problem is detected and when the source is detected so that the correct actions can be made to eliminate the source.

Environmental sampling is used to:

- Assess the risk of product contamination
- Establish a baseline for when the facility is considered under control
- Assess whether the environment is under control
- Investigate a source of contamination so corrective actions can be implemented

Two factors determine the effectiveness of a *Listeria* control program, the design of the environmental testing program and the response to a positive finding. Each plant, product, and process must be evaluated and should establish its own *L. monocytogenes* monitoring program. It is recommended that both food contact surfaces (primary sources) and non-food contact surfaces (secondary sources of potential contamination with *L. monocytogenes*) be tested. The number of samples per site per day/week will depend on the plant performance. Thus during periods where the prevalence of *Listeria* increases, several samplings per day may be required. Such samplings can determine if particular spots (e.g. a brining or slicing machine) harbor the contamination. Sites in a plant where *Listeria* is known to be able to reside should be sampled regularly during routine surveillance.

**ANNEX 2.4. GUIDELINES FOR CONTROL OF *LISTERIA MONOCYTOGENES* IN CHEESE PROCESSING**

**(Based on documents of the German Milk Industry Association)**

**1. Apart from the usual hygiene measures the following rules are to be strictly followed:**

- The white/black areas should be separated by the following means: locked doors, strict access control, different colored clothing/shoes, extra warning signs etc..
- At the hygiene stations: shoe cleaning machine, foot baths (white + deep) (disinfection mats are not suitable) to prevent the infiltration of ground contamination. All toilets should be outside the white area.
- Repairs in the production area can cause problems. The possibility of an area workshop should be looked into. It is important that the workman also wear the correct clothing.
- Precautions to be taken by leaving and reentering the white area, e.g. changing of shoes/overcoat etc.. Sufficient change of clothing for permanent staff is vital and also that each has two (2) separate lockers (civilian + production clothing).
- Each production phase when possible should be in separate rooms, e.g. preparation – production – packaging etc.
- For trucks etc. should be kept separate - white or black areas – not both.
- The ventilation system should be carefully controlled. Especially if there is a risk of condensation/water gathering in the system.
- The requirements on personal hygiene should be strictly followed. Regular schooling is just as important as the controlling of personal hygiene standards.
- It is necessary to control the airfilters (only EU standards).

**2. Specific aspects to *Listeria***

- Drains must be easy to clean. High pressure spray guns should not be used. It is advisable to install stainless steel drains.
- By CIP cleaning a regular valve control is required. For the removal of crustations a change in cleaning material is required. Contact with the manufacturer is required to inquire about conditions of use: by what temperature? How long? Etc.
- Certain cleaning/sterilization agents (approved by DGHM or DVG) are suitable for the elimination of *Listeria*. It is important that the recommended concentrations are strictly followed.
- The gathering of condensation water/puddles etc. is to be avoided to reduce the growth of *Listeria* and to prevent product contamination. Floors must be smooth, even and easy to clean.
- In the production area, transport containers and the maturing trays should be made of stainless steel.
- Certain accessories should be carefully controlled and where possible removed, i.e. stop valves, pipe seals, unscaled cavities, smooth, CIP cleanable surfaces.
- For the surfaces of different materials (plastic/steel/ceramics) apply different distances by cleaning.
- Regular dismantling of machinery (depending on conditions)
- Observe cleaning sequence (CIP cleaning ).
- Brushes used for smearing (not of wood) should be cleaned + disinfected daily, brushes made of plastic should be controlled for perforations. These brushes should be renewed at regular intervals
- Milk spillage should be removed from the floor. Immediately!

- In connection with the personnel demands and the hygiene schooling it should be emphasized that:
  - dropped cheese is not to be replaced on shelving. Problems arise when the cheese has to be returned per hand. When gloves are worn they should be changed after every break. Also to be noted that hand should be disinfected before the gloves are put on.
- Conveyer belts on which the “bare” cheese travels and the packing machines also are to be regularly cleaned and the conveyor are to be regularly changed to avoid contamination.

