

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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ALINORM 01/13A

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Twenty-fourth Session

Geneva, 2-7 July 2001

REPORT OF THE THIRTY THIRD SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

Washington DC, 23 -28 October 2000

NOTE: *This report includes Codex Circular Letter CL 2000/37-FH*

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CX 4/20.2

CL 2000/37 - 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-third Session of the Codex Committee on Food Hygiene (ALINORM 01/13A)

The report of the Thirty- third Session of the Codex Committee on Food Hygiene (CCFH) is attached. It will be considered by the Twenty-fourth Session of the Codex Alimentarius Commission, Geneva, 2001.

A. MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

1. Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables at Step 5, ALINORM 01/13A, paras 31-82 and Appendix II.

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 5 (*Procedural Manual of the Codex Alimentarius Commission*, Eleventh Edition, page 22). 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 (fax: +39 (06) 570.54593 or E-mail: codex@fao.org) **before 1 April 2001.**

B. REQUEST FOR COMMENTS AND INFORMATION ON:

1. Food Safety Objectives (FSO), as presented in Section 5.2.1.1 of CX/FH 00/6 of the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management. See also paras 83-95 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 the Governments and interested international organizations to provide information and views of Food Safety Objectives as presented in Section 5.2.1.1 of CX/FH 00/6 and, if possible, examples of FSOs. 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 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 **before 1 April 2001.**

2. Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods. See also paras 111-119 of this report.

Member Governments and interested international organizations are invited to provide their comments on the current document CX/FH 00/9. 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@bmv.g.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 **before 1 April 2001**.

3. Development of the Guidelines on the Application of HACCP in Small and/or Less Developed Businesses. See also paras 120-133 of this report.

While considering the Discussion paper on the Application of HACCP in small and/or Less developed Businesses (SLDBs), the Committee concluded that the document was useful, and there was general support to further elaborate it, therefore agreed to amendment to the existing HACCP Guidelines without altering the seven HACCP principles. Member Governments, especially from developing countries, and interested international organizations are invited to provide their comments on the current document CX/FH 00/10 on how to further develop the Guidelines. Comments should be forwarded to **Dr Jaap Jansen**, Ministry of Health, Welfare and Sports, P.O. Box 16108, 2500 BC Den Haag, The Netherlands, Fax: (31) 70 340-5435, E-mail: jaap.jansen@kvw.nl 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 **before 1 April 2001**.

4. Amendment to the Terms of Reference for the Committee (ALINORM 01/13A, Appendix III)

Governments and interested international organizations are invited to provide their comment on the above subject matter and should do so in writing to the 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) **before 1 February 2001**.

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SUMMARY AND CONCLUSIONS

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

MATTERS FOR ADOPTION BY THE CODEX ALIMENTARIUS COMMISSION:

- Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables at Step 5, ALINORM 01/13A, (paras 31-82 and Appendix II).

MATTERS FOR CONSIDERATION BY THE CODEX ALIMENTARIUS COMMISSION:

The following new work is proposed on:

- Proposed Draft Guidelines for the Control of *Listeria monocytogenes* in Foods (paras 111-119).;
- Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983) (para. 150).

The advice of the CAC is sought for:

1) Amendment to the HACCP Guidelines.

While considering this matter the Committee concluded that the discussion paper on the Application of HACCP in Small and/or Less Developed Businesses (SLDBs) was useful and there was general support to elaborate it further, therefore agreed to the amendment to the existing HACCP Guidelines without altering the seven HACCP principles and to inform the CAC (paras 120-133).

2) Coordination of work for antimicrobial resistance

Recognizing the importance of the issue of antimicrobial resistant bacteria in food and that the paper was prepared in a form of risk profile, as it was requested by the 47th Session of the Executive Committee, the Food Hygiene Committee agreed to ask the advice of the Commission on how to proceed with this issue in order to ensure coordination of work (paras 134-142).

OTHER MATTERS OF INTEREST TO THE COMMISSION:

The Committee:

- Identified and agreed on the questions to be raised by risk managers to risk assessors of the *ad hoc* Expert Consultation on Microbiological Hazards in Foods in relation of *Listeria monocytogenes* in ready to eat foods and *Salmonella* Enteritidis in eggs as well as *Salmonella* spp. in eggs, and suggested priorities for the next FAO/WHO Expert Consultation (see paras 14-25);
- Agreed to inform the Commission of its needs for a process for interaction between the Committee and the *ad hoc* Expert Consultations on Microbiological Risk Assessment (see paras 26-27);
- Returned to Step 3 for redrafting the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management while seeking the additional comments on Food Safety Objectives (see paras 83-95);
- Returned to Step 3 for redrafting the Proposed Draft Code of Hygienic Practice for Milk and Milk Products on the basis of comments received and discussions held during the session and to circulate it for further comments and consideration (see paras 96-102);
- Returned to Step 3 for redrafting the Proposed Draft Guidelines for Hygienic Reuse of Processing Water in Food Plants and further consideration by the Committee (paras 103-110);

- Agreed to consider further Discussion papers on Antimicrobial Resistant Bacteria in Food (see paras 134-142), on Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures (see paras 143-145), on Proposed Draft Guidelines for Evaluating Objectionable Matter in Food (see paras 146-147) and, in order to respond adequately to the referral of the Executive Committee, on Hazard analysis and Risk analysis (see para 153);
- Agreed that the term "Suitability" should be considered within the framework for the Code of Hygienic Practice for Milk and Milk Products (see para. 152);
- Considered holding the next meeting of the Committee in a developing country (Thailand) (see para 155).

MATTERS REFERRED TO OTHER COMMITTEES:

The Committee:

- Requested the Committee on General Principles to consider the proposed amendments to its Terms of Reference (see paras 28-30 and Appendix III);
- Drew the attention of the Committee on General Principles to the importance of reaching a resolution on the issue of precaution in order to make progress on the document on the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (see paras 83-95).

LIST OF ABBREVIATIONS USED IN THIS REPORT

ALA	Asociation Latinoamericana de Avicultura
CAC	Codex Alimentarius Commission
CCGP	Codex Committee on General Principles
CCFH	Codex Committee on Food Hygiene
COMISA	Confédération mondiale de l'industrie de la santé animale
CRD	Conference Room Document
EC	European Community
EXEC	Executive Committee of the Codex Alimentarius Commission
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
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OIE	Office international des epizoöties
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 33RD SESSION OF THE CODEX COMMITTEE ON FOOD HYGIENE

INTRODUCTION

1. The Codex Committee on Food Hygiene (CCFH) held its Thirty-third Session in Washington DC, USA, from 23 to 28 October 2000, hosted by the Government of the United States of America. The Session was chaired by Dr Ina K. Wachsmuth, Deputy Administrator, Office of Public Health and Science, Food Safety and Inspection Service, United States Department of Agriculture. The Session was attended by 262 participants representing sixty seven Member countries and eighteen International Organizations. A complete list of participants is included as Appendix I to this report.

OPENING OF THE SESSION

2. Dr Wachsmuth, as Chairperson of the Committee, welcomed the delegates and opened the Session. She advised that for the first time in the history of Codex a Committee Session would be broadcast on the world-wide-web. She expressed the wish that this would increase public awareness and transparency, and that the work of the Committee could be viewed by people who were not able to attend this meeting.

3. Ms Caren Wilcox, Deputy Under Secretary for Food Safety, Office of the Under Secretary for Food Safety, US Department of Agriculture also welcomed the delegates and emphasized the fundamental work of the Committee in the area of food safety and microbiological risk assessment. She also pointed out that all countries were coming under increased pressure to apply the HACCP principles and therefore the experience of the US in implementing HACCP in small business might be a useful guide to other countries.

4. Dr Jorgen Schlundt, Coordinator of the WHO/Food Safety Programme, at the request of the Host Government, made a presentation entitled "A Framework for Providing International Microbiological Risk Assessment Advice." In his presentation, Dr Schlundt described the recent activities of FAO and WHO as well as the Codex Alimentarius Commission regarding microbiological risk assessment/management. He stressed the need for further national and international cooperation and collaboration and especially emphasized the need to ensure the full participation of developing countries in handling this global issue.

ADOPTION OF THE AGENDA (Agenda Item 1)¹

5. The Committee adopted the Provisional Agenda as the Agenda for the Session, and agreed to consider a Discussion paper on the term "Suitability" (CRD 5) and an amendment to the Terms of Reference of the CCFH (CRD 7) under Agenda Item 15 "Other Business and Future Work".

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

6. The Committee noted matters arising from the 47th Session of the Executive Committee; the 15th Session of the Codex Committee on General Principles; the 32nd Session of the Committee on Food Additives and Contaminants; the 24th Session of the Committee on Fish and Fishery Products; the 4th Session of the Committee on Milk and Milk Products; as well as general matters from FAO and WHO.

7. The Committee decided to consider referrals concerning Heat Treatment Definitions, Antimicrobial Resistance and Food Safety Objectives under the relevant Agenda Items.

¹ CX/FH 00/1, CRD 5 (prepared by New Zealand), CRD 7 (comments of the USA).

² CX/FH 00/2

CAC Chairperson's Action Plan

8. Mr. Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA, and Chairperson of the Codex Alimentarius Commission, introduced the Chairperson's Action Plan. He indicated that as Chairman of the Codex Alimentarius Commission (CAC) he would promote initiatives in the following major areas in order to progress the work of Codex:

- increasing the speed and efficacy of the Codex process by holding CAC meetings every year, forming a new committee to assist the Chairman and Secretariat at Commission meetings and converting the commodity committees into task forces with sunset provisions;
- further strengthening scientific support in the decision-making process by restructuring the scientific expert bodies and developing the clear guidelines for their work;
- increasing the participation of developing countries by establishing a trust fund and by regularly holding a regular Codex meetings in developing countries;
- increasing transparency and the participation of NGO's through inclusion of NGO's as Observers to the Executive Committee meetings;
- split the CCFAC into two committees;
- increasing total support to Codex by the parent organizations by encouraging the World Health Organization (WHO) to match the level of support provided by FAO;
- increasing the use of new information technologies, such as Internet web casts, home pages and chat rooms, in order to improve communication and support for Codex.