### 3. *Listeria* monitoring

The following chart (Table 1 of Annex 2.4) is a tried and tested system. The test locations and frequency recommendations are not a maximal or minimal requirement. They are just guidelines. A set system that covers all different plants is not possible. Depending on size of production, quantity and variety of products each plant must develop its own system.

If during a routine control contamination is discovered, it is important that an investigation is carried out to discover the cause of the contamination (milk regulations), consideration should be given to walls, ceilings, drains.

Type of test	Frequency	Remarks
Drainage contents (production area)	Weekly - monthly	Random drains possible
Drainage contents (surrounding area)	Monthly – ¼ yearly	As above
Condensation in ventilation system	Monthly	As required
Spray-Water	Weekly - monthly	As above
Salted water bath	Weekly -monthly	
Cheese leftovers out of production machines	Weekly - monthly	
e.g. cutting knives, blades	Monthly	
Soft/blue/sliced cheese	Weekly - monthly	
Hard cheese	Monthly – ¼ year	
Sliced cheese	Monthly	Packaging material
Cheese near the end of shelf life	Monthly	
Sauermilk cheese Raw material store Ingredients store	weekly	
Noble cheese	Each charge	
End product	Daily charge	

### Annex 3: Establishing microbiological standards

#### ANNEX 3.1.: PERFORMANCE CRITERIA

When establishing performance criteria consideration must be given to the initial level of a hazard and changes occurring during production, distribution, storage, preparation and use of a product. A performance criterion of a finished product prior to consumption is preferably less but at least equal to the FSO and can be expressed by the following equation (1):

$$H_0 - \Sigma R + \Sigma I \leq \text{FSO} \quad (1)$$

Where: FSO = Food Safety Objective

$H_0$  = Initial level of the hazard

$\Sigma R$  = Total (cumulative) reduction of the hazard

$\Sigma I$  = Total (cumulative) increase of the hazard

FSO, and the performance criteria  $H_0$ , R and I are normally expressed in  $\log_{10}$  units.

Some performance criteria can be used to set microbiological criteria according to the Codex document (CAC/GL 21 – 1997) for instance for raw materials ( $H_0$ ). The microbiological criterion for *L. monocytogenes* in ready to eat foods in which no multiplication takes place, is another example of using a performance criterion for a finished product as basis for its establishment.

**ANNEX 3.2: ESTABLISHMENT OF SAMPLING PLANS FOR MICROBIOLOGICAL SAFETY CRITERIA FOR FOODS IN INTERNATIONAL TRADE**

**(Document prepared by the ICMSF for the Codex Food Hygiene Committee and discussed at its 29<sup>th</sup> meeting in 1996)**

**1. Introduction**

For certain foods Codex Alimentarius has developed microbiological criteria, but for many other foods such criteria do not exist. However the “Principles for the Establishment and Application of Microbiological Criteria for Foods”, (ALINORM 97/13 Appendix III) describe how such Criteria should be developed. The text clearly describes the principles, but it lacks details concerning sampling plans and their interpretation. This document is intended to provide further guidance and discussion of sampling plans for *L. monocytogenes*.

**2. Establishment of microbiological criteria**

According to the “Principles for the Establishment and Application of Microbiological Criteria for Foods”, consideration should be given to:

- evidence of actual or potential hazards to health,
- the microbiology of raw materials,
- effect of processing,
- likelihood and consequences of contamination and growth during handling, storage and use,
- the category of consumers at risk,
- the cost/benefit ratio of the application and
- the intended use of the food.

These considerations are of a very general nature and apply to all foods. When dealing with specific foods, decisions must be made where criteria are to be applied in the food chain and what would be achieved by applying them.

**3. Sampling plans**

In ALINORM 97/13 Appendix III, in developing sampling plans, the severity of the hazard and assessment of the likelihood of its occurrence must be considered. A scientific rationale for the development of sampling plans has been developed and published by the ICMSF (1986).

The ICMSF approach distinguishes three categories of hazards based upon the relative degree of severity :

- severe hazards,
- moderate hazards, potentially extensive spread,
- moderate hazards, limited spread.