9. Mr Billy informed the Committee that the Action Plan, when finalized, would be sent to Member Governments for their input and be placed on the Provisional Agenda of the Executive Committee next year. Finally, Mr Billy wished to begin the new millennium by taking a variety of steps to strengthen Codex as the internationally recognized body for deliberations regarding food safety, consumer health and fair trade.

Risk Analysis and Hazard Analysis

10. With respect to the referral of recommendations to the CCFH from the Executive Committee regarding the *Difference between the terms Risk Analysis and Hazard Analysis*, the Committee agreed that in order to eliminate confusion between those terms more detailed consideration would be necessary under "Other Business and Future Work" (see also para 150).

11. The Committee concluded that the recommendation regarding the *Quality Criteria for the Data Used for Risk Assessment* was relevant to experts engaged in risk assessment. The Committee noted the recommendation regarding the use of global data as a basis for risk assessment, and in particular including epidemiological surveillance data and exposure studies from developing countries.

Revision of the Code of Hygienic Practice for Meat and Poultry Products

12. The Committee expressed its support for the revision of the Codes of Hygienic Practice for Fresh Meat and Game and the drafting of a new code for Poultry by the Committee on Meat Hygiene while noting that there should be an interaction between both committees and that the revision be carried out in conformity with the Recommended International Code of Practice – General Principles of Food Hygiene.

Proposed Draft Code of Practice for Fish and Fishery Products

13. The Codex Secretariat reminded the Committee that the above Proposed Draft Code would be submitted to the 34th session of the CCFH for endorsement of the provisions on food hygiene. The Code had been appended to the report of the 24th Session of the CCFFP (ALINORM 01/18) and therefore was available to Member Countries for review.

PRELIMINARY REPORT OF THE *AD HOC* EXPERT CONSULTATION ON RISK ASSESSMENT OF MICROBIOLOGICAL HAZARDS AND RELATED MATTERS (Agenda Item 3)³

14. The Representatives of FAO and WHO introduced this Agenda Item and informed the Committee that in response to the request of the 32nd Session of the CCFH for expert advice on risk assessment FAO and WHO have undertaken a joint programme of work on microbiological risk assessment. This work focussed on the first two pathogen-commodity combinations identified as priority issues by the 32nd CCFH – *Listeria monocytogenes* in ready-to-eat foods and the *Salmonella* in poultry and eggs. The latter was divided into *Salmonella* Enteritidis in eggs and *Salmonella* spp. in chicken (broilers). The work carried out to date included hazard identification, hazard characterisation and exposure assessment. The final part of the risk assessment, risk characterization, will be carried out next year. It was pointed out that this risk assessment work was now at a critical crossroad and in order to proceed some specific risk management guidance was required.

15. A number of delegations expressed their appreciation for the body and quality of the work that had been undertaken by the joint FAO/WHO Expert Consultations in the past year. The Delegation of the US pointed out that clearly identifying the needs of the risk managers (i.e. CCFH) was the key issue to be addressed by CCFH. The Delegation of New Zealand suggested that the following areas be considered in the development of specific risk management questions - what is most useful to national governments; what is the programme of work of the CCFH; and are there trade related issues where risk assessment could be useful, for example in relation to equivalence or appropriate level of protection. The Delegation of France brought the Committees attention to CRD 19, which outlined the risk management questions proposed by the European Union. It was pointed out to the Committee that there was an Agenda Item relating to the management of *L. monocytogenes* in foods and that this be considered as a resource in formulating risk management questions.

16. Some delegations expressed concern regarding the ability of the FAO/WHO Expert Consultations to finalise a risk assessment next year considering that gaps in data still existed. In acknowledging this concern the Representatives of FAO and WHO assured the Committee that this work was a dynamic process whereby documents would be revised and updated, as more information became available.

17. The Representatives of FAO and WHO informed the Committee that the availability of data was one of the limiting factors in doing risk assessment and therefore, there was a need to generate additional data relevant to risk assessment. It was pointed out that during the past year accessing and collecting existing relevant data had been a particular problem. It was noted that one of the main reasons for this was the lack of mechanisms to collect and disseminate data available in different ministries and institutions. The Delegation of India referred to difficulties in collecting data in developing countries. It highlighted the need for assistance from FAO and WHO to generate these data and indicated that consideration should be given on how to improve data collection in both developing and developed countries. Some means of doing this might be to use regional centers, and the FAO and WHO regional offices. The Delegation of India further emphasized the need to make the microbiological risk assessment studies based on global data so that conclusions reached and actions to be taken were appropriate and available for all countries. The Delegation of Philippines pointed out that countries had difficulties in collecting data if their food safety policy did not include provision for this.

18. The Representatives of FAO and WHO provided the Committee with some examples of possible risk management questions for consideration by the risk assessors. In order to discuss this issue in a comprehensive manner and develop specific risk management questions an *ad hoc* Working Group, open to all delegates, was convened. The output of this working group was discussed in plenary and the following questions and recommendations put forward to the Joint FAO/WHO ad hoc expert consultations on microbiological risk assessment through FAO and WHO.

³ CX/FH 01/3, CRD 6 (comments of USA), CRD 7 (comments of USA), CRD 13 (comments of Finland), CRD 14 (comments of China); CRD 19 (European Community).

Questions and recommendations from the risk managers to the risk assessors for *Listeria monocytogenes* in ready to eat foods

- Estimate the risk for consumers in different susceptible population groups (elderly, infants, pregnant women, and immunocompromised patients) relative to the general population.
- 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.
- Estimate the risk from *L. monocytogenes* in food when the number of organisms ranges from absence in 25 g to 1000 CFU per gram, or does not exceed specified levels at the point of consumption.

19. The Committee identified other risk management questions which could be addressed by the expert consultations at a future date. These included estimating the change in risk likely to occur from specific interventions and evaluating the effect of strain variation of *L. monocytogenes* on the risk estimates.

Pathogenic *Salmonella* in chicken (broilers) and eggs

20. The Committee suggested that a useful approach for this pathogen-commodity combination would be the use of risk assessment to estimate the *relative risk*, which would focus on the change in risk relative to interventions rather than the risk estimate. Management interventions could then be ranked according to the decrease in risk resulting from the intervention.

Risk management questions for *Salmonella* Enteritidis in eggs

- Estimate the risk from *Salmonella* Enteritidis in eggs in the general population and in the various susceptible populations (e.g. elderly, children, immuno-compromised patients) at various prevalence and concentration levels of *Salmonella* Enteritidis in contaminated eggs.
- Estimate the change in risk likely to occur from each of the interventions below including their efficacy.
 - Reduce the prevalence of positive flocks
 - Destroy positive breeding and/or laying flocks.
 - Vaccinate egg laying flocks for *Salmonella* Enteritidis
 - Competitive exclusion
 - Reduce the prevalence of *Salmonella* Enteritidis positive eggs
 - Test and divert eggs from positive flocks to pasteurization
 - Reduce the number of *Salmonella* Enteritidis organisms in eggs
 - Heat treatment of egg products
 - Refrigeration of eggs after lay and during distribution
 - Require a specific shelf life for eggs stored at ambient temperatures

Risk management questions for *Salmonella* spp. in chicken (broilers)

- Estimate the risk from pathogenic *Salmonella* spp. in chicken (broilers) consequential to a range of levels in raw poultry for the general population and for various susceptible population groups (elderly, children, and immuno-compromised patients).
- Estimate the change in risk likely to occur for each of the interventions under consideration including their efficacy.
 - Reduce the prevalence of positive flocks
 - Destruction of positive breeder and chicken (broiler) flocks
 - Vaccination of breeding flocks
 - Competitive exclusion (e.g. with *Salmonella sofia*)
 - Reduce the prevalence of positive birds at the end of slaughter and processing
 - Use of chlorine in water chilling of chicken (broilers)
 - Water chilling vs air chilling for chicken (broilers)

- Evaluate the importance of various routes for introduction of pathogenic *Salmonella* into flocks including feed, replacement birds, vectors, and hygiene.
21. The Committee noted that a future question to be addressed in relation to pathogenic *Salmonella* in chicken (broilers) and eggs could be to model a range of risk reduction measures to facilitate risk management options assessment (this would not include cost-benefit analysis).
22. The Committee recommended that risk estimates for pathogens should always consider susceptible populations and suggested that the ad hoc expert consultations prioritize the gaps in data according to their importance in reducing the uncertainty of the risk estimates. The Committee acknowledged the need to finalize the current documents, and in addition, FAO and WHO should provide a means to update these risk assessments as new information becomes available.

Priority issues for future work

23. The representative of FAO reminded the Committee that the 32nd Session identified a number of priority issues for which it required expert risk assessment advice and suggested the revision of that list to take into consideration new food safety issues that may have arisen in the interim. FAO and WHO will consider this list in planning its future work. However, resource availability will affect the rate of progress of the work. It was suggested that Member Countries could assist in this process by hosting these expert consultations.
24. The Committee was of the view that the risk management questions to be addressed for *Campylobacter* in chicken (broilers) should be the same as those for *Salmonella* spp. in chicken (broilers) and suggested that a risk profile could be carried out to focus the work before embarking on the risk assessment. The Delegation of the US informed the Committee that it has completed a risk assessment of *Vibrio parahaemolyticus* in oysters and is willing to assist the ad hoc expert consultations. The European Community proposed that a separation be made between crustaceans, which are usually cooked before consumption, and bivalve molluscs which are filter feeders and can be eaten raw and to extend the work on microbiological risk assessment to other pathogenic vibrios such as *V. vulnificus*. Other priority issues identified by the Committee included quinolone resistant *Salmonella* and *Campylobacter* in poultry and histamine in fish. To better define future work, countries were encouraged to provide background information when they propose a pathogen-commodity combination for the consideration of the FAO/WHO ad hoc expert consultations.
25. However, the Committee recommended that any new work undertaken should not delay the progress of the current work.

Process for Interaction between the Committee and the *ad hoc* Expert Consultations on Microbiological Risk Assessment

26. The Secretariat informed the Committee that currently this matter fell outside the Terms of Reference of this Committee. However several delegations expressed the view that a process for more frequent interaction between the CCFH and the ad hoc expert consultations on risk assessment needs to be considered. The Delegation of the US introduced CRD 6, that presented as a suggested process for interaction between the CCFH and the *ad hoc* expert consultations. The Committee agreed to inform the CAC of its needs in this area.
27. In the absence of a formal process for interaction the following options could be used in the interim:
- The drafting group for the discussion paper, *Control of Listeria monocytogenes in food*, could act as a risk management advisory group for the risk assessment of *Listeria monocytogenes* in ready to eat foods.
 - An open internet discussion group could provide a means for interaction between interested risk managers and the *ad hoc* expert consultations through FAO and WHO.
 - A working group that would meet prior to the next Session of the Committee to facilitate discussion in the Committee.

Amendment to the Terms of Reference for the Committee

28. The Delegation of the US introduced CRD 7 to consider additional terms of reference for the Committee to facilitate its undertakings in the area of microbiological risk assessment. The Committee noted that, to date, the area of microbiological risk assessment and microbiological risk management were not specifically addressed in any of its Terms of Reference and that the work in these areas had been handled via Term of Reference “e”, through the approval of specific work items by the CAC.

29. The Committee acknowledged that the work in the area of microbiological risk assessment and risk management was very important internationally, in both protecting health of consumers and facilitating trade and it was likely that the Committee would have significant work in this area in the future. Therefore, the Committee expressed the need to amend its Terms of Reference to reflect this situation. These should address the relationship between the FAO/WHO Expert Consultations on Microbiological Risk Assessment (and any other body that may arise from them) through FAO and WHO and the Committee, and microbiological risk management activities the Committee may undertake.

30. The Committee agreed to ask the General Principles Committee to consider the amendment of additional Terms of Reference (see Appendix III to this report).

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRIMARY PRODUCTION, HARVESTING AND PACKAGING OF FRESH FRUITS AND VEGETABLES (Agenda Item 4)⁴

31. The Delegation of Canada introduced the document CX/FH 00/4 and highlighted the changes made in view of the comments made at the last session of the Committee. The Delegation indicated that a Proposed Draft Annex on Sprout Production was developed to cover hygienic practices specific to the primary production of seeds for sprouting and the production of sprouts for human consumption. The delegation indicated that many links between the Proposed Draft Code of Hygienic Practice for Primary Production and Packing of Fresh Fruits and Vegetables and the Proposed Draft Code of Hygienic Practice for Pre-cut Fruits and Vegetables were highlighted and that common issues were handled similarly where possible. The Committee considered the Proposed Draft Code, section-by-section, and made the following changes.

General comments

32. The Delegation of Italy, supported by Thailand, India and some other delegations, pointed out that the Proposed Draft Code had been developed for large scale industrialized production, while, in reality, in many countries of the world the production of fruits and vegetables was done by small producers with limited resources, and that some provisions of the document, such as requirements for testing, could add additional burdens to them. The Delegation of China supported comments of the Thailand delegation and advised the Committee that in China more than 70% of the population lived in the countryside and that in many areas the production of fruits and vegetables was based on traditional farming practices that did not appear to pose any greater health risk to consumers than industrialized production.

33. In view of those realities the Committee decided to provide more flexibility to accommodate traditional practices and methods of production around the world and inserted relevant wording in the Objectives.

34. The Delegation of France, speaking on behalf of the Member States of the European Union present at the Session, pointed out that there should be an adequate reflection on separation of the provisions relating to fruits and vegetables that had been washed from those that had not been washed, throughout the Code.

⁴ CX/FH 00/4; CX/FH 00/4-Add.1 (comments of Brazil, Denmark, Poland, Mexico and the United States of America); CRD 2 (comments of Peru); CRD 8 (comments of the European Community); CRD 17 (comments of Italy); CRD 20 (comments of Philippines); CRD 22 (comments of Brazil).

Section 2.1 Objectives and Section 2.2 Scope

35. To reflect last years discussion the title was changed to the “Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables”. The second paragraph in Section 2.2 was amended and moved to the Objectives Section in order to take into account the flexibility in the Code and to make this concept more visible.

Section 2.3 Definitions

36. The definitions of “*Agricultural worker*,” “*Biosolids*,” “*Hazardous material*,” and “*Manure*” were amended in order to make them more precise and flexible.

37. The Committee had an extensive debate on the type of definitions to be used for waters and on the content of the definition of “*Clean water*.” The Delegation of Austria supported by some other delegations indicated that clean water should be free from pathogens, while others argued that it was not always the case and questioned the exact criteria of this provision.

38. The Committee concluded that there was a justified need for two different types of waters (clean water and potable water) and agreed that the wording of the definition of clean water should be outcome-oriented and therefore amended this definition accordingly.

Section 3 Primary Production

39. In Section 3.1, *Environmental Hygiene*, the second bullet, regarding access of animals to the production site, was reworded in order to make it more practical.

40. The title of Section 3.2 was amended by inserting “primary” between “hygienic” and “production” to clarify the nature of the production.

41. In Section 3.2.1, specific reference to WHO Guidelines on the Safe Use of Wastewater and Excreta in Agriculture and Aquaculture was added.

42. The numbering of the sections on the waters, from 3.2.1.2 to 3.2.1.4, was rearranged to separate the water from the other agricultural inputs, (Section 3.2.1.2 became 3.2.1.1.1). Consequently, the numbering of remaining sub-sections throughout the Section, *Agricultural Input Requirements*, was also changed.

43. Bullets in sections 3.2.1.1 and 3.2.1.1.1 were amended to include the concept of prevention and with the aim of reducing the potential for chemical contamination.

44. In Section 3.2.1.5, *Manure, Biosolids and Other Natural Fertilizers*, the wording “where necessary” was inserted at the beginning of the last sentence of the introduction to provide more flexibility and the third bullet was amended as proposed by the Delegations of Canada and Belgium.

45. Section 3.2.1.6, *Soil*, was reworded to eliminate inconsistency and make it more general.

46. The Committee extensively debated the first bullet point in Section 3.2.1.4 regarding the use of antibiotics. Some delegations did not support the use of antibiotics in primary production of fruits and vegetables unless it was unavoidable and suggested that the reference to “antibiotics” be deleted while others favoured setting certain specific conditions for their use or had the opinion that antibiotics that were significant for the treatment of human and animal diseases should not be used in any case.

47. Some delegations indicated that antibiotics were used in the treatment of certain plant diseases as pesticides and that it was not possible to avoid completely their use.

48. The Delegation of the United Kingdom indicated that decisions about the uses of antibiotics were not matters for consideration by the Committee.

49. The Committee concluded that the use of antimicrobial agents to control plant diseases raised the need for more information on the degree to which the emergence of antimicrobial resistance was considered during the authorization of antimicrobial agents as “pesticides” and decided to request that

the Codex Committee on Pesticide Residues (CCPR) provide information on the procedures and criteria that CCPR used when establishing the appropriate uses of this class of pesticides.

50. The Committee agreed to substitute the term “antimicrobial agents” for “antibiotics”, delete the reference to the use of antibiotics in the first bullet point in Section on Agricultural Chemicals, and as a compromise agreed to insert three additional sentences containing provisions on residue levels and the appropriate uses of antimicrobial agents.

51. The fourth and the seventh bullets of this section were amended and a new bullet point, establishing an additional provision on containers used for agricultural chemicals, was inserted at the end of section. The term environment was clarified in the seventh bullet point.

52. In Section 3.2.1.5 the reference to “microorganisms” was deleted and in Section 3.2.2.2 one bullet point on control the quality of the water supply was added.

53. The first sentence in Section 3.2.3, Personnel Health, Hygiene and Sanitary Facilities was amended to recognize their importance at the time of harvesting. In the first bullet point in Section 3.2.3.1 the words “as much as possible” were deleted, and the reference to fingernails in the second paragraph in Section 3.2.3.4 were deleted.

54. At the end of Section 3.2.4 two new bullet points setting provisions on discarding containers and on equipment and tools were inserted. The last bullet point of Section 3.3.1 was deleted.

55. In the fourth bullet of Section 3.3.1 the word “potentially” was added and the wording “agricultural chemicals” were deleted from parenthesis.

56. A new sentence was inserted at the end of the first bullet point in Section 3.3.2 regarding the construction of storage facilities to reduce the opportunity for potential contamination, and the third bullet point was amended. The fourth bullet point of this Section regarding conditions for cleaning materials was deleted and moved to the end of introductory section 3.4 Cleaning, Maintenance and Sanitation.

57. The second bullet point of Section 3.4.1 was amended in order to accommodate more flexibility.

Section 5 Control of Operation

58. The Committee had an exchange of views regarding the use of disinfectants in post harvest treatment. The Representative of the European Commission proposed new wording, as contained in CRD 8, for the second bullet point in Section 5.2.2.1 to allow the use of disinfectants only where absolutely necessary. Some other delegations supported this view.