This categorization and the examples presented in Table 1 were based on the best epidemiological data available at the time of publication. Those categories may need to be revised as a result of new risk assessment procedures.

**Table 1. Categories of hazards**

<b>Severe :</b>	<b>C. botulinum V. cholera 01 S. typhi</b>
<b>Moderate, potentially extensive spread :</b>	<b>Salmonella (non typhi) Enterotoxigenic E. coli Shigella (non dysenteriae I)</b>
<b>Moderate, limited spread :</b>	<b>S. aureus V. parahaemolyticus B. cereus</b>

The other factor to be considered is the likelihood of occurrence, taking account of the anticipated conditions of use. Here the ICMSF again recognizes three categories:

- situations where the hazard would decrease,
- situations where the hazard would increase and
- situations where the hazard would remain the same.

Combining the three levels of severity with the categories of likelihood of occurrence, leads to different levels of concern called “cases” by the ICMSF, case 7 being of lowest concern to food safety and case 15 of the highest.

Taking into account the severity of the hazard, cases 9, 12 and 15 represent the highest levels of concern because they refer to situations where pathogens can multiply in the food under expected conditions of handling, storage, preparation and use. Cases 7, 10 and 13 represent the lowest levels of concern, because they refer to intermediate situations of concern where the degree of the hazard is likely to be reduced before consumption, for instance during preparation. Cases 8, 11 and 14 refer to situations where the degree of the hazard would remain the same between the time of sampling and the time of consumption.

Based on these nine cases, the ICMSF developed 2-class sampling plans in which “n” indicates the number of sample units to be tested and “c” the number of defective sample units which can be accepted. These sampling plans are summarized in Table 2. The plans direct more of the available resources for analysis towards those situations with a high level of concern. In most cases the weight of the analytical unit is 25 g, but the stringency of the sampling plan can be changed further by using other weights or volumes.

**Table 2. Plan stringency (Case) in relation to degree of health hazard and conditions of use**

Type of Hazard	Conditions in which food is expected to be handled and consumed after sampling in the usual course of events.		
	Reduce Degree of Hazard	Cause No Change in Hazard	May Increase Hazard
Health hazard moderate, direct, limited spread	Case 7 n = 5, c = 2	Case 8 n = 5, c = 1	Case 9 n = 10, c = 1
Health hazard moderate, direct, potentially extensive spread	Case 10 n = 5, c = 0	Case 11 n = 10, c = 0	Case 12 n = 20, c = 0
Health hazard Severe, direct	Case 13 n = 15, c = 0	Case 14 n = 30, c = 0	Case 15 n = 60, c = 0

n = the number of sample units tested,

c = the number of defective sample units which can be accepted

Although, for instance, examining 60 sample units may seem to be a high number; in practice, analytical sample units can be composited to reduce considerably the workload.

At a given % defectives, the number of sample units examined determines the probability of detecting lots of foods that are contaminated. The limitation of sampling is that it is neither practical nor cost-effective to attempt to detect, with a high degree of confidence, low levels of contamination in processed or prepared food. It must be realized that only positive results are meaningful, while negative results provide the level of confidence set by the number of sample units tested, assuming that there is a homogeneous distribution of the pathogen in the lot. For example, finding no defectives after testing 5 sample units gives 95% confidence that a lot is less than 50% contaminated, 30 samples that the lot is less than 10% contaminated; and 300 samples that the lot is 1% contaminated. This is a significant limitation of using microbiological testing of samples to assure food safety or to verify the effective implementation of HACCP.

Sampling plans must be included in the microbiological criteria inserted in the Codex documents. Those criteria should be regarded as minimum requirements to be met (safety objectives). Once the criteria have been established, the ICMSF emphasizes that routine testing of all imported foods is impractical, unnecessary, and not recommended. The decision to test must be made by regulatory authorities if it is not possible to judge the acceptability of the food on the basis of other factors.

Examples of factors that may influence whether or not to test an imported food for which microbiological criteria have been established are:

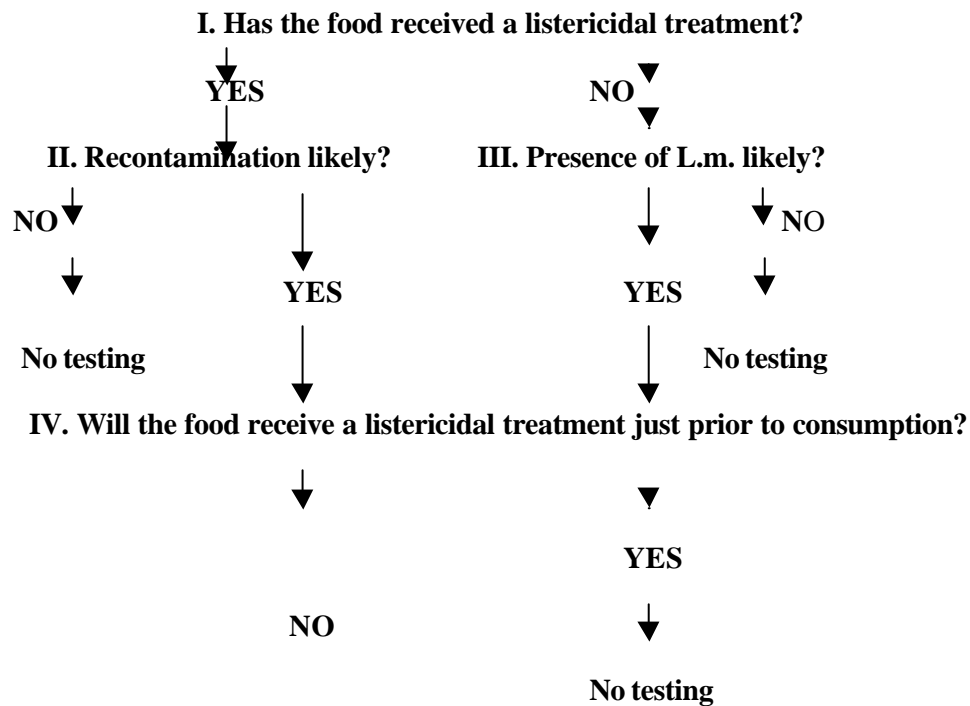
- Supplier's history of compliance with:
  - GMP
  - HACCP
  - Criteria, including microbiological criteria
- New information linking the food commodity with foodborne illness
- Whether the food is:
  - commonly involved in disease
  - primarily destined for sensitive population
- The country of origin is:



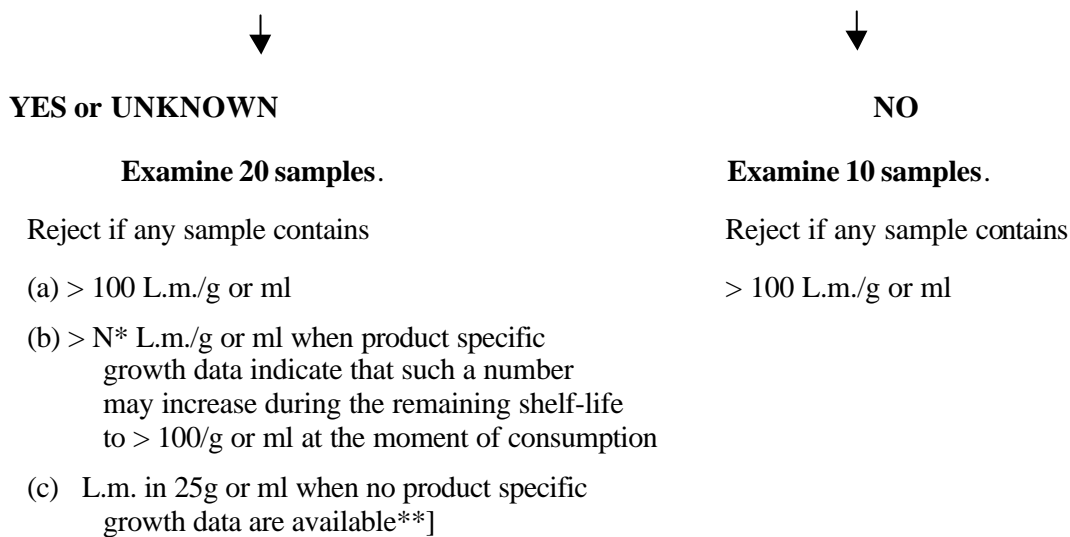
known to exercise control over the food  
not in an area with endemic disease of importance to food safety