59. The Delegation of the United States indicated that disinfectants were useful tools for minimizing cross-contamination of fruits and vegetables and preferred the current wording of the Section.

60. The Delegation of Singapore pointed out that the focus of the second bullet point in the Section 5.2.2. was the use of disinfectants and not the use of water although the section dealt with post harvest water use, and suggested moving this section to Section 5.2.2.2 which dealt with chemical treatments. The Delegation of Nigeria indicated that the residue levels of disinfectants should be those established by the CAC.

61. The Committee, as a compromise, agreed to accept the wording suggested by Canada and to accommodate the wording of the CRD 8 into the current wording of the second bullet to stress that disinfectants should be used only where absolutely necessary.

62. The Delegation of the United States expressed its very serious concern on the decision taken.

63. In Sections 5.7 and 5.8 the wording “where appropriate” was inserted in order to provide more flexibility.

64. The title of Section 5.8 was amended in order to accommodate trace-backs.

Section 10 Training

65. Section 10.2, *Training Programmes*, was amended to stress the need for training on techniques for hygienic handling and storage.

Proposed Draft Annex for Sprout Production

Section 3.2.1.2 Manure and Biosolids

66. The wording in square brackets “used during the growing season” was deleted as proposed by the Delegation of Denmark.

Section 3.5 Analyses

67. The word “may” was substituted by “should”.

Section 5.2.2.1 Water Used for Sprout Production

68. Provisions regarding the presence of pathogens in clean water were deleted in the last sentence of the paragraph in this and Sections 5.2.2.4 and 5.2.2.5.

Section 5.2.2.3 Seed Disinfection

69. In order to clarify provisions regarding the use of disinfection materials, a new bullet point was added at the end of section. Regarding the concern of the Delegation of Denmark of possible health problems associated with the use of chlorine in the water for rinsing, and possible referral of this matter to the CCFAC and JECFA, the Committee recalled the information provided by the Secretariat on Agenda Item 2, that the similar issue was considered by the Fish and Fishery Products Committee (see ALINORM 01/18, paras 146-149 and the document CX/FFP 00/13) and it concluded that there was no adverse scientific evidence associated with the current use of chlorine and therefore no further action was necessary.

Section 5.2.2.5 Pre-germination soak

70. The word “clean” was inserted to clarify the type of water in the second bullet point.

Section 5.2.2.6 Germination

71. The second bullet point was amended.

Section 5.2.2.9 Storage of finished products

72. Section was amended to put more emphasis on minimization of microbial growth.

Section 5.3.1 Specifications for incoming seeds

73. The second bullet of this Section was amended to put less emphasis on testing of the incoming seeds and make it more outcome oriented.

74. The Committee complimented Canada and its drafting partners for their excellent work.

Status of the Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables

75. The Committee agreed to advance the Proposed Draft Code with its Annex for Sprouts to the 24th Session of the Codex Alimentarius Commission for adoption it at Step 5 (see Annex II of this report).

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PRE-CUT FRUITS AND VEGETABLES (Agenda Item 5)⁵

76. The Delegation of France introduced the document (CX/FH 00/5) which was prepared by a drafting group. The Delegation informed the Committee that it was made clearer in the revised draft that fresh fruit and vegetable juice were outside of the scope of the Code. The Delegation further stated that the drafting group, which discussed both the Code and the Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables, considered the possibility to consolidate the two Codes and that most of the delegations at the drafting group were favourable to merging the two codes.

77. The Committee expressed its appreciation to the Delegation of France and the drafting group for their valuable work. It discussed the appropriateness of merging the two Codes and agreed to attach the Code to the Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables in the form of Annex. The Committee also agreed to inform the 24th Session of the Commission accordingly. Following this decision, the Committee further agreed that the Code for pre-cut fruits and vegetables should avoid duplication with the Code for fresh fruits and vegetables and that only the provisions specific to pre-cut fruits and vegetables should appear on the code for pre-cut fruits and vegetables.

78. The Committee discussed the Code section by section, and made the following changes in addition to several editorial changes. The Committee noted that the words “Ready-to-eat fresh” should appear on the title to more precisely reflect the scope of the Code. In Section 2.1 on *Scope*, the Committee agreed to revise the text to further clarify that fresh fruit and vegetable juices are not covered by this code. In Section 2.3 on *Definitions*, the definitions on clean water, potable water, and micro-organisms were deleted as those definitions are covered by the Code for the Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables.

79. In Section 5.2.2.1 on *Receipt of raw materials* and in Section 5.2.2.2 *Trimming/Coring/ Inspection of Raw Materials*, the delegation of Germany proposed to replace the word “truck” with the words “vehicles and containers” as truck was not the only mean for transportation. The Committee agreed to replace the word “truck” with “food transportation unit” in accordance with the Code of Hygienic Practice for the Transport of Foodstuffs in Bulk and Semi-Packed Foodstuffs. Several delegations proposed that these two sections could be combined into a section entitled *Receipt and inspection of raw material* as both sections deal with raw materials. The Committee accepted this proposal and also agreed to add an additional sentence regarding trimming, rotting and moulding. The Delegation of the United States expressed the view that the two sections should be kept separated as the key concepts in the two sections were different.

80. In Section 5.2.2.3 on *Washing and decontamination*, some delegations stated that the provisions under this section were common to the Code for Fresh Fruit and Vegetables and that the reference to that Code was sufficient in order to avoid redundancy. Other delegations pointed out that washing and decontamination of pre-cut fruits and vegetables required special care different from that of fresh fruits and vegetables in primary production and that washing should be done by potable water. The Delegation of France indicated that potable water was not always used in the process for producing pre-cut fruits and vegetables and the quality of the water depended on the steps of the cleaning. The Committee noted these comments and agreed to amend the title and add a sentence to read as follows: “Water used for final rinses should be of potable quality, particularly for these products as they are not likely to be washed before consumption”.

81. In Section 5.2.2.7 on *Cold Storage*, the Delegation of Belgium pointed out that special conditions should apply to the cold storage of pre-cut fruits and vegetables to minimize microbiological growth. The Committee agreed on this point and the section was amended accordingly. In Section 5.7 on

⁵ CX/FH 00/5, CX/FH 00/5 Add.1 (Comments from Canada, Brazil, Denmark, Islamic Republic of Iran, Mexico, and the United States of America), CRD 1 (comments of Peru), CRD 9 (comments European Community), CRD 20 (comments of Philippine), CRD 22 (comments of Brazil).

Documentation and Record, the word “ where appropriate” were added to improve the flexibility of the Code in application of small businesses. In Section 10.2 on *Training Programs*, “importance of temperature control and GMP” were added as a subject to be covered as part of training.

Status of the Proposed Draft Code of Hygienic Practice for Ready-to-Eat Fresh Pre-cut Fruits and Vegetables

82. The Committee agreed to attach the Proposed Draft Code of Hygienic Practice for Ready-to-Eat Fresh Fruits and Vegetables to the Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables in the form of an Annex, and advance it to the 24th Session of the Commission for adoption at Step 5 (see also paragraph 75).

PROPOSED DRAFT PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT (Agenda Item 6)⁶

83. The Delegation of France introduced document CX/FH 00/6 and pointed out that it had been restructured and revised since the last Session to take into account the recommendations of the joint FAO/WHO Expert Consultation on Risk Management and Food safety as well as comments received from Member Countries. The Delegation advised that the main changes were made to section 5.1 - Initial Risk Management Activities. The term Food Safety Objective (FSO) was changed to Microbiological Food Safety Objective (MFSO), though it was noted that this concept needed further development. The drafting group noted that no consensus had yet been reached on the “Precautionary Principle” in the CCGP and that, to facilitate the discussions in CCFH, the extract of the CCGP report was annexed to the document.

84. The Committee expressed its appreciation to the work of the Delegation of France and the drafting partners. The Delegation of New Zealand stressed the importance of the development of these principles and guidelines for the future work of the Committee and indicated that Microbiological Risk Management was a new area of work for the Committee. The Delegation pointed out that although the initial framework for this work had been borrowed from chemical risk assessment/ management, it has now become apparent that microbiological risk management was very different and that interaction between the risk assessor and the risk manager was a key factor in microbiological risk management. Also, there were many more risk management options to be considered for management of microbiological hazards compared to chemical hazards. It was also noted that, as of yet, there was no formal risk assessment for the Committee to consider.

85. Concerns were raised by a number of delegations regarding the definitions in this document. The Committee agreed that, where they existed, the definitions used should be those adopted by the CAC. The Delegation of the US requested that the definition of Microbiological Risk correlate to that of Risk already defined by the CAC. In relation to MFSO, it noted that it was premature to define this term as the concept was still under development. Delegations identified a number of additional terms that should be defined in section 2 of this document. These included: tolerable level of risk (TLR), microbiological hazard, appropriate level of protection, risk profile, interested parties, stakeholders, risk management policy and acceptable level of risk. The Delegation of Denmark pointed out that in defining terms such as TLR, MFSO, appropriate level of protection and microbiological criteria it was important to look at how these terms relate to each other and if all of them were necessary. The Committee also noted that for terms such as TLR and MFSO, further definition of the concepts was required before the terms can be defined.