- Practical considerations such as:
  - cost/benefit
  - the statistical limitations of the sampling plan for differentiating acceptable from unacceptable lots, particularly when a low level of defective units is expected.

**Annex 3.2: Figure 1: Decision tree for application of sampling plans for foods in international trade**



**V. Is it likely that multiplication to levels >100/g or ml at the moment of consumption will take place during the intended conditions of storage, distribution and use?**



\* N depends on the time of examination before consumption and the growth rate of *L.m.* in the product under the prevailing shelf-life conditions

[\*\* This is an exceptional situation because reliable growth rates can be predicted with available models when parameters such as pH,  $a_w$ , temperature are known.]

**NB:** If the food is specifically intended for highly susceptible individuals, the number of samples should be increased from 10 to 30, and from 20 to 60; reject if any sample contains *L. monocytogenes*. in 25 g.

### Annex 3.2: Explanation of the *Listeria monocytogenes* decision tree

#### *Question I: HAS THE FOOD RECEIVED A LISTERICIDAL TREATMENT ?*

The answer should be YES for all sterilized, pasteurized, cooked, fried, extruded etc. products. In this case, Question II has to be answered.

#### *Question II: IS RECONTAMINATION LIKELY ?*

The answer is NO for all products that received the treatment after packaging, or that were aseptically packed, filled etc.. In this case, no testing is recommended, because testing resources could be better used for other purposes.

If the answer is YES, because no in-pack treatment was applied and experience has shown that the product has been found contaminated in the past, or such information is not available, Question IV needs answered.

#### *Question IV: WILL THE FOOD RECEIVE A LISTERICIDAL TREATMENT JUST PRIOR TO CONSUMPTION?*

The answer depends on the normal preparation practices and instructions given by the manufacturer. If the heating can be relied upon as an adequate listericidal treatment, the answer is YES, and no testing is recommended. For all products eaten raw the answer is obviously NO, and question V has to be answered.

Question IV needs also to be answered when Question I was answered with NO, i.e., the food did not receive a listericidal treatment, and when

#### *Question III, i.e. IS THE PRESENCE OF L. MONOCYTOGENES LIKELY,*

was answered with YES. If Question III is answered with NO, again no testing is recommended. This is the case for many dry products, produced in dry (warm) environments and many other products where *L. monocytogenes* has not found a (cold) niche for multiplication.

#### *Question V: IS IT LIKEKLY THAT MULTIPLICATION TO LEVELS OF > 100/G OR ML AT THE MOMENT OF CONSUMPTION WILL TAKE PLACE DURING THE INTENDED CONDITIONS OF STORAGE, DISTRIBUTION AND USE?*

The acceptance of low numbers of *L. monocytogenes* (L.m.) in foods is closely related to the stability of foods against growth of *L. monocytogenes*. Such stability can be achieved by the use of a combination of several hurdles, which inhibit the growth of *L. monocytogenes*. The application of this concept is named hurdle technology, barrier technology or food preservation by combined processes. Therefore, in order to answer this question knowledge concerning intrinsic and extrinsic factors controlling the growth of *L. monocytogenes* in the product is necessary (see Guidelines for evaluation of the stability if a product, Annex 3.5):

If the  $a_w$  is below 0.90, or the pH below 4.5 or other values when combinations of such hurdles are used together with temperature control during the shelf life, the answer can be NO. In this case it is recommended to examine 10 samples, and to reject the lot when any sample contains >100 *L. monocytogenes* /g or ml.