86. The Delegation of the United Kingdom expressed some concern regarding the replacement of the term FSO with MFSO and suggested that this may be narrowing the concept of FSOs as it would be interpreted as microbiological criteria. To clarify this issue the Delegation of France pointed out that the scope of MFSO was identified in 5.2.1.1. The Representative of ICMSF informed the Committee that

⁶ CX/FH 00/6; CX/FH 00/6-Add.1 (comments of Mexico, New Zealand, Poland, the United States of America, European Community and Consumers International); CRD 13 (comments of Finland); CRD14 (comments of China); CRD 15 (comments of ALD); CRD 20 (comments of Philippine); CRD 22 (comments of Brazil).

“microbiological” was included to clarify that the paper was discussing FSOs as they relate to microbiological hazards and to avoid any confusion with the concept discussed in CCGP and CCFICS and was not intended to limit the concept of an FSO. The Chairperson indicated that as the situation has changed and CCFH is now the only Committee addressing this concept it was now possible for CCFH to return to the use the term FSO.

87. The Committee had an extensive discussion on Principle 4 that referred to the risk management - risk assessment interface. The Delegation of New Zealand proposed that this Principle be made more flexible to highlight the importance of interaction between risk managers and risk assessors and that risk assessment policy could not be completely determined before the risk assessment commenced. The Delegation of the US expressed the concern that the principle did not reflect the need for identification of bias and proposed the inclusion of an additional sentence as follows: “Risk assessors must document the impact of these policies on the assessment”. While many delegations expressed support for highlighting the need for interaction, the need to keep the principles as simple and focussed as possible was also stressed. The Committee decided to retain the first sentence of the principle with the addition of the phrase, “while ensuring transparent and appropriate interaction between them” based on the WHO Kiel Expert Consultation⁷ report. The second sentence of this principle as well as the inclusion proposed by the US delegation were moved to section 5.1.5.

88. Following discussion on Principle 6, the Committee decided to retain the square brackets, as the issue of precaution was still under discussion in the CCGP, and accepted the proposal of the European Commission to add “pending further scientific information” to the end of the sentence.

89. The Committee also had extensive discussions on Principle 8 that related to risk management decisions. Some delegations expressed concern over its inflexibility. The Committee, however, decided that this principle should focus on the importance of the whole food chain in risk management decisions, although it was recognized that not all risk management decisions require an examination of the whole food chain. Principle 8 was slightly modified to read "Risk Management decisions should take into account the whole food chain from primary production to consumption, including imported foods."

90. In relation to Principle 10 the Committee agreed to include the word “substantive” in recognition of the fact that it is not feasible to review a risk management decision every time a new piece of information becomes available. In Principle 11 the Committee noted that measures should be “revised” rather than “reviewed”.

91. The Delegation of New Zealand raised the issue of including monitoring and surveillance which are not currently included in this document as new principle principle of risk management. It was pointed out that these were important issues particularly in light of the data gaps identified by the Joint FAO/WHO Expert Consultation on Microbiological Risk Assessment. The Committee agreed that this issue be referred to the drafting group to consider its inclusion.

92. The Committee noted the status of the consideration of precaution by the CCGP. The Observer from Consumers International supported by some delegations suggested a circular letter be prepared requesting the Members to illustrate in a concrete way how precaution was or might be used in the context of microbiological risk assessment. The Secretariat informed the Committee that CCGP had already sent out a circular letter similar to that suggested. While there was some frustration at the lack of progress in this area, the Committee agreed that it was not the task of the CCFH to define the basic application of precaution in Codex work.

93. Following the proposal of the Delegation of Sweden, the Committee agreed that a Circular Letter be sent out to Member Countries requesting them to provide information on their views on Food Safety Objectives as presented in Section 5.2.1.1 of CX/FH 00/6 and, if possible, examples of FSO’s. Replies would be sent directly to the chair of the drafting group.

⁷ The Interaction between Assessors and Managers of Microbiological Hazards in Foods. Draft report of the WHO Expert Consultation, Kiel, Germany, 21-23 March 2000.

94. The following proposals for further developing the document were referred to the drafting group for consideration:

- Incorporate the changes proposed in CRD 13 (Finland), in particular, sampling and testing methods, in Section 5.2.3;
- Move section 5.1.8 to section 5.2;
- The report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards in Foods be considered in the further development of the text on Risk Profile;
- Include mass media in section 4;
- Change the title of section 5.1 to better describe the concept of “Initial risk management activities”;
- In Section 5.2.1, try to define what was meant by “scientific knowledge of the risk is insufficient”;
- ICMSF agreed to provide their results of deliberation regarding FSOs.

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

95. The Committee agreed to return the document to Step 3. It was further agreed that the Delegation of France, assisted by its drafting partners, would revise the document, taking into account the comments of this Session, the report of the WHO Kiel Expert Consultation on the Interaction between Assessors and Managers of Microbiological Hazards and any comments that are received in response to the CL on FSOs. The Committee decided to draw the attention of CCGP to the importance of reaching a resolution on the issue of precaution in order for this document to progress.

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (Agenda Item 7)⁸

96. The Delegation of the United States introduced document CX/FH 00/7, which was based on the framework approach that was agreed upon at the last session of the Committee. The Delegation noted that, while progress had been made on the document, much work remained to be done particularly with regard to the Annexes. The Delegation advised that some of the drafting partners had recognized that the issues of validation and suitability needed to be resolved and that they were fundamental to the development of the Code. The Delegation stated that the drafting partners needed to have another meeting to further develop the Code, in particular the annexes, before the next session of the Committee.

97. The Committee expressed its appreciation for the work of the United States and the drafting partners and generally supported the approach taken in the development of the Code.

98. The Committee recalled that the Codex Committee on Milk and Milk Products had referred the Heat Treatment Definitions⁹ to the Committee on Food Hygiene. The Representative of IDF noted that these definitions would be incorporated into the appropriate section of the Proposed Draft Code, in particular in the Annex that dealt with microbiocidal treatments. The Delegation of Canada stressed the importance of these definitions as they are closely related to the protection of health. The Delegation of Korea pointed out that variation between countries in practices of microbiocidal treatment should be taken fully into account in the process of drafting.

99. Some delegations noted the importance of "suitability" with respect to the Code and that this issue could be discussed as a general issue applying to other food hygiene texts (see also paragraph 152 of Agenda Item 15). The Committee confirmed that discussion on the nature of "suitability" does not prevent its immediate consideration within the Code. The Delegation of France, speaking on behalf of the Member States of the European Union present at the Session, expressed the view that the Code

⁸ CX/FH 00/7; CX/FH 00/7-Add.1 (comments of Brazil, Canada, Denmark, Kenya, Mexico, New Zealand, the United States of America, International Dairy Federation (IDF) and the Office International des Epizooties (OIE)); CRD 10 (comments of European Community).

⁹ ALINORM 01/11, paras 106-109, CX/FH 00/2, Section 2.3.

should reflect the importance of Good Agricultural Practices at primary production and that appropriate guidance should be developed within the annexes.

100. The Observer from Consumers International drew the attention of the Committee to the work of the Codex Committee on Residues of Veterinary Drugs in Food with regard to “control of veterinary drug residues in milk and milk products and suggested that consideration be given to the labeling of raw milk products.” The Delegation of Switzerland pointed out that the use of terms in the Code should be fully aligned with the Codex General Standard for the use of Dairy Terms.

101. The Delegation of the United Kingdom stressed the need to reserve significant time at the next session to consider the Code in detail and the Committee so noted. The Committee concluded that due to the lack of technical development, particularly with respect to the Annexes that were the integral part of the Code, it was not possible to advance the Code.

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

102. The Committee 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 Observer of the European Commission offered the same facilities in terms of venue and the translation for the drafting group, as it was done for the previous meeting.

PROPOSED DRAFT GUIDELINES FOR THE HYGIENIC REUSE OF PROCESSING WATER IN FOOD PLANTS (Agenda Item 8)¹⁰

103. The Delegation of the United States introduced document CX/FH 00/8 and noted that the Proposed Draft Guidelines (Annex A to CX/FH 00/08) were recommended to be a new Annex to the *International Recommended Code of Practice: General Principles of Food Hygiene*. The Delegation indicated that the commodity specific examples of water reuse, presented in Annex B, were for informational purposes only and should be removed from this text, although specific examples could usefully be incorporated while developing individual codes of hygienic practice, such as those for fresh cut fruits and vegetables or those for dairy foods.

104. The Committee agreed to consider further only the Proposed Draft Guidelines, section by section.

105. The Delegation of the United Kingdom, supported by the Representative of the EC and suggested that a new section, “Objective,” be added to the Guidelines document in which the primacy of potable water would be emphasized, and that deviations from this standard practice be fully justified. The Delegation of Austria indicated that reused water should be at least free of pathogens. Some delegations noted that reused water coming in contact with food should always be potable. However, other delegations noted that, in fact, non-potable water was routinely and extensively used in food processing and that Section 5.5.1 (Water in Contact with Food) of the *Recommended International Code of Practice: General Principles of Food Hygiene* allowed exceptions. It was noted that this section indicated that “water recirculated for reuse should be treated and maintained in such a way that no risk to the safety and suitability of food results from its use”. There was a general agreement to add a new section “Objective” to emphasize the importance of potable water and recognize the exceptions in case of reused water, and that precise wording of the content of Objectives be further discussed by drafting partners.

106. Concerning the Scope of Annex A, it was noted that the second sentence of the Introduction section should also include reference to recirculated water in addition to recycled and reclaimed water. The Committee agreed to move the second and third sentences of the Introduction to the Scope. It was noted that also the last line of Introduction should be included in the Scope. The Committee agreed to reconsider the Scope.

¹⁰ CX/FH 00/8; CX/FH 00/8-Add.1 (comments of Denmark, Mexico, the United States of America and IDF); CRD 17 (comments of Italy, CRD 20 (comments of Philippines).

107. Regarding Definitions, the Committee agreed to remove prescriptive statements concerning the need for reconditioning from the definitions for recirculated, recycled and reclaimed water and that such statements should appear later in the text.
108. The Committee had significant initial discussions on the Guidelines. Several Delegations noted the need for greater flexibility with respect to HACCP (Section 4.3 of Guideline). The Committee agreed that the wording in Section 5.1 of the *Recommended International Code of Practice: General Principles of Food Hygiene* provided less rigid wording and agreed to its use for Section 4.3 of the Guidelines. The use of the term “quality” in Section 4.4 of the Guidelines was questioned and the Committee agreed that the term should be replaced by “suitability”. It was further agreed to move Section 4.10 of the Guidelines toward the top of the "Guidelines" listing in order to give it added prominence.
109. The Committee noted that the current document lacked clarity regarding the difference between reuse water that comes into contact with food and reuse water that does not. The Committee concluded that this difficulty needs to be resolved and that the focus of the document should be on water that comes into contact with food.
110. The Committee agreed to return the Proposed Draft Code to Step 3 for redrafting by the United States with the assistance of their drafting partners in light of the comments received and the discussions of the current session, and to circulate it for comments prior to the next session of the Committee.

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS (Agenda Item 9)¹¹

111. The Committee accepted the proposal of some delegations and Observers to consider this agenda item in conjunction with Agenda Item 3 in order to identify the risk management questions to be put forward to the Expert Consultation on microbiological risk assessment. The Delegation of Germany introduced the document and indicated that it was prepared in accordance with the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (CX/FH 00/6). The document reflects a consideration of the preliminary report of the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, particularly in Section 5.1, “Initial Risk Management Activities”.
112. The Delegation of Germany pointed out that the completion of the work of the FAO/WHO Expert Consultation on risk assessment of *Listeria monocytogenes* in ready-to-eat foods would add substantial data to the document, and that the proposed tolerable level of risk would need to be assessed in light of the results of risk assessment. The Delegation also indicated that the risk management options presented in Section 5.2 included measures at primary production, food processing, and distribution, as well as the use of microbiological criteria.
113. The Committee expressed its appreciation to the Delegation of Germany and the drafting group for their valuable work and had an exchange of views regarding types of risk management options and related risk management questions to be considered by the Joint FAO/WHO Expert Consultation. The results of the discussion on this subject are shown in paragraphs 18-19 under Agenda Item 3 regarding the risk management questions on the three pathogen commodity combinations. With regard to the comparison of the cost effectiveness of various management options, the Committee concluded that it was the task of the risk managers.
114. Some delegations and the Observers from IDF and the EC questioned the concept of the Tolerable Level of Risk (TLR) in Section 5.1.8 and suggested the following points 1) the relationship between TLR and the Appropriate Level of Protection was not clear; 2) the identification of TLR would not necessarily be done prior to the completion of risk assessment; 3) since pathogens can multiply, TLR as reflected by the number of pathogens at the point of consumption could not be fully predicted by the number of pathogens during production or at the point of importation; 4) preventive measure

¹¹ CX/FH 00/9; CRD 14 (comments of China). CRD 15 (comments of ALDA). CRD 16 (comments of Italy).

such as HACCP were more important than setting certain levels. These concerns were to be communicated to the drafting groups on risk assessment.

115. Replying to a question, the Representative from WHO clarified that the objective of the Expert Consultation was not to define TLR but to provide advice on the most efficient measures to control *Listeria monocytogenes* in foods with the aim of lowering the disease incidence in the population. The Committee recognised the need for further discussion on the concept and application of tolerable level of risk

116. Some delegations pointed out that differences in nutritional conditions and food consumption patterns were not properly reflected in the document and that the data presented in the Annex of the document were relatively old and did not include data from developing countries.

117. The Delegation of the United States noted that the format of Agenda Item 9 was based on the document, "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management," which was at Step 3 of the Procedure, represented a departure in format from other Codex documents. Since CX/FH 00/6 was a concept document that was likely to change as a result of further deliberations the Delegation suggested that the *ad hoc* Drafting Group consider whether this was the best format for conveying the information covered by Agenda Item 9.

118. The Delegation of Argentina expressed concern regarding the use of the term, "precautionary principle," and was of the view that it could not be used until the matter is resolved in the Committee on General Principles.

119. The Committee concurred with the general approach of the document and agreed that the Delegation of Germany, with the assistance of drafting partners, would prepare a revised document that would incorporate comments provided at the Session and the results of risk characterization to be finalized by the Joint FAO/WHO Expert Consultation in April 2001. Member countries and interested International Organizations were invited to submit additional comments on the current document CX/FH 00/9 to the Delegation of Germany by 1 April 2001. The revised document would be circulated at Step 3 for comments prior to the next session of the Committee, pending a Commission decision to approve this as new work.

DISCUSSION PAPER ON THE APPLICATION OF HACCP IN SMALL AND/OR LESS DEVELOPED BUSINESSES (SLDBs) (Agenda Item 10)¹²

120. The Delegation of the Netherlands introduced the document which was revised by the drafting group and indicated that this issue had been on the Agenda of the Committee for several years. The delegation pointed out that despite a growing consensus in applying HACCP throughout the world, (as a science based, well structured, preventive system and the best way to control food safety), problems such as the lack of technical expertise, economical and cultural difficulties existed in the application of HACCP in SLDBs, especially in developing countries.

121. The Delegation reminded the Committee that to resolve the above difficulties, WHO, in cooperation with the Government of the Netherlands, convened a Consultation on Strategies for Implementing HACCP in Small and/or Less Developed Business to develop strategies for governments, trade and industry in order to assist the SLDBs, in implementing HACCP. The Delegation pointed out that the seven basic principles of the HACCP system could be applied in SLDBs, however the existing HACCP Guidelines did not provide enough guidance and flexibility for application to SLDBs, as for example in the Guidelines there was a requirement for a team of experts to identify hazards and establish corrective actions, therefore SLDBs had to rely on external expertise.

122. The Delegation recommended that the preferable way to overcome those difficulties in SLDBs could be an amendment of the existing HACCP Guidelines, by incorporating additional text into specific areas for the use in SLDBs without altering the seven principles of HACCP in any way.

¹² CX/FH 00/10, CRD 3 (comments of Peru); CRD 11 (comments of European Community); CRD 17 (comments of Italy); CRD 21 (comments of Chilli); CRD 22 (comments of Brazil).

123. The Committee expressed its appreciation to the Netherlands and its drafting partners for their work and efforts to progress this issue.
124. The Delegation of US, supported by Consumers International stated that original the seven HACCP Principles and the Guidelines should remain unaltered in their approach and meaning and indicated that it could support advancement of the document only if the proposed changes were considered as specific amendments to the HACCP Annex of the Recommended International Code of Practice-General Principles of Food Hygiene.
125. The Delegation of India pointed out problems associated with financial constraints, extensive documentation and lack of expertise and etc in developing countries were not fully reflected in the proposed amendments and were, in some cases, even more stringent than the current Guidelines, and that input from developing countries was required. This view was supported by many other delegations. In view of this, the Delegation of India proposed revision of the document which should be kept at a discussion paper status.
126. The Delegation of France, speaking on behalf of the Member States of the European Community present at the Session, supported the approach recommended by the drafting group and indicated that proposed amendments allowed more flexibility in application of HACCP Guidelines without compromising public health. This view was supported by several delegations.
127. The Delegation of Peru, in addition to its written observations presented in CRD 3, indicated the necessity of a process of adjustment in the application of HACCP requirements and that FAO/WHO should provide more training on the matter. The request for training was supported by many other delegations.
128. The Delegation of Venezuela pointed out that inconsistencies in the current document, CX/FH 00/10, could be eliminated at a later stage. Some delegations pointed out the necessity of participation of developing countries and involvement of all stakeholders in this process. The need for application of GHP and GMP as the prerequisite of HACCP and the exchange of experience in application of HACCP was emphasized.
129. Some delegations indicated the necessity to define SLDBs and indicated that it should be left to national authorities to decide.
130. The Delegation of Chile referring to the CRD 21 of Peru indicated that its country strove to apply the seven principles of HACCP that would not to be made more flexible, that HACCP was not the only tool to achieve food safety and that the CCFICS should provide guidance on equivalent systems.
131. The Observer of Consumers International expressed concern that while redrafting the document the basic principles of HACCP should not be diluted.
132. The Observer of IDF, while recognizing the usefulness of the HACCP system to ensure food safety, indicated that problems could be different in various kinds of industries and favoured using sector specific hygiene codes in dairy industry.
133. The Committee concluded that the document was useful, and there was general support to further elaborate it, and therefore agreed to an amendment to the existing HACCP Guidelines without altering the seven HACCP principles and to inform the CAC accordingly. However the Committee decided to ask for comments on the current document CX/FH 00/10 especially from developing countries on how to develop the Guidelines and requested the Delegation of the Netherlands, together with its drafting partners to revise the document that will be circulated at Step 3 for comments prior to the next session of the Committee. The Committee invited the delegations of developing countries to actively participate in this process.

DISCUSSION PAPER: RISK PROFILE ON ANTIMICROBIAL RESISTANT BACTERIA IN FOOD (Agenda Item 11)¹³

134. The Committee recalled that it had agreed at the last session that the Delegation of Denmark, together with its drafting partners, would revise discussion paper CX/FH 99/12 in the form of a risk profile. The Delegation of Denmark introduced the revised document, CX/FH 00/11, and emphasised that the emergence of microbial resistant bacteria in foods was a significant public health problem which also needs to be addressed from a food hygiene perspective and that immediate action by various Committees including CCRVDF and the ad hoc Intergovernmental Task Force on Animal Feeding was important.