When it is not known whether *L. monocytogenes* can multiply in the product under the prevailing conditions of storage and distribution, or how rapidly they can multiply it is recommended to examine 20 samples. This reflects to concept of taking a more precautionary approach. Clearly the lot should be rejected if any sample contains >100 *L. monocytogenes* /g or ml.

In any case where the stabilization of foods can be evaluated as being marginal or questionable it can be necessary to require documentation from the manufacturer that his product is stabilized against growth of *L. monocytogenes*. To provide such documentation it can be necessary over a period of time to carry out repeated shelf life studies on products found positive for *L. monocytogenes*. If natural contaminated material is not available challenge tests may be carried out. Also predictive modeling programs can be useful for research in this area or data are available from the safety records (market experience) of the product.

If these data concerning the multiplication rate in the product during the time and temperature conditions are available, the level of *L. monocytogenes* at the moment of examination can be calculated, which would ensure that no sample could reach the limit at the moment of consumption.

*Although it is suggested, for instance by the delegation of Denmark, to examine 25g samples for the presence of L. monocytogenes when Question V is answered with YES or UNKNOWN, this proposal is in this version of the discussion paper not retained. The report of the FAO/WHO risk assessment shows that reducing the levels of L. monocytogenes below 100/g or ml will have an enormous impact on the incidence of listeriosis. High levels of L. monocytogenes are a consequence of inadequate temperature and time control. Intervention measures should therefore directed at improving the temperature conditions of storage and distribution and adjusting the shelf life time where necessary. Keeping the limit of L. monocytogenes at < 100/g or ml at the moment of consumption in the microbiological criterion would support the intervention strategy and prevent that products may be rejected for reasons that are scientifically not justified.*

**ANNEX 3.3. GUIDELINES FOR EVALUATION OF THE STABILITY OF A PRODUCT AGAINST GROWTH OF *LISTERIA MONOCYTOGENES*:**

The evaluation of the stability of foods against growth of *L. monocytogenes* is important for food manufacturers and food controlling authorities. In this respect the following **guidelines** can be used.

Stability achieved without limitation in shelf life:

- Freezing
- pH < 4,5
- pH < 5,0 + chilled storage
- aw < 0,90
- aw < 0,92 + chilled storage
- aw < 0,95 + pH < 5,5

Stability achieved with limitation in shelf life:

- Lactate 2% + chilled storage (max 4 weeks shelf life)
- Lactate 2% + nitrite 150 ppm + chilled storage (max 5 weeks shelf life)
- Lactate 2% + glucone-delta-lactone + chilled storage (max 5 weeks storage)

Foods are complex eco-systems and experience has shown that interactions among known and unknown hurdles can provide stability against growth of *L. monocytogenes* without fulfillment of above mentioned criteria. Factors of significance in this respect can be modified atmosphere, smoke ingredients, bacteriocins, bacterial competition, available nutrients etc.

**Appendix V****CLARIFICATION OF THE TERMS “HAZARD ANALYSIS” AND “RISK ANALYSIS”****HAZARD ANALYSIS vs. RISK ANALYSIS**

A hazard analysis is not synonymous with a risk analysis. The difference primarily lies in the entity that does the work, the output and the scope of analysis.

**Hazard Analysis**

A hazard analysis is normally carried out at a company level, is processing plant/commodity specific, and is usually done in conjunction with the development of a HACCP plan.

A hazard analysis involves both hazard identification and hazard evaluation. A hazard analysis considers all potential hazards that may be associated with a food. The hazard analysis considers the nature of the hazard(s), the extent of the hazard(s) in the food under consideration and a determination as to the need to control the hazard(s) to assure the safety of the food (i.e., that the level of protection for the hazard(s) in the food is achieved). In the context of HACCP, a hazard analysis determines the potential hazards that are significant, i.e., reasonably likely to occur in the absence of control of control, and thus should be addressed in the HACCP plan.

In conducting a hazard analysis, wherever possible the following should be included<sup>1</sup>:

- The likely occurrence of hazards and severity of their adverse health effects;
- The qualitative and/or quantitative evaluation of the presence of hazards;
- Survival or multiplication of microorganisms of concern;
- Production or persistence in foods of toxins, chemicals or physical agents; and,
- Conditions leading to the above.