135. The Delegation recommended that the Committee commission a risk assessment for specific scenarios relating to antimicrobial-resistant bacteria in foods and suggested that quinolone-resistant *Salmonella* and *Campylobacter* in poultry should be the top priority.

136. The Delegation proposed that the Committee consider developing recommendations for the management of specific antimicrobial-resistant bacteria in foods, taking into account the outcome of future risk assessments and that the WHO Global Principles for the Containment of Antimicrobial Resistance Due to Antimicrobial Use in Livestock be elaborated into a Codex document by the relevant Committees. The Delegation noted that the problem could be better addressed at the source and that the prohibition of certain classes of antibiotic might be a possible management option.

137. The Committee thanked the Delegation of Denmark and its drafting partners for their work. It acknowledged the public health risks associated with antimicrobial-resistant bacteria in foods. Several delegations stated that the Committee should commission a risk assessment as proposed, however some other delegations expressed the view that the risk profile should be further elaborated before commissioning the risk assessment. The Delegation of Norway pointed out that antimicrobial-resistant bacteria in foods was a food hygiene issue that also needed to be addressed by the CCFH.

138. The Committee recalled that it had agreed at the last session to ask the advice of the Executive Committee on how to ensure proper coordination of work between concerned Committees, and that the Executive Committee at its 47th session in June 2000 recognized the importance of a risk profile to determine which subjects falls within the terms of reference of the CCFH¹⁴. The Committee discussed the appropriateness of forwarding the discussion paper (CX/FH 00/11) to the Executive Committee as the document had been prepared in a requested format. While several delegations and the Observer from the Consumers International supported this idea particularly given the importance of this problem to public health, some other delegations emphasised the need for further scrutiny of the document before forwarding it.

139. The Delegation of Germany indicated that: 1) in Section B, "*Bacterial pathogens with food animal reservoirs*," in both the first and second paragraphs, the words "the principle" should be replaced with "one", as there were other reservoirs of antibiotic resistance strains of *Salmonella* and *Campylobacter* in humans and water; 2) on page 3, the paragraph on *Antimicrobial use*, the need for international validation of the principle of "reservation for human medicine" should be included in the recommendations of the document; 3) on page 6, Section 5 on *Distribution of Benefits and Risks*, the idea that the use of antibiotics as growth promoters has greater risk than their prophylactic use needs detailed risk assessment to be so concluded; and 4) on page 7, Section , *HACCP*, the introduction of "good farming practice" is a more suitable tool at the farm level than the introduction of HACCP.

140. The Representative of WHO fully supported the document and stated that it was in line with WHO policy and reports and scientific understanding of the problem. The representative noted that the implementation of measures which control existing misuse of antimicrobials is at least as important as risk assessments. This view was supported by Consumers International.

¹³ CRD 4 (comments of COMISA and OIE).

¹⁴ ALINORM 01/03 paragraph 51

141. The Delegation of Australia pointed out that on page 6, under *Distribution of Benefit and Risk*, in the first paragraph, the statement that “the benefit of this use may be relatively small” needs further review with data. The Delegation of Japan indicated that on page 6, fourth paragraph, the sentence “the use of antibiotics for growth promotion should be prohibited” be deleted as this point was being discussed at the Task Force on Animal Feeding. The Observer from COMISA referred to its CRD 4 which included the concerns to be further addressed by the Committee (that document would be archived by the Secretariat in Rome).

142. The Committee agreed that the current document CX/FH 00/11 be forwarded to the Codex Executive Committee to assist their decision on the coordination of the work between the Committees concerned with the consideration for the work of other international organizations (OIE). There was some support for the conclusions and recommendations in the discussion paper and the Committee requested that the Delegation of Denmark revise the discussion paper taking into account the comments made at the Session. The revised discussion paper would be circulated prior to the next session of the Committee.

DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR THE VALIDATION OF FOOD HYGIENE CONTROL MEASURES (Agenda Item 12)¹⁵

143. The Delegation of the United States introduced document CX/FH 00/12 and indicated that the basic elements to be addressed by the Guidelines were shown in Section 10 of this Discussion paper. The Delegation informed the Committee that there could be a need to address validation from a general perspective.

144. The Delegation of the France, speaking on behalf of the Member States of the European Community present at the Session, expressed the view that it was necessary to clarify the concepts of validation first and suggested that the paper be revised.

145. The Committee decided to request that the United States, with the assistance of its drafting partners, redraft the Discussion Paper for further consideration by the next session of the Committee.

DISCUSSION PAPER ON PROPOSED DRAFT GUIDELINES FOR EVALUATING OBJECTIONABLE MATTER IN FOOD (Agenda Item 13)¹⁶

146. The Delegation of the United States introduced document CX/FH 00/13 and indicated that there was a need for these guidelines since the “Recommended International Code of Practice: General Principles for Food Hygiene” did not provide sufficient guidance on this subject. The Delegation noted that the focus of the guidelines should be exclusively on issues of food safety and wholesomeness of foods. Some delegations questioned whether the use of HACCP could suffice for the purposes proposed for the Guidelines. It was suggested that the relationship to hygiene and food safety (including allergens) be more clearly defined.

147. While recognizing the potential value of having guidelines in this field, the Committee concluded that the discussion paper needed to be redrafted to provide more focus, clarity and justification for the Guidelines. The Committee requested the United States to redraft the discussion paper for consideration by the Committee at its next session.

PRIORITIES FOR THE REVISION OF CODES OF HYGIENIC PRACTICE (Agenda Item 14)¹⁷

148. The Committee recalled that the last session requested the Delegation of Australia to prepare a document on the priorities which would identify 1) which codes were superseded and 2) which codes

¹⁵ CRD 16 (comments of Italy).

¹⁶ CX/FH 00/13; CRD 12 (comments of the European Community).

¹⁷ CX/FH 00/14.

could be combined. The Delegation of Australia introduced the document CX/FH 00/14, which was prepared with assistance of its drafting partners.

149. The Committee agreed that some codes of practice could be combined and revised on a commodity basis as shown in the Attachment 1 of the paper.

150. Regarding the priority for the revision, while some delegations expressed their view on assigning higher priority to some codes that appeared on the priority list, the Committee generally recognized the necessity of revision on Code for Egg and Egg Products and the Code for Foods for Infant and Children. The Committee agreed to start the revision of the Code for Egg and Egg Products pending the approval of the Commission. 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 this Code.

151. The Committee agreed that Australia, with the assistance of the United States and ALA, prepare the revision of the Code for Egg and Egg Products. The Committee supported the elaboration of Code of Practice for poultry.

OTHER BUSINESS AND FUTURE WORK (Agenda Item 15)¹⁸

Discussion Paper on the Term “Suitability”¹⁹

152. The Delegation of New Zealand introduced the discussion paper (CRD 5) and indicated that the matter of the term “suitability” had arisen while developing the Proposed Draft Code of Hygienic Practice for Milk and Milk Products and that there was a need for clarifying the content of this term, especially as to where to draw the line between “suitability” and “quality”. The Delegation also indicated that the issue was relevant not only to the Milk Code but also to other hygiene texts and therefore there was a need for guidance from the Committee. While recognizing the generic nature of this subject, the Committee agreed that the issue should be considered within the framework for the Milk Code, for the time being.

Hazard Analysis and Risk Analysis²⁰

153. In order to respond adequately to the referral of the Executive Committee (see para 10 of this report) regarding a clear statement of the difference between the terms “hazard analysis” and “risk analysis”, the CCFH accepted the offer of the Delegation of the United States to prepare a short paper for consideration by the next session of the Committee.

Proposed Draft Amendments to the Terms of Reference of the Committee on Food Hygiene

154. See paras 28-30 of the report.

DATE AND PLACE OF NEXT SESSION (Agenda Item 16)

155. In response to the initiatives proposed by the Chairperson of the Codex Alimentarius Commission, the Delegation of Thailand offered to provide the venue for the 34th Session of the Committee in Thailand, in October - November 2001. The Committee was informed that the decision on the site selection could not be taken at present time. The Delegations would be informed about the precise venue and the dates in due course.

¹⁸ CRD 5 (Discussion paper on the term “Suitability”, prepared by New Zealand); CRD 7 (Prepared by the USA).

¹⁹ CRD 5 (Prepared by New Zealand)

²⁰ CRD 18 (Hazard Analysis and Risk Analysis prepared by WHO and FAO)

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Reference in ALINORM 01/13A
Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packing of Fresh Fruits and Vegetables	5	Governments, 24th Session of the CAC, 34th Session of the CCFH	paras 31-82 and Appendix II
Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management	3	Governments, France, 34th Session of the CCFH	paras 83-95
Proposed Draft Code of Hygienic Practice for Milk and Milk Products	3	US, Governments, 34th Session of the CCFH	paras 96-102
Proposed Draft Guidelines for Hygienic Reuse of Processing Water in Food Plants	3	US, Governments, 34th Session of the CCFH	paras 103-110.
Proposed Draft Guidelines for the Control of <i>Listeria monocytogenes</i> in Foods	3	Governments, 24th Session of the CAC, Germany, 34th Session of the CCFH	paras 111-119
Application of HACCP in Small and/or Less Developed Businesses	1/2/3	Governments, The Netherlands, 34th Session of the CCFH	paras 120-133
Proposed Draft Revision of the Code of Hygienic Practice for Egg Products (CAC/RCP 30-1983)	1/2/3	24th Session of the CAC, Australia, 34th Session of the CCFH	paras 148-151
Discussion Paper Risk Profile on the Antimicrobial Resistant Bacteria in Food	-	24th Session of the CAC, Denmark, 34th Session of the CCFH	paras 134-142
Discussion Paper on the Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures	-	US, 34th Session of the CCFH	paras 143-145
Discussion Paper on Proposed Draft Guidelines for Evaluating Objectionable Matter in Food	-	US, 34th Session of the CCFH	paras 146-147.
Discussion Paper on Hazard Analysis and Risk Analysis	-	US, 34th Session of the CCFH	para. 153

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Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables (at Step 5 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 draft 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 draft 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 *Proposed Annex for Sprout Production* is a supplement to this code and includes additional recommendations to cover 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 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 document 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. It 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 *Proposed 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 cultivation, packing and/or harvesting of fresh fruits and vegetables.

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 residual water 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 agriculture 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.

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.

Microbial hazards - pathogenic or other microorganisms at levels that have the potential to cause an adverse health effect.

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.

Definitions 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.

[Re-used irrigation water]

[Recycled water]

3. PRIMARY PRODUCTION

Fresh fruits and vegetables are grown and harvested under a wide range of climatic 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 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 risk 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 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 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 of sufficient quality for its intended use.

3.2.1.1.1 Water for irrigation and harvesting

Water used for agricultural purposes (e.g. irrigation, pest control, application of chemical products) 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. sprinkler) 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. sprinklers) 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 should purchase manure, biosolids and other natural fertilizers that have been treated to reduce microbial or chemical contaminants only from suppliers capable of providing documentation 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 the occurrence of levels of hazards that may compromise the safety of crops. If the evaluation concludes that such levels exist, 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. The use of antimicrobial agents significant to human and animal therapy should be avoided. Antimicrobial agents not significant to human and animal therapy should only be used when absolutely unavoidable.
- 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 and harvested fruits or vegetables, and disposed of in a manner that does not pose a risk of contaminating crops 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 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 water supplies by exposure to agricultural inputs used for growing fresh produce.
- Clean and disinfect potable 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 risk of contaminating 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

Personnel hygiene 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.
- 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 at all times.

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 fresh, 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 facilitate adequate cleaning, disinfected and maintained. Specific hygienic 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 risk 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 further processed should be disposed of properly to avoid contamination of fresh fruits and vegetables or agricultural inputs.
- Harvest employees 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 not to contaminate containers or bins by exposure to soil, 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 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, 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. [*Refer to Proposed Draft Guidelines for the Hygienic Reuse of Processing Water in Food Plants.*]

- Post-harvest systems that use water should be designed in a manner to minimize places where product lodges and dirt builds up.
- Disinfectants 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 disinfectant levels should be monitored and controlled to ensure that they are maintained at effective concentrations. Application of disinfectants, 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 trace back 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 AND TRACEBACK

Refer to the General principles of Food Hygiene.

In addition, where appropriate:

- Growers and packers should have trace-back programmes to ensure effective lot identification. This system 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: PERSONNEL 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.

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 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, [distributers, storage, handlers] and consumer

ANNEX I

Proposed Draft Annex for Sprout Production

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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 field planting where the good agricultural practices (GAP) 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 seed disinfection 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 disinfection treatments which would provide sufficient pathogen reduction on seeds especially if pathogens are internalized.

1. OBJECTIVES OF THE ANNEX

This present 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 GAPs and good hygienic practices are aimed at preventing microbial pathogen contamination of seeds. During sprout production, the seed disinfection 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 AND USE

This document 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 the General Principles of Food Hygiene and Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables. 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.

2.3 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 Draft Code of Practice for the Primary Production and Packing of Fresh Fruits and Vegetables. In addition:

3.2 HYGIENIC PRODUCTION OF SEEDS

When seeds are destined for sprout production, animals should not be allowed to graze the fields where seeds are grown (e.g., employing sheep for spring clip back of alfalfa).

3.2.1.2 Manure and biosolids

It is particularly important to prevent microbial contamination during the production of seeds 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 sprout production.

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 sprout production.

3.3 HANDLING, STORAGE AND TRANSPORT

Seeds produced for sprout production should be segregated from product to be used as animal feed (e.g., for silage production) 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.

3.5 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, seeds should not be sold or used for sprout production. 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. Seed producers, distributors and sprout producers should refer to the *Codex Principles for the Establishment and the Application of Microbiological Criteria for Foods*, CAC/GL 21-1977, for guidance on establishing a sampling plan.

3.6 TRACEBACKS AND RECALLS

Seed producers for sprout production should ensure that traceback 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 and provide detailed information to assist in the identification and investigation of any contaminated seeds and sprouts. The following should be adopted:

- Seed production and distribution practices to minimize the quantity of seed identified as a single lot and avoid the mixing of multiple lots of different origins that would complicate traceback and provide greater opportunity for cross-contamination. Seed producers and distributors and sprout producers should maintain a record of traceability 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 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 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 food hygiene practices, including protection against cross-contamination between and during operations. Storage, seed rinsing and disinfection, 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 seed disinfection and subsequent operations) should be of potable quality or at least clean water.

5.2.2.2 Initial rinse

The seeds should be rinsed thoroughly before the disinfection treatment to remove dirt and increase the efficiency of the disinfection 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 Seed disinfection

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 may be other options, liquid disinfection is the treatment that is generally used. During the disinfection treatment sprout producers should adhere to the following:

- Seeds should be well agitated in large volumes of disinfectant to maximise surface contact.
- The duration of treatment and the concentration of disinfectant used should be accurately measured and recorded.
- Strict measures should be in place to prevent re-contamination of seeds after the disinfection treatment.
- Disinfection material 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 disinfection treatment with potable water or at least clean water. Rinsing should be repeated sufficiently to eliminate disinfectant.

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 clean water for the shortest possible time to minimize microbial growth.
- This step may also employ disinfectants.
- 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 disinfected equipment such as a food grade centrifugal dryer.
- 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° 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 are tested before entering production (i.e. before seed disinfection steps).

- 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 disinfection treatment at the sprouting facility.

5.2.3.2 Testing irrigation water and/or sprouts

Current seed treatments cannot guarantee total elimination of pathogens. Further, if even a few pathogens survive 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 *Draft Code of Practice for the Primary Production and Packing of 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 sprout production.
- 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 *Draft Code of Practice for the Primary Production and Packing of 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 trace back and 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 trace back 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 *Draft Code of Practice for the Primary Production and Packing of Fresh Fruits and Vegetables*. In addition:

- The producer should have a written training program 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.

ANNEX II

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

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INTRODUCTION

Scientific research over the last decades has shown that a diet rich in fruits and vegetables is protective, among others, 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 an on-going consumer interest in ready-to-eat fresh foods have contributed to a substantial increase in consumption of fresh pre-cut fruits and vegetables over the past two decades. However, the recent increase in reports of food borne illness associated with ready-to-eat fresh fruits and vegetables has raised concerns from public health agencies and consumers about the safety of these products.

1. OBJECTIVE

The recommendations for the primary production of fresh fruits and vegetables are covered under the *Draft Code*

of Practice for the Primary Production and Packing of Fresh Fruits and Vegetables. This present draft Annex deals with good manufacturing practices (GMP) 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. It provides a general framework of recommendations that can be adopted uniformly by the sector rather than offering detailed recommendations concerning activities or products. The fresh produce industry is very complex. A wide variety of fruits and vegetables are processed and packaged under variable climatic and environmental conditions. For this reason, this Annex is flexible by necessity and can be adapted to various systems used to control and prevent contamination in various food groups.

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 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 the General Principles of Food Hygiene and Proposed Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables. This Annex contains only the recommendations complementing the General Principles necessary to take into account the requirements of plant-based foodstuffs that it specifically deals with.

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 *Proposed Draft Code of Hygienic Practice for Primary Production and Packing of 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.

5. CONTROL OF OPERATIONS

Refer to the *Proposed Draft Code of Hygienic Practice for the Primary Production and Packing of 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 *Proposed Code of Hygienic Practice for the Primary Production and Packing of 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

Inspect incoming produce delivery food transportation unit for cleanliness and raw materials for evidence of contamination. There should be trimming to remove any damaged, rotten or mouldy material.

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.

5.2.2.2 Washing and disinfection

Refer to section 5.2.2.1 of the *Proposed Code of Hygienic Practice for the Primary Production and Packing of*

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.

5.2.2.3 Pre-cooling Fresh Fruits and Vegetables

Refer to section 5.2.2.3 of the Proposed Code of Hygienic Practice for the Primary Production and Packing of Fresh Fruits and Vegetables.

5.2.2.4 Cutting, slicing, shredding, and similar pre-cut processes

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

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

Washing cut produce with potable water may reduce microbial 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 microbial 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.
- Drying or draining to remove water after washing may be important to minimize microbial growth.

5.2.2.6 Cold Storage

Refer to section 5.2.2.4 of the Proposed Code of Hygienic Practice for the Primary Production and Packing of 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 microbial 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 a traceback with fresh pre-cut fruits and vegetables. Records should be kept long enough to facilitate trace back 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 AND TRACEBACK

Refer to the *General Principles of Food Hygiene*.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

Refer to the *General Principles of Food Hygiene*.

7. ESTABLISHMENT: PERSONNEL 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* and the *Proposed Code of Hygienic Practice for the Primary Production and Packing of 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 microbial growth involved in this method;
- the importance of temperature control and GMPs.

Appendix III**Proposed Draft Amendments to the Terms of Reference of the Committee on Food Hygiene**

Section III of the Procedural Manual. Subsidiary Bodies Under Rule IX.1 (B) (I)

Add the following provisions to the Terms of Reference to the Committee on Food Hygiene:

- To suggest and prioritize areas where there is a need for risk assessment at the international level and to develop questions to be addressed by the risk assessors;
- To consider risk management matters in relation to food hygiene and in relation to risk assessment activities of FAO and WHO.