While a hazard analysis has a number of factors in common with the risk characterization phase of a risk assessment, they differ in their focus and intent. The hazard analysis is directed to the development of a risk management strategy whereas the hazard characterization's focus is on the determination of the relationship between the extent of exposure to a hazard and the frequency and severity of adverse public health events. Typically, hazard analyses are qualitative in nature while risk characterizations are ideally quantitative in nature.

**Risk Analysis**

A risk analysis is normally carried out by regulatory authorities, or a unit larger than an individual company, and focuses on the control of an industry-wide public health problem (e.g., listeriosis in ready-to-eat food). Risk analysis is a complex activity that encompasses risk assessment, risk management and risk communication. The outcome of risk analysis is normally a determination of the level of risk from the hazard to one or more populations, preferably expressed in a quantitative fashion, the development of one or more options to manage the risk, and the development of recommendations to communicate the management of the risk to consumers.

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<sup>1</sup> From the HACCP Annex to the *Recommended International Code of Practice: General Principles of Food Hygiene*, CAC/RCP-1, 1969 Rev. 3 (1997).

### **Interrelationships Between Hazard Analysis and Risk Analysis**

Much of the information required for the hazard analysis will also be required for components of risk analysis. For example, determining the source of the hazard, the prevalence and level of the hazard in the food, determining disease incidence and types and severity of adverse effects, determining the populations affected and determining means through which the hazard can be controlled are all elements that are common to both hazard analysis and risk analysis.

As a specific example, many of the elements of hazard analysis will also be required for several of the components of risk assessment, particularly the hazard identification, hazard characterization and exposure assessment components. The output of a risk assessment is a qualitative or quantitative estimate of the likelihood of an adverse consequence due to exposure to a hazard. The results of a risk assessment permits risk managers to better select the most appropriate food safety control measures. The results of a risk assessment may also help to refine a hazard analysis.

Additionally, elements of a hazard analysis are components of the risk profile portion of risk management. A risk profile involves describing the food safety problem and its context for the purpose of identifying those elements of a hazard or risk that are relevant to the risk management decisions; the elements of a hazard analysis outlined above are often elements of a risk profile. A hazard analysis is usually discussed in relation to specific processing establishments while a risk profile is discussed in relation to an industry-wide/country public health problem. However, conceptually, they are very similar.

One might also view HACCP (which contains the component of hazard analysis) as a plant/product specific risk analysis system which is based on a qualitative or semi-quantitative risk assessment and a qualitative or semi-quantitative risk management system.

## DEFINITIONS OF HAZARD, HAZARD ANALYSIS AND RISK ANALYSIS

Definitions for Hazard, Hazard Analysis and Risk Analysis are found within Codex texts as follows.

**Hazard**<sup>2</sup>: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**Hazard Analysis**<sup>3</sup>: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

**Risk Analysis**<sup>4</sup>: A process consisting of three components: risk assessment, risk management and risk communication.

## OTHER DEFINITIONS

For purposes of the following discussion, it may be helpful to also present Codex definitions for hazard identification, hazard characterization, risk, and risk assessment<sup>5</sup> and a proposed draft definition for risk profile<sup>6</sup>.

**Hazard Identification**: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.

**Hazard Characterization**: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response should be performed if the data are obtainable.

**Risk**: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in a food.

**Risk Assessment**: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Profile**: [A description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions.]

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<sup>2</sup> Codex Procedural Manual, 11<sup>th</sup> Edition, p. 46. Also in the Codex *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 3 (1997)), Section 2.3 and the HACCP Annex to this document.

<sup>3</sup> HACCP Annex to the Codex *Recommended International Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969), Rev. 3 (1997)).

<sup>4</sup> Codex Procedural Manual, 11<sup>th</sup> Edition, p. 48

<sup>5</sup> Codex Procedural Manual, 11<sup>th</sup> Edition, p. 48.

<sup>6</sup> From the Codex *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* (in preparation).



